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 June 30, 2025

or

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

For the transition period from to

Commission File Number: 001-33500

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value $0.0001 per share	JAZZ	The Nasdaq Stock Market LLC

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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	☐	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 July 30, 2025, 60,658,809 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 JUNE 30, 2025

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Defined Terms and Products

Defined terms

We use several terms in this Form 10-Q, including but not limited to those that are finance, regulation and disease-state related as well as names of other companies, which are given below.

Term	Description
2024 Notes	1.50% exchangeable senior notes due 2024
2026 Notes	2.00% exchangeable senior notes due 2026
2030 Notes	3.125% exchangeable senior notes due 2030
Aetna	Aetna Inc.
AFL Plan Lawsuit	On July 31, 2020, a class action lawsuit was filed in the United States District Court for the Southern District of New York by the A.F. of L.-A.G.C. Building Trades Welfare Plan on behalf of itself and all others similarly situated, against Jazz Pharmaceuticals plc
AG	authorized generic
ALL	acute lymphoblastic leukemia
Almaject	Almaject Inc., Alvogen, Inc., and Alvogen PB Research and Development LLC
Amended Credit Agreement	Credit Agreement amended to include the Repricing Amendment No. 1, the Repricing Amendment No. 2 and Amendment No. 3
Amended Revolving Credit Facility	Revolving credit facility amended to increase the Initial Revolving Credit Facility to $885.0 million and extend the maturity date
Amendment No. 3	amendment to the Credit Agreement entered into by Jazz Lux in November 2024
AML	acute myeloid leukemia
Amneal	Amneal Pharmaceuticals LLC
ANDA	abbreviated new drug application
API	active pharmaceutical ingredient
ASD	ASD Specialty Healthcare LLC
ASU	Accounting Standards Update
Avadel	Avadel Pharmaceuticals plc
BCBS	Blue Cross and Blue Shield Association
BCBS Defendants	Roxane Laboratories, Inc., Hikma Pharmaceuticals USA Inc., Eurohealth (USA), Inc., Hikma Pharmaceuticals plc, Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals Inc., and Lupin Inc.
BCBS Lawsuit	On June 17, 2020, a class action lawsuit was filed in the United States District Court for the Northern District of Illinois by BCBS against Company Defendants
BLA	Biologics License Application
BTC	biliary tract cancers
Chimerix	Chimerix, Inc.
Chimerix Acquisition	our acquisition of Chimerix on April 21, 2025
Chimerix Common Stock	the common stock, par value $0.001 per share, of Chimerix
Chimerix Shareholder Litigation	two suits filed in the Supreme Court of the State of New York, County of New York, by purported Chimerix shareholders against Chimerix and its Board of Directors, but which do not name any Jazz Pharmaceuticals parties
Chimerix Transaction Litigation	the Rosenthal Lawsuit as well as the Chimerix Shareholder Litigation
CHMP	Committee for Medicinal Products for Human Use
City of Providence Defendants	Jazz Pharmaceuticals plc, and Roxane Laboratories, Inc., West-Ward Pharmaceuticals Corp., Hikma Labs Inc., Hikma Pharmaceuticals USA Inc., and Hikma Pharmaceuticals plc
CMS	U.S. Centers for Medicare & Medicaid Services
CODM	chief operating decision maker
COG	Children’s Oncology Group
Company Defendants	Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland Limited

Term	Description
Credit Agreement	Credit Agreement entered into on May 5, 2021, by and among us, Jazz Lux, and certain of our other subsidiaries, as borrowers, the lenders and issuing banks from time to time party thereto, Bank of America, N.A., as administrative agent and U.S. Bank Trust Company, National Association, as collateral trustee
DDI	drug-drug interaction
Defendants	Express Scripts, Inc., Express Scripts Holding Company, Express Scripts Specialty Distribution Services, Inc., Curascript, Inc. d/b/a Curascript, S.D., Priority Healthcare Distribution, Inc. d/b/a Curascript SD and Curascript Specialty Distribution SD, Caring Voice Coalition, and Adira Foundation (collectively with the Company Defendants)
Dollar Term Loan	our former seven-year $3.1 billion term loan B facility under the Credit Agreement
DS	Dravet syndrome
EC	European Commission
EDS	excessive daytime sleepiness
EEA	European Economic Area
Epidiolex ANDA Filers	Teva Pharmaceuticals, Inc.; Padagis US LLC; Apotex Inc.; API Pharma Tech LLC and InvaGen Pharmaceuticals, Inc.; Lupin Limited; Taro Pharmaceutical Industries Ltd.; Zenara Pharma Private Limited and Biophore Pharma, Inc.; MSN Laboratories Pvt. Ltd. and MSN Pharmaceuticals, Inc.; Alkem Laboratories Ltd.; and Ascent Pharmaceuticals, Inc.
ESPP	employee stock purchase plan
ESSDS	Express Scripts Specialty Distribution Services, Inc.
EU	European Union
Euro Term Loan	our now repaid seven-year €625.0 million term loan B facility under the Credit Agreement
Exchangeable Senior Notes	our 2026 Notes and 2030 Notes
Fair value step-up expense	the acquisition accounting inventory fair value step-up expense
FASB	Financial Accounting Standards Board
FDA	U.S. Food and Drug Administration
Finance Act	the Finance (No. 2) Act 2023
FTC	Federal Trade Commission
GEA	gastroesophageal adenocarcinoma
GEHA Lawsuit	Class action lawsuits filed on June 23, 2020 against the Company Defendants and the BCBS Defendants by Government Employees Health Association Inc. in the United States District Court for the Northern District of Illinois
GW	GW Pharmaceuticals plc
GW Acquisition	our acquisition of GW Pharmaceuticals plc in May 2021
Hikma	Hikma Pharmaceuticals PLC
HSCT	post-hematopoietic stem-cell transplantation
IFNα	interferon alpha
IH	idiopathic hypersomnia
IM	intramuscular
Initial Revolving Credit Facility	our five-year $500.0 million revolving credit facility under the Credit Agreement entered into in May 2021
IPR&D	in-process research and development
IRA	Inflation Reduction Act of 2022
Jazz Investments	Jazz Investments I Limited
Jazz Lux	Jazz Financing Lux S.à.r.l.
KRAS	Kirsten rat sarcoma virus
LBL	lymphoblastic lymphoma
LGS	Lennox-Gastaut syndrome
Lupin	Lupin Inc.
McKesson	McKesson Corporation
MDS	Myelodysplastic Syndrome

Term	Description
MWT	Maintenance of Wakefulness Test
NDA	new drug application
New Repurchase Program	our share repurchase program announced on July 31, 2024
NHS	U.K. National Health Service
ODE	Orphan Drug Exclusivity in the U.S.
OECD	Organisation for Economic Co-operation and Development
Old Repurchase Program	our share repurchase program authorized by our board of directors in November 2016
Orange Book	FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations"
Par	Par Pharmaceutical, Inc.
PBMs	pharmacy benefit managers
PDUFA	Prescription Drug User Fee Act
PharmaMar	Pharma Mar, S.A.
Pillar Two	the OECD framework proposal to implement a global minimum tax rate of 15% for large multinational corporations on a jurisdiction-by-jurisdiction basis
Pinetree	Pinetree Acquisition Sub, Inc., an indirect, wholly-owned subsidiary of Jazz Pharmaceuticals plc
PRSUs	Performance-based restricted stock units
PRV	Priority Review Voucher
R&D	research and development
R/R	relapsed/refractory
Recommendation Statement	Chimerix's Schedule 14D-9 Solicitation/Recommendation Statement
Redx	Redx Pharma plc
REMS	risk evaluation and mitigation strategy
Repricing Amendment No.1	amendment to the Credit Agreement entered into by Jazz Lux in January 2024
Repricing Amendment No.2	amendment to the Credit Agreement entered into by Jazz Lux in July 2024
RK Pharma	RK Pharma, Inc., Apicore US LLC, Archis Pharma LLC, Vgyaan Pharmaceuticals LLC
Roche	F. Hoffmann-La Roche Ltd
Rosenthal Lawsuit	a lawsuit filed in the Supreme Court of the State of New York, County of Chemung, by David Rosenthal, purportedly on behalf of Chimerix Shareholders
RSUs	restricted stock units
sBLA	supplemental Biologics License Application
SCLC	small cell lung cancer
SEC	U.S. Securities and Exchange Commission
Section 232	Section 232 of the Trade Expansion Act of 1962
Secured Notes	our issued $1.5 billion in aggregate principal amount of 4.375% senior secured notes, due 2029
Self-Insured Schools Lawsuit	On August 14, 2020, a class action lawsuit was filed in the United States District Court for the Southern District of New York by the Self-Insured Schools of California on behalf of itself and all others similarly situated, against the Company Defendants, as well as Hikma Pharmaceuticals plc, Eurohealth (USA) Inc., Hikma Pharmaceuticals USA, Inc., West-Ward Pharmaceuticals Corp., Roxane Laboratories, Inc., Amneal Pharmaceuticals LLC, Endo International, plc, Endo Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals Inc., Lupin Inc., Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Holdings USA, Inc., Sun Pharmaceutical Industries, Inc., Ranbaxy Laboratories Ltd., Teva Pharmaceutical Industries Ltd., Watson Laboratories, Inc., Wockhardt Ltd., Morton Grove Pharmaceuticals, Inc., Wockhardt USA LLC, Mallinckrodt plc, and Mallinckrodt LLC
sNDA	supplemental New Drug Application
Sumitomo	Sumitomo Pharma Co., Ltd
sVOD	severe VOD
T-DXd	trastuzumab deruxtecan

Term	Description
Tender Offer Documents	our Tender Offer Statement together with the Recommendation Statement
Teva	Teva Pharmaceuticals, Inc.
Tranche B-1 Dollar Term Loans	upon entry into the Repricing Amendment No.1, the then outstanding Dollar Term Loan was refinanced into a new tranche of U.S. dollar term loans
Tranche B-2 Dollar Term Loans	upon entry into the Repricing Amendment No.2, the then outstanding Tranche B-1 Dollar Term Loans were refinanced into a new tranche of U.S. dollar term loans
TSC	tuberous sclerosis complex
U.S.	United States of America
U.S. GAAP	U.S. generally accepted accounting principles
UFCW Defendants	Jazz Pharmaceuticals Ireland Ltd., Jazz Pharmaceuticals, Inc., Roxane Laboratories, Inc., Hikma Pharmaceuticals plc, Eurohealth (USA), Inc. and West-Ward Pharmaceuticals Corp.
UFCW Lawsuit	On June 30, 2020, a class action lawsuit was filed in the United States District Court for the Northern District of Illinois by UFCW Local 1500 Welfare Fund on behalf of itself and all others similarly situated, against the UFCW Defendants
UHS Lawsuit	On March 18, 2021, United Healthcare filed a lawsuit in the United States District Court for the District of Minnesota against the Company Defendants, Hikma Pharmaceuticals plc, Roxane Laboratories, Inc., Hikma Pharmaceuticals USA Inc., Eurohealth (USA) Inc., Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc.
United Healthcare	United Healthcare Services, Inc.
USPTO	U.S. Patent and Trademark Office
VOD	veno-occlusive disease
Werewolf	Werewolf Therapeutics, Inc.
Zepzelca ANDA Filers	Sandoz Inc., InvaGen Pharmaceuticals, Inc., CIPLA USA, Inc. CIPLA (EU) Limited, CIPLA Limited, Zydus Lifesciences Global FZE, Zydus Pharmaceuticals (USA) Inc., Zydus Lifesciences Limited, RK Pharma, Inc., Apicore US LLC, Archis Pharma LLC, Vgyaan Pharmaceuticals LLC, MSN Pharmaceuticals Inc., and MSN Laboratories PVT. LTD.
Zymeworks	Zymeworks Inc.

Products

The brand names of our products, our delivery devices and certain of our product candidates and their associated generic names are given below.

Term	Description
CombiPlex	CombiPlex® (delivery technology platform)
Defitelio	Defitelio® (defibrotide sodium), Defitelio® (defibrotide)
dordaviprone	Dordaviprone (ONC201)
Epidiolex	Epidiolex® (cannabidiol) oral solution, Epidyolex® (the trade name in Europe and other countries outside the U.S. for Epidiolex)
Rylaze	Rylaze® (asparaginase erwinia chrysanthemi (recombinant)-rywn), Enrylaze® (the trade name in Europe and other countries outside the U.S. and Canada for Rylaze)
Sativex	Sativex® (nabiximols) oral solution
Suvecaltamide	Suvecaltamide (JZP385)
Vyxeos	Vyxeos® (daunorubicin and cytarabine) liposome for injection, Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion
Xyrem	Xyrem® (sodium oxybate) oral solution
Xywav	Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution
Zepzelca	Zepzelca® (lurbinectedin)
Ziihera	Ziihera® (zanidatamab-hrii)

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®, Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution, Xyrem® (sodium oxybate) oral solution, Epidiolex® (cannabidiol) oral solution, Epidyolex® (the trade name in Europe and other countries outside the U.S. for Epidiolex), Rylaze® (asparaginase erwinia chrysanthemi (recombinant)-rywn),

Enrylaze® (the trade name in Europe and other countries outside the U.S. and Canada for Rylaze), Zepzelca® (lurbinectedin), Defitelio® (defibrotide sodium), Defitelio® (defibrotide), Vyxeos® (daunorubicin and cytarabine) liposome for injection, Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion, CombiPlex®, Sativex® (nabiximols) oral solution and Ziihera® (zanidatamab-hrii).

This Quarterly Report on Form 10-Q 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)

	June 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,189,880	$ 2,412,864
Investments	480,000	580,000
Accounts receivable, net of allowances	714,004	716,765
Inventories	504,989	480,445
Prepaid expenses	164,000	177,411
Other current assets	297,560	261,543
Total current assets	3,350,433	4,629,028
Property, plant and equipment, net	184,975	173,413
Operating lease assets	63,082	53,582
Intangible assets, net	4,768,987	4,755,695
Goodwill	1,843,974	1,716,323
Deferred tax assets, net	602,903	560,245
Deferred financing costs	8,516	9,489
Other non-current assets	121,271	114,482
Total assets	$ 10,944,141	$ 12,012,257
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 89,366	$ 77,869
Accrued liabilities	874,811	910,947
Current portion of long-term debt	1,028,478	31,000
Income taxes payable	78,550	18,757
Total current liabilities	2,071,205	1,038,573
Long-term debt, less current portion	4,335,616	6,077,640
Operating lease liabilities, less current portion	55,107	38,938
Deferred tax liabilities, net	682,123	676,736
Other non-current liabilities	93,731	86,614
Commitments and contingencies (Note 10)		
Shareholders' equity:		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	473	473
Additional paid-in capital	4,000,280	3,913,542
Accumulated other comprehensive loss	(485,768)	(947,667)
Retained earnings	191,313	1,127,347
Total shareholders' equity	3,706,359	4,093,756
Total liabilities and shareholders' equity	$ 10,944,141	$ 12,012,257

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenues:				
Product sales, net	$ 985,571	$ 964,144	$ 1,824,989	$ 1,806,246
Royalties and contract revenues	60,141	59,681	118,564	119,562
Total revenues	1,045,712	1,023,825	1,943,553	1,925,808
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technologies)	116,268	109,902	220,888	205,389
Selling, general and administrative	358,399	338,523	872,412	690,235
Research and development	189,972	220,734	370,624	443,581
Intangible asset amortization	162,103	155,223	316,551	310,953
Acquired in-process research and development	905,362	—	905,362	10,000
Total operating expenses	1,732,104	824,382	2,685,837	1,660,158
Income (loss) from operations	(686,392)	199,443	(742,284)	265,650
Interest expense, net	(47,363)	(62,023)	(101,069)	(128,139)
Foreign exchange gain (loss)	(1,799)	507	(2,012)	(1,186)
Income (loss) before income tax benefit and equity in loss of investees	(735,554)	137,927	(845,365)	136,325
Income tax benefit	(17,170)	(30,653)	(34,982)	(18,984)
Equity in loss of investees	86	12	628	1,359
Net income (loss)	$ (718,470)	$ 168,568	$ (811,011)	$ 153,950
Net income (loss) per ordinary share:				
Basic	$ (11.74)	$ 2.68	$ (13.28)	$ 2.45
Diluted	$ (11.74)	$ 2.49	$ (13.28)	$ 2.35
Weighted-average ordinary shares used in per share calculations - basic	61,194	62,882	61,087	62,710
Weighted-average ordinary shares used in per share calculations - diluted	61,194	69,625	61,087	69,684

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Net income (loss)	$ (718,470)	$ 168,568	$ (811,011)	$ 153,950
Other comprehensive income (loss):				
Foreign currency translation adjustments	299,790	(6,081)	462,686	(50,149)
Unrealized gain on cash flow hedging activities, net of income tax expense of $142, $529, $5 and $2,249 respectively	458	1,592	15	6,769
Gain on cash flow hedging activities reclassified from accumulated other comprehensive loss to interest expense, net of income tax expense of $119, $446, $251 and $897 respectively	(406)	(1,344)	(802)	(2,700)
Other comprehensive income (loss)	299,842	(5,833)	461,899	(46,080)
Total comprehensive income (loss)	$ (418,628)	$ 162,735	$ (349,112)	$ 107,870

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

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Ordinary Shares		Non-voting Euro Deferred		Capital Redemption Reserve	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2024	60,631	$ 6	4,000	$ 55	$ 473	$ 3,913,542	$ (947,667)	$ 1,127,347	$ 4,093,756
Issuance of ordinary shares in conjunction with exercise of share options	93	—	—	—	—	11,447	—	—	11,447
Issuance of ordinary shares in conjunction with vesting of restricted stock units	811	—	—	—	—	—	—	—	—
Issuance of ordinary shares in conjunction with vesting of performance-based restricted stock units	88	—	—	—	—	—	—	—	—
Shares withheld for payment of employees' withholding tax liability	—	—	—	—	—	(67,163)	—	—	(67,163)
Share-based compensation	—	—	—	—	—	67,335	—	—	67,335
Other comprehensive income	—	—	—	—	—	—	162,057	—	162,057
Net loss	—	—	—	—	—	—	—	(92,541)	(92,541)
Balance at March 31, 2025	61,623	$ 6	4,000	$ 55	$ 473	$ 3,925,161	$ (785,610)	$ 1,034,806	$ 4,174,891
Issuance of ordinary shares in conjunction with exercise of share options	1	—	—	—	—	—	—	—	—
Issuance of ordinary shares under employee stock purchase plan	117	—	—	—	—	10,497	—	—	10,497
Issuance of ordinary shares in conjunction with vesting of restricted stock units	41	—	—	—	—	—	—	—	—
Shares withheld for payment of employees' withholding tax liability	—	—	—	—	—	(2,249)	—	—	(2,249)
Share-based compensation	—	—	—	—	—	66,871	—	—	66,871
Shares repurchased	(1,142)	—	—	—	—	—	—	(125,023)	(125,023)
Other comprehensive income	—	—	—	—	—	—	299,842	—	299,842
Net loss	—	—	—	—	—	—	—	(718,470)	(718,470)
Balance at June 30, 2025	60,640	$ 6	4,000	$ 55	$ 473	$ 4,000,280	$ (485,768)	$ 191,313	$ 3,706,359

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Ordinary Shares		Non-voting Euro Deferred		Capital Redemption Reserve	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2023	62,255	$ 6	4,000	$ 55	$ 473	$ 3,699,954	$ (842,147)	$ 878,656	$ 3,736,997
Issuance of ordinary shares in conjunction with exercise of share options	7	—	—	—	—	494	—	—	494
Issuance of ordinary shares in conjunction with vesting of restricted stock units	686	—	—	—	—	—	—	—	—
Issuance of ordinary shares in conjunction with vesting of performance-based restricted stock units	80	—	—	—	—	—	—	—	—
Shares withheld for payment of employees' withholding tax liability	—	—	—	—	—	(49,296)	—	—	(49,296)
Share-based compensation	—	—	—	—	—	63,131	—	—	63,131
Other comprehensive loss	—	—	—	—	—	—	(40,247)	—	(40,247)
Net loss	—	—	—	—	—	—	—	(14,618)	(14,618)
Balance at March 31, 2024	63,028	$ 6	4,000	$ 55	$ 473	$ 3,714,283	$ (882,394)	$ 864,038	$ 3,696,461
Issuance of ordinary shares in conjunction with exercise of share options	4	—	—	—	—	54	—	—	54
Issuance of ordinary shares under employee stock purchase plan	122	—	—	—	—	10,886	—	—	10,886
Issuance of ordinary shares in conjunction with vesting of restricted stock units	49	—	—	—	—	—	—	—	—
Shares withheld for payment of employees' withholding tax liability	—	—	—	—	—	(2,847)	—	—	(2,847)
Share-based compensation	—	—	—	—	—	56,738	—	—	56,738
Shares repurchased	(1,458)	—	—	—	—	—	—	(161,428)	(161,428)
Other comprehensive loss	—	—	—	—	—	—	(5,833)	—	(5,833)
Net income	—	—	—	—	—	—	—	168,568	168,568
Balance at June 30, 2024	61,745	$ 6	4,000	$ 55	$ 473	$ 3,779,114	$ (888,227)	$ 871,178	$ 3,762,599

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)

	Six Months Ended June 30,	
	2025	**2024**
Operating activities		
Net income (loss)	$ (811,011)	$ 153,950
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Acquired in-process research and development	905,362	10,000
Intangible asset amortization	316,551	310,953
Share-based compensation	132,154	118,095
Acquisition accounting inventory fair value step-up adjustment	66,989	62,186
Depreciation	22,331	15,465
Non-cash interest expense	21,914	11,200
Provision for losses on accounts receivable and inventory	6,771	13,186
Deferred tax benefit	(110,252)	(141,568)
Other non-cash transactions	7,042	15,520
Changes in assets and liabilities:		
Accounts receivable	10,530	277
Inventories	(61,852)	(17,591)
Prepaid expenses and other current assets	8,212	34,872
Operating lease assets	12,440	7,199
Other non-current assets	(802)	(5,699)
Accounts payable	6,465	(4,148)
Accrued liabilities	(75,351)	5,404
Income taxes payable	59,270	18,030
Operating lease liabilities, less current portion	(2,887)	(6,909)
Other non-current liabilities	4,763	(1,841)
Net cash provided by operating activities	518,639	598,581
Investing activities		
Asset acquisition, net of cash acquired	(858,053)	—
Acquisition of investments	(680,050)	(705,000)
Purchases of property, plant and equipment	(26,848)	(13,995)
Acquisition of intangible assets	(25,000)	—
Proceeds from maturity of investments	780,000	200,000
Acquired in-process research and development	—	(10,000)
Net cash used in investing activities	(809,951)	(528,995)
Financing activities		
Repayments of long-term debt	(765,500)	(15,500)
Share repurchases	(125,023)	(161,428)
Payment of employee withholding taxes related to share-based awards	(69,412)	(52,143)
Proceeds from employee equity incentive and purchase plans	21,944	11,434
Net cash used in financing activities	(937,991)	(217,637)
Effect of exchange rates on cash and cash equivalents	6,319	(2,457)
Net decrease in cash and cash equivalents	(1,222,984)	(150,508)
Cash and cash equivalents, at beginning of period	2,412,864	1,506,310
Cash and cash equivalents, at end of period	$ 1,189,880	$ 1,355,802

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 a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases - often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines, including leading therapies for sleep disorders and epilepsy, and a growing portfolio of cancer treatments. Our patient-focused and science-driven approach powers pioneering research and development advancements across our robust pipeline of innovative therapeutics in oncology and neuroscience.

Our lead marketed products, listed below, are approved in countries around the world to improve patient care.

Neuroscience

- **Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution**, a product approved by FDA in July 2020, and launched in the U.S. in November 2020 for the treatment of cataplexy or EDS in patients seven years of age and older with narcolepsy, and also approved by FDA in August 2021 for the treatment of IH in adults and launched in the U.S. in November 2021. Xywav contains 92% less sodium than Xyrem®. Xywav is also approved in Canada for the treatment of cataplexy in patients with narcolepsy.
- **Epidiolex® (cannabidiol) oral solution**, a product approved by FDA and launched in the U.S. in 2018 by GW and currently indicated for the treatment of seizures associated with LGS, DS, or TSC in patients one year of age or older; in the EU and Great Britain (where it is marketed as Epidyolex®) and other markets, it is approved for adjunctive treatment of seizures associated with LGS or DS, in conjunction with clobazam (EU and Great Britain only), in patients 2 years of age and older and for adjunctive treatment of seizures associated with TSC in patients 2 years of age and older.

Oncology

- **Rylaze® (asparaginase erwinia chrysanthemi (recombinant)-rywn)**, a product approved by FDA in June 2021 and launched in the U.S. in July 2021 for use as a component of a multi-agent chemotherapeutic regimen for the treatment of ALL or LBL in adults and pediatric patients aged one month or older who have developed hypersensitivity to *E. coli*-derived asparaginase. In September 2023, the EC granted marketing authorization under the trade name Enrylaze®. This therapy is also approved in markets including Great Britain, Canada, Switzerland and Australia.
- **Zepzelca® (lurbinectedin)**, a product approved by FDA in June 2020 under FDA's accelerated approval pathway and launched in the U.S. in July 2020 for the treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy; in Canada, Zepzelca received conditional approval in September 2021 for the treatment of adults with Stage III or metastatic SCLC, who have progressed on or after platinum-containing therapy.
- **Ziihera® (zanidatamab-hrii)**, a product approved by FDA in November 2024 under FDA's accelerated approval pathway and launched in the U.S. in December 2024 for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC, as detected by an FDA-approved test. In June 2025, the EC granted conditional marketing authorization for Ziihera® for the treatment of adults with unresectable locally advanced or metastatic HER2-positive (IHC3+) BTC previously treated with at least one prior line of systemic therapy.

In April 2025, we acquired Chimerix for a total cash consideration of $944.2 million. For further information regarding the Chimerix Acquisition, please see Note 2.

Throughout this Quarterly Report on Form 10-Q, unless otherwise indicated or the context otherwise requires, all references to "Jazz Pharmaceuticals," "the registrant," "the Company," "we," "us," and "our" refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries. Throughout this Quarterly Report on Form 10-Q, 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 for interim reporting. As permitted under those rules, certain footnotes and other financial information that are normally required by 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 audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2024.

In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual audited 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 six months ended June 30, 2025, are not necessarily indicative of the results to be expected for the year ending December 31, 2025, for any other interim period or for any future period.

Our significant accounting policies have not changed substantially from those previously described in our Annual Report on Form 10-K for the year ended December 31, 2024.

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

Our operating segment is reported in a manner consistent with the internal reporting provided to the 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 CODM assesses performance and decides how to allocate resources for the segment based on net income (loss) and measure of segment assets which is reported on the condensed consolidated statements of income (loss) and condensed consolidated balance sheet.

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.

Adoption of New Accounting Standards

In December 2023, the FASB issued ASU 2023-09, “Income Taxes (Topic 740) - Improvements to Income Tax Disclosures”, which requires enhanced tax disclosures providing greater disaggregation of information in the Company's effective tax rate reconciliation and disaggregates income taxes paid by jurisdiction. The amendments are effective on a prospective basis, with the option to apply it retrospectively, for fiscal years beginning after December 15, 2024. The adoption of ASU 2023-09 will expand our income tax disclosures in our Annual Report on Form 10-K, but will have no impact on reported income tax (benefit) expense or related tax assets or liabilities.

Significant Risks and Uncertainties

We expect that our business will continue to meaningfully depend on oxybate revenues; however, there is no guarantee that oxybate revenues will remain at current levels. In this regard, our ability to maintain oxybate revenues and realize the anticipated benefits from our investment in Xywav are subject to a number of risks and uncertainties including, without limitation, those related to the commercialization of Xywav for the treatment of IH in adults and adoption in that indication; competition from the introduction of two AG versions of high-sodium oxybate and a branded fixed-dose, high-sodium oxybate, Avadel’s Lumryz, for treatment of cataplexy and/or EDS in narcolepsy in the U.S. market, as well as potential future competition from additional AG versions of high-sodium oxybate and from generic versions of high-sodium oxybate and from other competitors; increased pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors, including our ability to maintain adequate coverage and reimbursement for Xywav; increased rebates required to maintain access to our products; challenges to our intellectual property around Xywav and/or Xyrem, including from pending antitrust and intellectual property litigation; and continued acceptance of Xywav by physicians and patients. A significant decline in oxybate revenues could cause us to reduce our operating expenses or seek to raise additional funds and would have a material adverse effect on our business, financial condition, results of operations and growth prospects, including on our ability to acquire, in-license or develop new products to grow our business.

Our financial condition, results of operations and growth prospects are also dependent on our ability to maintain or increase sales of Epidiolex/Epidyolex in the U.S. and Europe, which is subject to many risks and there is no guarantee that we will be able to continue to successfully commercialize Epidiolex/Epidyolex for its approved indications. The commercial success of Epidiolex/Epidyolex depends on the extent to which patients and physicians accept and adopt Epidiolex/Epidyolex as a treatment for seizures associated with LGS, DS and TSC, and we do not know whether our or others’ estimates in this regard will be accurate. Physicians may not prescribe Epidiolex and patients may be unwilling to use Epidiolex/Epidyolex if

coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for Epidiolex/Epidyolex in the market, in clinical development for additional indications, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of Epidiolex/Epidyolex.

In addition to risks related specifically to Xywav and Epidiolex/Epidyolex, we are subject to other challenges and risks related to successfully commercializing a portfolio of oncology products and other neuroscience products, and other risks specific to our business and our ability to execute on our strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, including, without limitation, risks and uncertainties associated with: pharmaceutical product development, ongoing clinical research activity and related outcomes; obtaining regulatory approval of our late-stage product candidates, including dordaviprone; effectively commercializing our approved products such as Rylaze, Zepzelca and Ziihera; obtaining and maintaining adequate coverage and reimbursement for our products; contracting and rebates to pharmacy benefit managers and similar organizations that reduce our net revenue; increasing scrutiny of pharmaceutical product pricing and resulting changes in healthcare laws and policy; market acceptance; regulatory concerns with controlled substances generally and the potential for abuse; future legislation; action by the U.S. Federal Government authorizing the sale, distribution, use, and insurance reimbursement of non-FDA approved cannabinoid products; delays or problems in the supply of our products; loss of single source suppliers or failure to comply with manufacturing regulations; delays or problems with third parties that are part of our manufacturing and supply chain; identifying, acquiring or in-licensing additional products or product candidates; our ability to realize the anticipated benefits of acquired or in-licensed products or product candidates, such as Ziihera and dordaviprone, at the expected levels, with the expected costs and within the expected timeframe; the challenges of protecting and enhancing our intellectual property rights; complying with applicable regulatory requirements; the impact of new or increased tariffs and escalating trade tensions; and possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations.

Concentrations of Risk

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

We manage our foreign currency transaction risk and interest rate risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. As of June 30, 2025 and December 31, 2024, we had foreign exchange forward contracts with notional amounts totaling $372.3 million and $461.2 million, respectively. As of June 30, 2025 and December 31, 2024, the outstanding foreign exchange forward contracts had a net asset fair value of $6.3 million and a net liability fair value of $7.9 million, respectively. As of June 30, 2025 and December 31, 2024, we had interest rate swap contracts with notional amounts totaling $500.0 million. As of June 30, 2025 and December 31, 2024, these outstanding interest rate swap contracts had a net liability fair value of $42 thousand and a net asset fair value of $1.0 million, respectively. The counterparties to these contracts are large multinational commercial banks, and we believe the risk of nonperformance is not significant.

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to pharmaceutical wholesale distributors and specialty pharmaceutical distribution companies, primarily in the U.S., and to other international distributors and hospitals. Customer creditworthiness is monitored and collateral is not required. We monitor economic conditions in certain European countries which may result in variability of the timing of cash receipts and an increase in the average length of time that it takes to collect accounts receivable outstanding. Historically, we have not experienced significant credit losses on our accounts receivable and, as of June 30, 2025 and December 31, 2024, allowances on receivables were not material. As of June 30, 2025, five customers accounted for 81% of gross accounts receivable, including ESSDS, which accounted for 41% of gross accounts receivable, ASD, which accounted for 15% of gross accounts receivable and McKesson, which accounted for 11% of gross accounts receivable. As of December 31, 2024, five customers accounted for 80% of gross accounts receivable, including ESSDS, which accounted for 39% of gross accounts receivable, ASD, which accounted for 15% 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. With respect to our oxybate products, the API is manufactured for us by a single source supplier and the finished products are manufactured both by us in our facility in Athlone, Ireland and by our U.S.-based supplier, which is certified to produce Xyrem and Xywav.

Recent Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, "Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-04) - Disaggregation of Income Statement Expenses", which requires additional disclosure in the notes to the financial statements of the nature of certain expenses included in the income statement. The amendments are effective on a prospective basis, with the option to apply them retrospectively, for fiscal years beginning after December 15, 2026. We are currently evaluating the impact of adopting this new accounting guidance.

In November 2024, the FASB issued ASU 2024-04, "Induced Conversions of Convertible Debt Instruments", which clarifies the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion or extinguishment of convertible debt. The amendments are effective on a prospective basis, with the option to apply them retrospectively, for fiscal years beginning after December 15, 2025. We are currently evaluating the impact of adopting this new accounting guidance.

2. Asset Acquisition

On April 21, 2025, we acquired the entire issued share capital of Chimerix at a price of $8.55 per share, payable in cash at closing, representing a total cash consideration of $944.2 million, funded with our cash and cash equivalents. As a result of this, Chimerix became an indirect wholly owned subsidiary of the Company. The acquisition of Chimerix was accounted for as an asset acquisition because it did not meet the definition of a business.

The total consideration paid and the allocation to assets acquired and liabilities assumed was (in thousands):

Consideration		
Cash consideration to acquire Chimerix's outstanding common stock	$	802,023
Cash consideration for Chimerix's outstanding equity awards		142,131
Total cash consideration paid to Chimerix		944,154
Transaction costs		13,237
Total consideration	$	957,391
Assets Acquired and Liabilities Assumed		
Cash	$	99,338
In-process research and development		905,362
Accrued liabilities		(53,066)
Other assets and liabilities		5,757
Total net assets acquired	$	957,391

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

3. Cash and Available-for-Sale Securities

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

	June 30, 2025					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 672,211	$ —	$ —	$ 672,211	$ 672,211	$ —
Time deposits	480,000	—	—	480,000	—	480,000
Money market funds	517,669	—	—	517,669	517,669	—
Totals	$ 1,669,880	$ —	$ —	$ 1,669,880	$ 1,189,880	$ 480,000

	December 31, 2024					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 948,894	$ —	$ —	$ 948,894	$ 948,894	$ —
Time deposits	790,000	—	—	790,000	210,000	580,000
Money market funds	1,253,970	—	—	1,253,970	1,253,970	—
Totals	$ 2,992,864	$ —	$ —	$ 2,992,864	$ 2,412,864	$ 580,000

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 (loss). Our investment balances represent time deposits with original maturities of greater than three months and less than one year. Interest income from available-for-sale securities was $19.1 million and $46.8 million in the three and six months ended June 30, 2025, respectively, and $25.4 million and $48.6 million in the three and six months ended June 30, 2024, respectively.

4. Fair Value Measurement

The following table summarizes, by major security type, our available-for-sale securities and derivative contracts as of June 30, 2025 and December 31, 2024, that were measured at fair value on a recurring basis and were categorized using the fair value hierarchy (in thousands):

	June 30, 2025			December 31, 2024		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Assets:						
Available-for-sale securities:						
Money market funds	$ 517,669	$ —	$ 517,669	$ 1,253,970	$ —	$ 1,253,970
Time deposits	—	480,000	480,000	—	790,000	790,000
Foreign exchange forward contracts	—	9,137	9,137	—	2,250	2,250
Interest rate contracts	—	6	6	—	991	991
Totals	$ 517,669	$ 489,143	$ 1,006,812	$ 1,253,970	$ 793,241	$ 2,047,211
Liabilities:						
Foreign exchange forward contracts	$ —	$ 2,801	$ 2,801	$ —	$ 10,198	$ 10,198
Interest rate contracts	—	48	48	—	—	—
Totals	$ —	$ 2,849	$ 2,849	$ —	$ 10,198	$ 10,198

As of June 30, 2025 and December 31, 2024, our available-for-sale securities included money market funds and time deposits and their carrying values were approximately equal to their fair values. Money market funds were measured using quoted prices in active markets, which represent Level 1 inputs and time deposits were measured at fair value using Level 2 inputs. Level 2 inputs are obtained from various third party data providers and 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 2025 or 2024.

As of June 30, 2025 and December 31, 2024, the carrying amount of investments measured using the measurement alternative for equity investments without a readily determinable fair value was $4.3 million. The carrying amount, which is recorded within other non-current assets, is based on the latest observable transaction price.

As of June 30, 2025 and December 31, 2024, the estimated fair values of the 2026 Notes, the 2030 Notes and the Secured Notes were $1.0 billion, $1.1 billion and $1.4 billion, respectively. The estimated fair value of the Tranche B-2 Dollar Term Loans as of June 30, 2025 and December 31, 2024 was $1.9 billion and $2.7 billion, respectively. The fair values of each of these debt facilities was estimated using quoted market prices obtained from brokers (Level 2).

5. Derivative Instruments and Hedging Activities

We are exposed to certain risks arising from operating internationally, including fluctuations in foreign exchange rates primarily related to the translation of sterling and euro denominated net monetary liabilities, including intercompany balances, held by subsidiaries with a U.S. dollar functional currency and fluctuations in interest rates on our outstanding term loan borrowings. 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.

We enter into foreign exchange forward contracts, with durations of up to 12 months, designed to limit the exposure to fluctuations in foreign exchange rates related to the translation of certain non-U.S. dollar denominated liabilities, including intercompany balances. Hedge accounting is not applied to these derivative instruments as gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of June 30, 2025 and December 31, 2024, the notional amount of foreign exchange contracts where hedge accounting is not applied was $372.3 million and $461.2 million, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
Foreign Exchange Forward Contracts:	**2025**	**2024**	**2025**	**2024**
Gain (loss) recognized in foreign exchange gain (loss)	$ 12,393	$ (825)	$ 21,000	$ (4,911)

To achieve a desired mix of floating and fixed interest rates on our variable rate debt, we entered into interest rate swap agreements in April 2023, which are effective until April 2026. These agreements hedge contractual term loan interest rates. As of June 30, 2025, the interest rate swap agreements had a notional amount of $500.0 million. As a result of these agreements, the interest rate on a portion of our term loan borrowings is fixed at 3.9086%, plus the borrowing spread, until April 30, 2026.

The impact on accumulated other comprehensive loss and earnings from derivative instruments that qualified as cash flow hedges was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
Interest Rate Contracts:	**2025**	**2024**	**2025**	**2024**
Gain recognized in accumulated other comprehensive loss, net of tax	$ 458	$ 1,592	$ 15	$ 6,769
Gain reclassified from accumulated other comprehensive loss to interest expense, net of tax	(406)	(1,344)	(802)	(2,700)

The cash flow effects of our derivative contracts for the six months ended June 30, 2025 and 2024 are included within net cash provided by operating activities in the condensed consolidated statements of cash flows.

The following tables summarize the fair value of outstanding derivatives (in thousands):

	Classification	June 30, 2025	December 31, 2024
Assets			
Derivatives designated as hedging instruments:			
Interest rate contracts	Other current assets	$ 6	$ 959
	Other non-current assets	—	32
Derivatives not designated as hedging instruments:			
Foreign exchange forward contracts	Other current assets	9,137	2,250
Total fair value of derivative asset instruments		$ 9,143	$ 3,241
Liabilities			
Derivatives designated as hedging instruments:			
Interest rate contracts	Accrued liabilities	$ 48	$ —
Derivatives not designated as hedging instruments:			
Foreign exchange forward contracts	Accrued liabilities	2,801	10,198
Total fair value of derivative liability instruments		$ 2,849	$ 10,198

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 and foreign exchange forward contracts subject to such provisions (in thousands):

	June 30, 2025					
				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	$ 9,143	$ —	$ 9,143	$ (2,834)	$ —	$ 6,309
Derivative liabilities	(2,849)	—	(2,849)	2,834	—	(15)

	December 31, 2024					
				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	$ 3,241	$ —	$ 3,241	$ (2,910)	$ —	$ 331
Derivative liabilities	(10,198)	—	(10,198)	2,910	—	(7,288)

6. Inventories

Inventories consisted of the following (in thousands):

	June 30, 2025	December 31, 2024
Raw materials	$ 39,566	$ 20,161
Work in process	300,459	311,752
Finished goods	164,964	148,532
Total inventories	$ 504,989	$ 480,445

As of June 30, 2025 and December 31, 2024, inventories included $138.0 million and $191.2 million, respectively, related to the purchase accounting inventory fair value step-up on inventory acquired as part of our GW acquisition.

7. Goodwill and Intangible Assets

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

Balance at December 31, 2024	$ 1,716,323
Foreign exchange	127,651
Balance at June 30, 2025	$ 1,843,974

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

	June 30, 2025				December 31, 2024		
	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	7.3	$ 8,240,335	$ (3,471,348)	$ 4,768,987	$ 7,699,423	$ (2,943,728)	$ 4,755,695
Manufacturing contracts	—	12,545	(12,545)	—	11,121	(11,121)	—
Trademarks	—	2,903	(2,903)	—	2,868	(2,868)	—
Total finite-lived intangible assets		$ 8,255,783	$ (3,486,796)	$ 4,768,987	$ 7,713,412	$ (2,957,717)	$ 4,755,695

The increase in the gross carrying amount of intangible assets as of June 30, 2025, compared to December 31, 2024, relates to the positive impact of foreign currency translation adjustments primarily due to the strengthening of sterling against the U.S. dollar.

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 June 30, 2025, 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
2025 (remainder)	$ 340,354
2026	678,197
2027	669,802
2028	646,640
2029	644,906
Thereafter	1,789,088
Total	$ 4,768,987

8. Certain Balance Sheet Items

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

	June 30, 2025	December 31, 2024
Manufacturing equipment and machinery	$ 96,286	$ 87,451
Land and buildings	73,772	71,902
Computer software	58,399	42,635
Leasehold improvements	56,119	70,201
Construction-in-progress	36,334	34,493
Computer equipment	21,487	20,137
Furniture and fixtures	8,902	8,551
Subtotal	351,299	335,370
Less accumulated depreciation and amortization	(166,324)	(161,957)
Property, plant and equipment, net	$ 184,975	$ 173,413

Accrued liabilities consisted of the following (in thousands):

	June 30, 2025	December 31, 2024
Rebates and other sales deductions	$ 429,142	$ 342,717
Employee compensation and benefits	103,074	153,133
Clinical trial accruals	44,557	49,962
Inventory-related accruals	41,670	25,509
Accrued interest	40,703	41,626
Accrued royalties	31,627	36,802
Sales return reserve	29,816	26,428
Consulting and professional services	24,425	26,221
Selling and marketing accruals	23,265	26,981
Accrued development expenses	20,613	23,099
Current portion of lease liabilities	13,883	14,779
Accrued construction-in-progress	7,705	10,061
Derivative instrument liabilities	2,849	10,198
Accrued collaboration expenses	2,339	18,005
Accrued milestones	—	27,500
Other	59,143	77,926
Total accrued liabilities	$ 874,811	$ 910,947

9. Debt

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

	June 30, 2025	December 31, 2024
2026 Notes	$ 1,000,000	$ 1,000,000
Unamortized - debt issuance costs	(2,522)	(3,747)
2026 Notes, net	997,478	996,253
2030 Notes	1,000,000	1,000,000
Unamortized - debt issuance costs	(17,735)	(19,135)
2030 Notes, net	982,265	980,865
Secured Notes	1,485,338	1,483,841
Term Loan [1]	1,899,013	2,647,681
Total debt	5,364,094	6,108,640
Less current portion [2]	1,028,478	31,000
Total long-term debt	$ 4,335,616	$ 6,077,640

(1) In January 2025, we made a voluntary repayment on the Tranche B-2 Dollar Term Loan totaling $750.0 million.
(2) Balance as of June 30, 2025 includes the 2026 Notes since they mature in June 2026.

Exchangeable Senior Notes

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

In September 2024, Jazz Investments completed a private placement of $1.0 billion aggregate principal amount of the 2030 Notes. The 2030 Notes are accounted for as a single liability measured at its amortized cost. The total liability is reflected net of issuance costs of $19.2 million which will be amortized over the term of the 2030 Notes. The effective interest rate of the 2030 Notes is 3.47%. During the three months ended June 30, 2025, we recognized interest expense of $8.5 million, of which $7.8 million related to the contractual coupon rate and $0.7 million related to the amortization of debt issuance costs. During the six months ended June 30, 2025, we recognized interest expense of $17.0 million, of which $15.6 million related to the contractual coupon rate and $1.4 million related to the amortization of debt issuance costs.

The total liability of the 2026 Notes is reflected net of issuance costs of $15.3 million which will be amortized over the term of the 2026 Notes. The effective interest rate of the 2026 Notes is 2.26%. During the three months ended June 30, 2025 and 2024, we recognized interest expense of $5.6 million, of which $5.0 million related to the contractual coupon rate and $0.6 million related to the amortization of debt issuance costs. During the six months ended June 30, 2025 and 2024, we recognized interest expense of $11.1 million, of which $10.0 million related to the contractual coupon rate and $1.1 million related to the amortization of debt issuance costs.

On August 15, 2024, the maturity date for the 2024 Notes, we repaid the $575.0 million aggregate principal amount, plus accrued and unpaid interest thereon. The effective interest rate of the 2024 Notes was 1.79%. During the three months ended June 30, 2024, we recognized interest expense of $2.5 million, of which $2.1 million related to the contractual coupon rate and $0.4 million related to the amortization of debt issuance costs. During the six months ended June 30, 2024, we recognized interest expense of $5.0 million, of which $4.2 million related to the contractual coupon rate and $0.8 million related to the amortization of debt issuance costs.

Maturities

Scheduled maturities with respect to our long-term debt principal balances outstanding as of June 30, 2025 were as follows (in thousands):

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2025 (remainder)	$ 15,500
2026	1,031,000
2027	31,000
2028	1,848,500
2029	1,500,000
Thereafter	1,000,000
Total	$ 5,426,000

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, 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 June 30, 2025 and December 31, 2024. 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.

Legal Proceedings

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

Xyrem Antitrust Litigation

From June 2020 to May 2022, a number of lawsuits were filed on behalf of purported direct and indirect Xyrem purchasers, alleging that the patent litigation settlement agreements we entered with generic drug manufacturers who had filed ANDAs violate state and federal antitrust and consumer protection laws, as follows:

On June 17, 2020, a class action lawsuit was filed in the United States District Court for the Northern District of Illinois by BCBS against the Company Defendants. The BCBS Lawsuit also the BCBS Defendants.

On June 18 and June 23, 2020, respectively, two additional class action lawsuits were filed against the Company Defendants and the BCBS Defendants: one by the New York State Teamsters Council Health and Hospital Fund in the United States District Court for the Northern District of California, and another by the Government Employees Health Association Inc. in the United States District Court for the Northern District of Illinois.

On June 18, 2020, a class action lawsuit was filed in the United States District Court for the Northern District of California by the City of Providence, Rhode Island, on behalf of itself and all others similarly situated, against the City of Providence Defendants.

On June 30, 2020, a class action lawsuit was filed in the United States District Court for the Northern District of Illinois by UFCW Local 1500 Welfare Fund on behalf of itself and all others similarly situated, against UFCW Defendants.

On July 13, 2020, the plaintiffs in the BCBS Lawsuit and the GEHA Lawsuit dismissed their complaints in the United States District Court for the Northern District of Illinois and refiled their respective lawsuits in the United States District Court for the Northern District of California. On July 14, 2020, the plaintiffs in the UFCW Lawsuit dismissed their complaint in the United States District Court for the Northern District of Illinois and on July 15, 2020, refiled their lawsuit in the United States District Court for the Northern District of California.

On July 31, 2020, a class action lawsuit was filed in the United States District Court for the Southern District of New York by the A.F. of L.-A.G.C. Building Trades Welfare Plan on behalf of itself and all others similarly situated, against Jazz Pharmaceuticals plc. The AFL Plan Lawsuit also names Roxane Laboratories Inc., West-Ward Pharmaceuticals Corp., Hikma Labs Inc., Hikma Pharmaceuticals plc, Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc., and Lupin Inc.

On August 14, 2020, an additional class action lawsuit was filed in the United States District Court for the Southern District of New York by the Self-Insured Schools of California on behalf of itself and all others similarly situated, against the Company Defendants, as well as Hikma Pharmaceuticals plc, Eurohealth (USA) Inc., Hikma Pharmaceuticals USA, Inc., West-Ward Pharmaceuticals Corp., Roxane Laboratories, Inc., Amneal Pharmaceuticals LLC, Endo International, plc, Endo Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals Inc., Lupin Inc., Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Holdings USA, Inc., Sun Pharmaceutical Industries, Inc., Ranbaxy Laboratories Ltd., Teva Pharmaceutical Industries Ltd., Watson Laboratories, Inc., Wockhardt Ltd., Morton Grove Pharmaceuticals, Inc., Wockhardt USA LLC, Mallinckrodt plc, and Mallinckrodt LLC.

On September 16, 2020, an additional class action lawsuit was filed in the United States District Court for the Northern District of California, by Ruth Hollman on behalf of herself and all others similarly situated, against the same defendants named in the Self-Insured Schools Lawsuit.

In December 2020, the above cases were centralized and transferred to the United States District Court for the Northern District of California, where the multidistrict litigation will proceed for the purpose of discovery and pre-trial proceedings.

On March 18, 2021, United Healthcare filed the UHS Lawsuit in the United States District Court for the District of Minnesota against the Company Defendants, Hikma Pharmaceuticals plc, Roxane Laboratories, Inc., Hikma Pharmaceuticals USA Inc., Eurohealth (USA) Inc., Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc., raising similar allegations. On March 24, 2021, the U.S. Judicial Panel on Multidistrict Litigation conditionally transferred the UHS Lawsuit to the United States District Court for the Northern District of California, where it was consolidated for discovery and pre-trial proceedings with the other cases.

On August 13, 2021, the United States District Court for the Northern District of California granted in part and denied in part the Company Defendants' motion to dismiss the complaints in the cases referenced above.

On October 8, 2021, Humana Inc. filed a lawsuit in the United States District Court for the Northern District of California against the Company Defendants, Hikma Pharmaceuticals plc, Hikma Pharmaceuticals USA Inc., Hikma Labs, Inc., Eurohealth (USA), Inc., Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc., and Lupin Inc, raising similar allegations.

On October 8, 2021, Molina Healthcare Inc. filed a lawsuit in the United States District Court for the Northern District of California against the Company Defendants, Hikma Pharmaceuticals plc, Hikma Pharmaceuticals USA Inc., Hikma Labs, Inc., Eurohealth (USA), Inc., Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc., and Lupin Inc, raising similar allegations.

On February 17, 2022, Health Care Service Corporation filed a lawsuit in the United States District Court for the Northern District of California against the Company Defendants, Hikma Pharmaceuticals plc, Hikma Pharmaceuticals USA Inc., Hikma Labs, Inc., Eurohealth (USA), Inc., Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc., and Lupin Inc, raising similar allegations.

On April 19, 2023, the Court held a hearing on class certification in the consolidated multi-district litigation referenced above. On May 12, 2023, the Court granted the plaintiffs' motion and preliminarily certified classes of Xyrem purchasers seeking monetary and injunctive relief. The Court excluded Xywav purchasers from the classes. On April 26, 2024, we, Hikma, and the plaintiffs filed motions for summary judgment. The Court held oral argument on these motions on July 19, 2024. On August 26, 2024, the Court issued a decision granting in part and denying in part the parties' motions for summary judgment. Certain administrative service organization plaintiffs filed a motion for reconsideration of a portion of the Court's summary judgment ruling. On December 16, 2024, the Court denied the motion for reconsideration. On January 15, 2025, Aetna, Inc., which is not a party to the consolidated multi-district litigation, filed a notice of appeal of the order denying reconsideration. On March 26, 2025, we and Hikma filed a motion to dismiss Aetna's appeal. On May 20, 2025, the Ninth Circuit denied our motion to dismiss.

On June 13, 2024, we filed a motion to decertify the class. On June 28, 2024, the plaintiffs filed a motion to amend the definition of the certified class. The Court held oral argument on these motions on August 22, 2024. On October 18, 2024, the Court issued a decision denying our motion to decertify the class and granting the plaintiffs' motion to amend the class definition. On November 1, 2024, we filed a petition with the United States Court of Appeals for the Ninth Circuit seeking leave to appeal the Court's decision amending the class definition. On January 29, 2025, the Ninth Circuit denied our petition for permission to appeal.

On April 7, 2025, Jazz Pharmaceuticals Ireland Limited, our wholly-owned subsidiary, entered into a class settlement agreement with the class of indirect Xyrem purchasers to settle all claims of participating class members against the Company with respect to our actions leading up to, and entering into, patent litigation settlement agreements with the ANDA filers.

Pursuant to the class settlement agreement, which was entered into with counsel representing the class representatives, we agreed to pay a total of $145 million in a lump sum. The class settlement agreement remains subject to court approval. The class settlement agreement, in which we deny all alleged wrongdoing, also includes specified releases by class members of Jazz and its past, present and future affiliates, directors, officers, employees and other related parties, for all conduct concerning any of the matters alleged, or that could have been alleged, in the lawsuit. Plaintiffs who affirmatively opt out of the class will not be bound by the release and will not receive any settlement proceeds. Additionally, the class settlement agreement grants us the right to rescind the settlement agreement in the event an agreed upon percentage based on Xyrem purchases or payments made by potential class members that opt out. This settlement, if finalized on the agreed-upon terms, will resolve the majority of claims at issue in the multidistrict litigation. If the class settlement agreement is not approved by the Court, or we terminate the class settlement agreement, we intend to defend against these claims vigorously. We also remain confident in our defenses to the other claims brought by plaintiffs described above, including that the patent settlement agreements at issue were and are pro-competitive, and intend to continue to vigorously defend against these claims.

The Court held a preliminary approval hearing regarding the class settlement agreement on May 15, 2025, and granted the motion for preliminary approval on May 16, 2025. The Court scheduled a final approval hearing regarding the class settlement for October 23, 2025.

On May 20, 2025, Jazz Pharmaceuticals Ireland Limited entered into a settlement agreement with United Healthcare to settle all of United Healthcare's claims against us with respect to our actions leading up to, and entering into, patent litigation settlement agreements with the ANDA filers. Pursuant to that settlement agreement, on June 23, 2025, United Healthcare filed a motion for voluntary dismissal with prejudice of its claims against us. The Court granted United Healthcare's motion on July 16, 2025. The terms of the settlement between Jazz Pharmaceuticals Ireland Limited and United Healthcare are confidential.

Trial between Jazz and the remaining plaintiffs in the consolidated multidistrict litigation in this matter is scheduled for March 2, 2026.

On January 13, 2023, Amneal Pharmaceuticals LLC, Lupin Ltd., Lupin Pharmaceuticals, Inc., and Lupin Inc, notified the Court that they had reached a settlement-in-principle with the class action plaintiffs. On April 19, 2023, the Court held a hearing on a motion for preliminary approval of this proposed settlement. On May 12, 2023, the Court granted the motion for preliminary approval of the proposed settlement. On January 11, 2024, the Court held a hearing on the motion for final approval of the proposed settlement. The Court deferred ruling and scheduled a further hearing for final approval of the proposed settlement on April 17, 2024. During February and March 2024, the parties notified the Court of settlements between certain non-class action plaintiffs and each of Amneal and Lupin, and the Court dismissed those plaintiffs' claims against the applicable parties. On April 17, 2024, the Court issued an order granting the motion for final approval of the settlement between the class action plaintiffs, Amneal, and Lupin.

On December 11, 2023, Blue Cross and Blue Shield of Florida, Inc. and Health Options, Inc. filed a lawsuit in the United States District Court for the Middle District of Florida against the Company Defendants, Hikma Pharmaceuticals plc, Hikma Pharmaceuticals USA Inc., Hikma Labs, Inc., and Eurohealth (USA), Inc., raising similar allegations. On January 23, 2024, the Blue Cross Florida case was transferred to the United States District Court for the Northern District of California and consolidated with the above referenced multidistrict litigation for pretrial purposes.

On May 9, 2022, Aetna filed a lawsuit in the Superior Court of California for the County of Alameda against the Company Defendants, Hikma Pharmaceuticals plc, Hikma Pharmaceuticals USA Inc., Hikma Labs, Inc., Eurohealth (USA), Inc., Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc., and Lupin Inc, raising similar allegations. On December 27, 2022, the Court granted in part and denied in part our motion to dismiss Aetna's complaint. As a result of that ruling, the generic defendants have been dismissed from the case, and certain of Aetna's claims against Jazz have been dismissed. On January 27, 2023, Aetna filed an amended complaint against Jazz. On March 22, 2023, we filed motions to dismiss and to strike portions of the amended complaint. On June 26, 2023, the Court granted our motions, and granted Aetna leave to further amend its complaint. On November 17, 2023, Aetna filed its second amended complaint. On February 2, 2024, we filed our answer to the second amended complaint and Hikma filed a motion to quash service. The

Court held hearings on Hikma's motion on December 4, 2024 and June 4, 2025. Trial in this case is scheduled for June 16, 2026.

The plaintiffs in certain of these lawsuits are seeking to represent a class of direct purchasers of Xyrem, and the plaintiffs in the remaining lawsuits are seeking to represent a class of indirect purchasers of Xyrem. Each of the lawsuits generally alleges violations of U.S. federal and state antitrust, consumer protection, and unfair competition laws in connection with the Company Defendants' conduct related to Xyrem, including actions leading up to, and entering into, patent litigation settlement agreements with each of the other named defendants. Each of the lawsuits seeks monetary damages, exemplary damages, equitable relief against the alleged unlawful conduct, including disgorgement of profits and restitution, and injunctive relief. It is possible that additional lawsuits will be filed against the Company Defendants making similar or related allegations. If the plaintiffs were to be successful in their claims, they may be entitled to injunctive relief or we may be required to pay significant monetary damages, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We recognized an expense of $172.0 million within selling, general and administrative expenses in our condensed consolidated statements of income (loss) for the six months ended June 30, 2025 for charges related to the resolution of a portion of the Xyrem antitrust litigation, including the class settlement.

Patent Infringement Litigation

Avadel Litigation

On May 13, 2021, we filed a patent infringement suit against Avadel, and several of its corporate affiliates in the United States District Court for the District of Delaware. The suit alleges that Avadel's Lumryz will infringe five of our patents related to controlled release formulations of oxybate and the safe and effective distribution of oxybate. The suit seeks an injunction to prevent Avadel from launching a product that would infringe these patents, and an award of monetary damages if Avadel does launch an infringing product. Avadel filed an answer to the complaint and counterclaims asserting that the patents are invalid or not enforceable, and that its product will not infringe our patents. Avadel filed a motion for partial judgment on the pleadings on its counterclaim that one of our patents should be delisted from the Orange Book. On November 18, 2022, the Court issued an order that we delist the patent from the Orange Book. On November 22, 2022, we filed a notice of appeal to the United States Court of Appeals for the Federal Circuit. The Federal Circuit temporarily stayed the District Court's delisting order. On February 24, 2023, the Federal Circuit affirmed the District Court's delisting order, lifted the temporary stay, and gave Jazz 14 days to request that FDA delist the patent from the Orange Book. Jazz complied with the Federal Circuit's order and requested delisting on February 28, 2023. On March 3, 2023, we and Avadel stipulated to the dismissal without prejudice of the claims and counterclaims related to infringement and validity of the delisted patent in both this suit and a later-filed suit described below related to the same patent.

On August 4, 2021, we filed an additional patent infringement suit against Avadel in the United States District Court for the District of Delaware. The second suit alleges that Avadel's Lumryz will infringe a newly-issued patent related to sustained-release formulations of oxybate. The suit seeks an injunction to prevent Avadel from launching a product that would infringe this patent, and an award of monetary damages if Avadel does launch an infringing product. Avadel filed an answer to the complaint and counterclaims asserting that the patents are invalid or not enforceable, and that its product will not infringe our patents.

On November 10, 2021, we filed an additional patent infringement suit against Avadel in the United States District Court for the District of Delaware. The third suit alleges that Avadel's Lumryz will infringe a newly-issued patent related to sustained-release formulations of oxybate. The suit seeks an injunction to prevent Avadel from launching a product that would infringe this patent, and an award of monetary damages if Avadel does launch an infringing product. Avadel filed an answer to the complaint and counterclaims asserting that the patents are invalid or not enforceable, and that its product will not infringe our patents.

On April 14, 2022, Avadel sued us in the United States District Court for the District of Delaware. Avadel's suit alleges that we misappropriated trade secrets related to Avadel's once-nightly sodium oxybate development program and breached certain contracts between the parties. Avadel seeks monetary damages, an injunction preventing us from using Avadel's confidential information, and an order directing the United States Patent and Trademark Office to modify the inventorship of one of our oxybate patents. On July 8, 2022, we filed a motion for judgment on the pleadings, which the Court denied on July 18, 2023. The denial is not a ruling that Jazz misappropriated Avadel's trade secrets or breached any contract. The case will go forward in discovery and the Court instructed the parties to submit a proposed scheduling order.

On June 7, 2022, we received notice from Avadel that it had filed a "paragraph IV certification" regarding one patent listed in the Orange Book for Xyrem. A paragraph IV certification is a certification by a generic applicant that alleges that patents covering the branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product. On July 15, 2022, we filed an additional lawsuit against Avadel asserting infringement of that patent. The

suit alleges that the filing of Avadel's application for approval of FT218 is an act of infringement, and that Avadel's product would infringe the patent if launched. The suit seeks an injunction to prevent Avadel from launching a product that would infringe the patent, and an award of damages if Avadel does launch an infringing product. Avadel filed an answer to the complaint and counterclaims asserting that the patent is invalid, that its product would not infringe, and that by listing the patent in the Orange Book, we engaged in unlawful monopolization in violation of the Sherman Act. On December 9, 2022, we filed a motion to dismiss Avadel's counterclaims. On June 29, 2023, we filed a motion seeking leave to supplement our motion to dismiss, as well as a motion to stay discovery pending resolution of the motion to dismiss. As noted above, on March 3, 2023, we and Avadel stipulated to the dismissal without prejudice of the claims and counterclaims related to infringement and validity of the delisted patent.

On November 1, 2023, the Court held a claim construction hearing relating to disputed terms in the asserted patents. On December 15, 2023, the Court issued a written opinion and order resolving the parties' remaining claim construction disputes. On November 20, 2023, we and Avadel each filed motions for summary judgment. On February 14, 2024, the Court issued a written opinion and order denying both parties' motions for summary judgment.

Trial regarding our patent infringement claims against Avadel began on February 26, 2024, and concluded on March 4, 2024, with the jury finding both of our asserted patents valid, and awarding us damages for infringement for Avadel's past sales of Lumryz. On April 12, 2024, we filed a motion for a permanent injunction and ongoing royalties. On August 27, 2024, the Court granted our motion for an injunction in part, and requested additional briefing about ongoing royalties. The issued injunction prevents Avadel from seeking FDA approval or marketing Lumryz for the treatment of idiopathic hypersomnia or other indications not already a part of Lumryz's product labeling as of March 4, 2024, and enjoins Avadel from infringing in any way Claim 24 of our '782 patent by making, using or selling Lumryz through and including the February 2036 expiration date of the '782 patent, subject to certain exclusions including, among other things (i) for the treatment of narcolepsy, (ii) for the treatment of patients who have been prescribed Lumryz as of the effective date of the injunction conditioned on the payment of an amount to be determined and (iii) in clinical trials and studies ongoing as of the effective date of the injunction. The Court also granted our motion for an ongoing royalty for any future sale of Lumryz to patients with narcolepsy at a rate to be determined based upon further briefing by the parties on the appropriate ongoing rate above 3.5%. Avadel appealed this injunction to the United States Court of Appeals for the Federal Circuit. The Federal Circuit held oral argument on this appeal on February 7, 2025, and on May 6, 2025, published its opinion in which it reversed-in-part, vacated-in-part, and remanded to the District Court for reconsideration in light of the Federal Circuit's opinion.

The Court scheduled a trial regarding Avadel's counterclaims for unlawful monopolization for November 3, 2025 and a trial regarding Avadel's trade secret misappropriation claims for December 15, 2025. On March 13, 2024 and March 19, 2024, we filed motions to stay Avadel's unlawful monopolization counterclaim and trade secret claims, respectively, pending resolution of post-trial motions and potential appeals in the patent infringement suit. On May 24, 2024, the Court denied the motion to stay the unlawful monopolization counterclaim and the previously-filed motion to dismiss the same. On June 7, 2024, we filed a motion for reargument or, in the alternative, to certify the decision for interlocutory appeal. That motion remains pending and no hearing date has been set. The Court stayed Avadel's trade secret misappropriation claims pending appeal of the injunction in the related patent matter. We filed a further motion to stay the unlawful monopolization counterclaims. On May 29, 2025, the Court denied our supplemental motion to stay the unlawful monopolization counterclaims. On June 17, 2025, we filed a petition for a writ of mandamus with the United States Court of Appeals for the Third Circuit seeking relief from the Court's denial of the supplemental motion to stay. On July 8, 2025, the Third Circuit denied the petition.

Following the Federal Circuit's decision in the patent matter, the Court lifted the stay of Avadel's trade secret misappropriation claims and scheduled trial in that matter for February 7, 2028.

On July 21, 2022, Avadel filed a lawsuit against FDA in the United States District Court for the District of Columbia, challenging FDA's determination that Avadel was required to file a paragraph IV certification regarding one of our Orange Book listed patents. Avadel filed a motion for preliminary injunction or, in the alternative, summary judgment, seeking relief including a declaration that FDA's decision requiring patent certification was unlawful, an order setting aside that decision, an injunction prohibiting FDA from requiring such certification as a precondition to approval of its application for FT218, and an order requiring FDA to take final action on Avadel's application for approval of FT218 within 14 days of the Court's ruling. On July 27, 2022, we filed a motion to intervene in that case, which the Court granted. The Court held a hearing on the parties' respective motions for summary judgment on October 7, 2022. On November 3, 2022, the Court granted our and FDA's motions for summary judgment and denied Avadel's motion.

From December 2024 through April 2025, Avadel filed a series of patent infringement suits against us in the United States District Court for the District of Delaware. The suits allege that Jazz's sales of Xywav infringe on certain newly-issued Avadel patents, and Avadel seeks an award of monetary damages. No trial date has been set for these matters.

Xywav Patent Litigation

In June 2021, we received notice from Lupin, that it has filed with FDA an ANDA, for a generic version of Xywav. The notice from Lupin included a paragraph IV certification with respect to ten of our patents listed in FDA's Orange Book for Xywav on the date of our receipt of the notice. The asserted patents relate generally to the composition and method of use of Xywav, and methods of treatment when Xywav is administered concomitantly with certain other medications.

In July 2021, we filed a patent infringement suit against Lupin in the United States District Court for the District of New Jersey. The complaint alleges that by filing its ANDA, Lupin has infringed ten of our Orange Book listed patents. We are seeking a permanent injunction to prevent Lupin from introducing a generic version of Xywav that would infringe our patents. As a result of this lawsuit, we expect that a stay of approval of up to 30 months will be imposed by FDA on Lupin's ANDA. In June 2021, FDA recognized seven years of Orphan Drug Exclusivity for Xywav through July 21, 2027. On October 4, 2021, Lupin filed an answer to the complaint and counterclaims asserting that the patents are invalid or not enforceable, and that its product, if approved, will not infringe our patents.

In April 2022, we received notice from Lupin that it had filed a paragraph IV certification regarding a newly-issued patent listed in the Orange Book for Xywav. On May 11, 2022, we filed an additional lawsuit against Lupin in the United States District Court for the District of New Jersey alleging that by filing its ANDA, Lupin infringed the newly-issued patent related to a method of treatment when Xywav is administered concomitantly with certain other medications. The suit seeks a permanent injunction to prevent Lupin from introducing a generic version of Xywav that would infringe our patent. On June 22, 2022, the Court consolidated the two lawsuits we filed against Lupin.

In November 2022, we received notice from Lupin that it had filed a paragraph IV certification regarding a newly-issued patent listed in the Orange Book for Xywav. On January 19, 2023, we filed an additional lawsuit against Lupin in the United States District Court for the District of New Jersey alleging that by filing its ANDA, Lupin infringed the newly-issued patent referenced in its November 2022 paragraph IV certification, as well as another patent that issued in January 2023. The suit seeks a permanent injunction to prevent Lupin from introducing a generic version of Xywav that would infringe the two patents in suit. On February 15, 2023, the Court consolidated the new lawsuit with the two suits we previously filed against Lupin. No trial date has been set in the consolidated case against Lupin.

In February 2023, we received notice from Teva that it had filed with FDA an ANDA for a generic version of Xywav. The notice from Teva included a paragraph IV certification with respect to thirteen of our patents listed in FDA's Orange Book for Xywav on the date of the receipt of the notice. The asserted patents relate generally to the composition and method of use of Xywav, and methods of treatment when Xywav is administered concomitantly with certain other medications.

In March 2023, we filed a patent infringement suit against Teva in the United States District Court for the District of New Jersey. The complaint alleges that by filing its ANDA, Teva has infringed thirteen of our Orange Book listed patents. We are seeking a permanent injunction to prevent Teva from introducing a generic version of Xywav that would infringe our patents. As a result of this lawsuit, we expect that a stay of approval of up to 30 months will be imposed by FDA on Teva's ANDA. On May 23, 2023, Teva filed an answer to the complaint and counterclaims asserting that the patents are invalid or not enforceable, and that its product, if approved, will not infringe our patents.

On December 15, 2023, based on a stipulation between all parties, the Court consolidated the Lupin lawsuits and the Teva lawsuit for all purposes. No trial date has been set in the consolidated case.

In July 2024, we received notices from Lupin and Teva that they had each filed a paragraph IV certification regarding a newly-issued patent listed in the Orange Book for Xywav. On August 27, 2024, we filed an additional lawsuit in the United States District Court for the District of New Jersey against each of Lupin and Teva, alleging that, by filing its ANDA, each party infringed the newly-issued patent related to a method of treatment using Xywav. The suits seek orders that the effective date of FDA approval of each defendant's application shall be a date no earlier than the expiration of the newly-issued patent.

Zepzelca Patent Litigation

In July and August 2024, we received notices from the Zepzelca ANDA Filers that they have each filed with FDA an ANDA for a generic version of Zepzelca (lurbinectedin). As of the date of this filing, we are not aware of other ANDA filers. The notices from the Zepzelca ANDA Filers each included a paragraph IV certification with respect to a patent listed in the Orange Book for Zepzelca on the date of the receipt of the notice. The listed patent relates to the drug substance, drug product and approved use of Zepzelca. Jazz is the exclusive licensee to this Zepzelca patent pursuant to an agreement with PharmaMar. A paragraph IV certification is a certification by a generic applicant that alleges that the patent covering the branded product is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product.

On September 11, 2024, we and PharmaMar filed a patent infringement suit against the Zepzelca ANDA Filers in the United States District Court for the District of New Jersey. The complaint alleges that by filing their ANDAs, the Zepzelca

ANDA Filers have infringed the Orange Book listed patent for Zepzelca, and seeks an order that the effective date of FDA approval of the ANDAs shall be a date no earlier than the expiration of the asserted patent.

In December 2024, we received the Zepzelca ANDA Filers' answers to the complaint. The answers include defenses and counterclaims asserting that the Zepzelca ANDA Filers' products, if launched, would not infringe our patents and that our patents are invalid. No trial date has been set in this matter.

On March 26, 2025, we and Sandoz stipulated to the dismissal of our lawsuit against Sandoz without prejudice.

On September 12, 2024, we and PharmaMar filed a patent infringement suit against RK Pharma, in the United States District Court for the District of Delaware. The complaint alleges that by filing its ANDA, RK Pharma has infringed the Orange Book listed patent for Zepzelca, and seeks an order that the effective date of FDA approval of RK Pharma's ANDA shall be no earlier than the expiration of the asserted patent. On November 13, 2024, we voluntarily dismissed this action against RK Pharma in the United States District Court for the District of Delaware. RK Pharma remains a defendant in the litigation referenced above in the United States District Court for the District of New Jersey.

Defitelio Patent Litigation

In March 2025, we received a notice from Almaject that it had filed with FDA an ANDA for a generic version of Defitelio (defibrotide sodium). The notice from Almaject included a paragraph IV certification respect to certain of our patents listed in FDA's Orange Book for Defitelio on the date of the notice. The listed patents relate generally to the Defitelio drug product and its approved use. On April 16, 2025, we filed a patent infringement lawsuit against Almaject in the United States District Court for the District of New Jersey. The complaint alleges that by filing its ANDA, Almaject has infringed certain of our Orange Book listed patents, and seeks an order that the effective date of FDA approval for the Almaject ANDA shall be on a date no earlier than the expiration of the last to expire of the asserted patents. As a result of this lawsuit, we expect that a stay of approval of up to 30 months will be imposed by FDA on Almaject's ANDA.

FDA Litigation

On June 22, 2023, we filed a complaint in the United States District Court for the District of Columbia seeking a declaration that FDA's approval on May 1, 2023, of the NDA for Avadel's Lumryz was unlawful. In the complaint, we alleged that FDA acted outside its authority under the Orphan Drug Act, when, despite ODE protecting Jazz's low-sodium oxybate product Xywav, FDA approved the Lumryz NDA and granted Lumryz ODE based on FDA's finding that Lumryz makes a major contribution to patient care and is therefore clinically superior to Xywav and Xyrem. Jazz further alleged that, in doing so, FDA failed to follow its own regulations, failed to follow established agency policy without providing a reasoned explanation for the departure, reversed prior decisions by its own staff and experts without a reasoned explanation, and disregarded the relevant scientific literature and data. The complaint, filed pursuant to the Administrative Procedure Act, asked the Court to vacate and set aside FDA's approval of the Lumryz NDA and sought a declaration that FDA's approval of the Lumryz NDA was arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law and that approval of the Lumryz NDA was in excess of FDA's statutory authority and was made without observance of procedure required by law.

On September 15, 2023, we filed a motion for summary judgment. On October 20, 2023, Avadel and FDA filed cross motions for summary judgment. Oral argument on these motions was held on May 10, 2024 and on October 30, 2024, the District Court issued an order denying Jazz's motion for summary judgment and granting Avadel's and FDA's cross-motions for summary judgment. Jazz appealed the matter to the United States Court of Appeals for the District of Columbia Circuit. We filed our opening appeal brief on January 31, 2025 and the D.C. Circuit held oral argument on the appeal on May 5, 2025. On June 27, 2025, the D.C. Circuit affirmed District Court's ruling.

Qui tam matter

In July 2022, we received a subpoena from the USAO for the District of Massachusetts requesting documents related to Xyrem and U.S. Patent No. 8,772,306 ("Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters"), product labeling changes for Xyrem, communications with FDA and the USPTO, pricing of Xyrem, and other related documents. On July 18, 2024, the United States District Court for the District of Massachusetts unsealed a qui tam whistleblower lawsuit underlying the USAO's subpoena, captioned 1:21-cv-10891-PBS and originally filed under seal on May 27, 2021. The public docket in this matter indicates that on May 24 and June 7, 2024, respectively, the United States and a number of states named in the whistleblower complaint declined to intervene in this matter. As such, private whistleblower litigation will proceed in the United States District Court for the District of Massachusetts. The Court set a deadline of September 1, 2024, for the plaintiff to file an amended complaint, and December 2, 2024, for us to file a motion to dismiss the amended complaint. The plaintiff filed the amended complaint on September 1, 2024. We filed our motion to dismiss on December 2, 2024. The Court held oral argument on the motion to dismiss on April 2, 2025.

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.

Chimerix Acquisition Litigation

On March 21, 2025, Chimerix filed a Recommendation Statement with the SEC in relation to the proposed acquisition of Chimerix by Jazz. Also on March 21, 2025, Jazz disseminated a Tender Offer Statement to Chimerix shareholders in relation to the proposed transaction.

Following filing of the filing and dissemination of the Tender Offer Documents, Jazz Pharmaceuticals plc, its wholly-owned subsidiary Pinetree Acquisition Sub, Inc., Chimerix Inc., the Chimerix Board of Directors, Centerview Partners LLC, were named as defendants in the Rosenthal Lawsuit in the Supreme Court of the State of New York, County of Chemung. In addition to the Rosenthal Lawsuit, the Chimerix Shareholder Litigation was filed in the Supreme Court of the State of New York, County of New York. Collectively, in the Chimerix Transaction Litigation, the plaintiffs alleged that the Tender Offer Documents omitted material information and contained misrepresentations, in violation of various New York and North Carolina laws. The plaintiffs in the Chimerix Transaction Litigation sought various remedies, including injunctive relief to prevent the consummation of the Chimerix Acquisition unless certain allegedly material information was disclosed, or in the alternative, rescission or damages.

On April 7, 2025, Chimerix filed an amended Recommendation Statement and Jazz filed an amended Tender Offer Document, each containing supplemental disclosures related to the Chimerix Acquisition. Pursuant to a memorandum of understanding between the parties, the Rosenthal Lawsuit was dismissed on April 7, 2025. The remaining lawsuits in the Chimerix Transaction Litigation were dismissed on June 26, 2025.

11. Shareholders' Equity

Share Repurchase Program

In July 2024, our board of directors authorized the New Repurchase Program, to repurchase ordinary shares having an aggregate purchase price of $500.0 million, exclusive of any brokerage commissions. Under the New Repurchase Program, which has no expiration date, we may repurchase ordinary shares from time to time by any methods and/or structures permitted by applicable law. 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 and the indenture for our Secured Notes, corporate and regulatory requirements and market conditions. The New Repurchase Program may be modified, suspended or discontinued at any time without our prior notice. The New Repurchase Program replaces and supersedes the Old Repurchase Program, a share repurchase program to repurchase ordinary shares having an aggregate purchase price of $1.5 billion, exclusive of any brokerage commissions. During the three and six months ended June 30, 2025, we spent a total of $125.0 million to repurchase 1.1 million of our ordinary shares, all under the New Repurchase Program, at a purchase price, including commissions, of $109.52 per share. During the three and six months ended June 30, 2024, we spent a total of $161.4 million to repurchase 1.5 million of our ordinary shares, all under the Old Repurchase Program, at a purchase price, including commissions, of $110.75 per share. As of June 30, 2025, the remaining amount authorized for repurchases under the New Repurchase Program was $225.0 million, exclusive of any brokerage commissions.

Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as of June 30, 2025 and December 31, 2024 were as follows (in thousands):

	Net Unrealized Gain (Loss) From Hedging Activities	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Loss
Balance at December 31, 2024	$ 740	$ (948,407)	$ (947,667)
Other comprehensive income before reclassifications	15	462,686	462,701
Amounts reclassified from accumulated other comprehensive loss	(802)	—	(802)
Other comprehensive income (loss), net	(787)	462,686	461,899
Balance at June 30, 2025	$ (47)	$ (485,721)	$ (485,768)

During the six months ended June 30, 2025, other comprehensive income (loss) primarily reflects foreign currency translation adjustments, primarily due to the strengthening of the sterling and the euro against the U.S. dollar.

12. Net Income (Loss) per Ordinary Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Numerator:				
Net income (loss)	$ (718,470)	$ 168,568	$ (811,011)	$ 153,950
Effect of interest on assumed conversions of the 2026 Notes, net of tax	—	4,878	—	9,733
Net income (loss) for dilutive net income (loss) per ordinary share	$ (718,470)	$ 173,446	$ (811,011)	$ 163,683
Denominator:				
Weighted-average ordinary shares used in per share calculations - basic	61,194	62,882	61,087	62,710
Dilutive effect of the 2026 Notes	—	6,418	—	6,418
Dilutive effect of employee equity incentive and purchase plans	—	325	—	556
Weighted-average ordinary shares used in per share calculations - diluted	61,194	69,625	61,087	69,684
Net income (loss) per ordinary share:				
Basic	$ (11.74)	$ 2.68	$ (13.28)	$ 2.45
Diluted	$ (11.74)	$ 2.49	$ (13.28)	$ 2.35

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans are determined by applying the treasury stock method to the assumed vesting of outstanding RSUs and PRSUs, the assumed exercise of share options and the assumed issuance of ordinary shares under our ESPP.

In July 2024, we irrevocably elected to fix the settlement method for exchanges of the 2026 Notes to a combination of cash and ordinary shares of Jazz Pharmaceuticals plc with a specified cash amount per $1,000 principal amount of 2026 Notes exchanged equal to or in excess of $1,000. As a result of the election, an exchanging holder will receive (i) up to $1,000 in cash per $1,000 principal amount of 2026 Notes exchanged and (ii) cash, ordinary shares, or any combination thereof, at our election, in respect of the remainder, if any, of its exchange obligation in excess of $1,000 per $1,000 principal amount of 2026 Notes exchanged. The potential issue of ordinary shares upon exchange of the 2026 Notes was anti-dilutive and had no impact on diluted net loss per ordinary share for the three and six months ended June 30, 2025.

For the 2030 Notes, we are required to settle the principal amount in cash and have the option to settle the conversion feature for the amount above the conversion price, or the conversion spread, in cash, ordinary shares or a combination of cash and ordinary shares. The conversion spread will have a dilutive impact on diluted net income per ordinary share when the average market price of our ordinary shares for a given period exceeds the conversion price, of approximately $153.05 per ordinary share, of the 2030 Notes. The average market price of our ordinary shares for the three and six months ended June 30, 2025 did not exceed the conversion price of the 2030 Notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Employee equity incentive and purchase plans	6,805	6,928	5,345	4,820

13. Revenues

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Xywav	$ 415,321	$ 368,472	$ 760,125	$ 683,772
Xyrem	35,349	62,180	72,590	126,412
Epidiolex/Epidyolex	251,730	247,102	469,467	445,818
Sativex	4,615	6,383	10,022	9,118
Total Neuroscience	707,015	684,137	1,312,204	1,265,120
Rylaze/Enrylaze	100,659	107,829	194,892	210,579
Zepzelca	74,541	81,047	137,574	156,147
Defitelio/defibrotide	48,106	45,421	88,768	93,097
Vyxeos	44,851	43,012	74,395	75,035
Ziihera	5,991	—	7,966	—
Total Oncology	274,148	277,309	503,595	534,858
Other	4,408	2,698	9,190	6,268
Product sales, net	985,571	964,144	1,824,989	1,806,246
High-sodium oxybate AG royalty revenue	54,138	54,164	103,084	104,111
Other royalty and contract revenues	6,003	5,517	15,480	15,451
Total revenues	$ 1,045,712	$ 1,023,825	$ 1,943,553	$ 1,925,808

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
United States	$ 936,283	$ 924,592	$ 1,734,797	$ 1,732,806
Europe	82,763	82,159	165,801	153,514
All other	26,666	17,074	42,955	39,488
Total revenues	$ 1,045,712	$ 1,023,825	$ 1,943,553	$ 1,925,808

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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
ESSDS	43 %	42 %	42 %	42 %
ASD	11 %	10 %	11 %	8 %
McKesson	10 %	12 %	11 %	12 %

Financing and payment

Our payment terms vary by the type and location of our customer but payment is generally required in a term ranging from 30 to 65 days.

14. Share-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Selling, general and administrative	$ 40,999	$ 35,137	$ 82,673	$ 75,350
Research and development	20,651	17,272	41,581	36,103
Cost of product sales	2,851	4,245	7,900	6,642
Total share-based compensation expense, pre-tax	64,501	56,654	132,154	118,095
Income tax benefit from share-based compensation expense	(12,259)	(9,629)	(21,793)	(13,028)
Total share-based compensation expense, net of tax	$ 52,242	$ 47,025	$ 110,361	$ 105,067

15. Income Taxes

Our income tax benefit was $17.2 million and $35.0 million for the three and six months ended June 30, 2025, respectively, compared to an income tax benefit of $30.7 million and $19.0 million for the same periods in 2024, relating to tax arising on income or losses in Ireland, the U.K., the U.S. and certain other foreign jurisdictions and Pillar Two top-up taxes, offset by deductions on subsidiary equity, patent box and foreign derived intangible income benefits and tax credits. The income tax benefit in the six months ended June 30, 2025, was primarily due to the tax impact of certain Xyrem antitrust litigation settlements.

Our net deferred tax liability is primarily related to acquired intangible assets, and is net of deferred tax assets related to U.S. federal and state tax credits, U.S. federal and state and foreign net operating loss carryforwards and other temporary differences. We maintain a valuation allowance against certain 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 recorded an unrecognized tax benefit for certain tax benefits which we judge may not be sustained upon examination. We file income tax returns in multiple tax jurisdictions, the most significant of which are Ireland, the U.K. and the U.S. (both at the federal level and in various state jurisdictions). For Ireland, we are no longer subject to income tax examinations by taxing authorities for the years prior to 2020. For the U.K., we are no longer subject to income tax examinations by taxing authorities for the years prior to 2016. The U.S. jurisdictions generally have statute of limitations three to four years from the later of the return due date or the date when the return was filed. However, in the U.S. (at the federal level and in most states), carryforwards that were generated in 2020 and earlier may still be adjusted upon examination by the taxing authorities. One of our subsidiaries was under examination by the Luxembourg tax authorities for the years ended December 31, 2017, 2018 and 2019. In October 2022 and in January 2023, we received tax assessment notices from the Luxembourg tax authorities for all years under examination relating to certain transfer pricing and other adjustments. In June 2025, the Luxembourg tax authorities formally withdrew all assessments for the periods under examination.

The Government of Ireland, the jurisdiction in which Jazz Pharmaceuticals Plc is incorporated, transposed the Global Minimum Tax Pillar Two rules into domestic legislation as part of the Finance Act. The Finance Act closely follows the EU Minimum Tax Directive and certain OECD Guidance released to date. The Company is within the scope of these rules, which took effect from January 1, 2024. Under the legislation, we are liable to pay a top-up tax for the difference between the Pillar Two effective tax rate per jurisdiction and the 15% minimum rate. The rules on how to calculate the Pillar Two effective tax rate are detailed and highly complex and specific adjustments envisaged in the Pillar Two legislation can give rise to different effective tax rates compared to those calculated for accounting purposes. We account for Pillar Two top-up taxes as a current tax when they are incurred. The income tax benefit for the six months ended June 30, 2025 includes an amount for forecasted Pillar Two top-up taxes, as required under the applicable rules. The proportion of our profit before tax which is subject to the

top-up tax and our exposure to Pillar Two top-up taxes in future years will depend on factors such as future revenues, costs and foreign currency exchange rates. We will continue to monitor changes in law and guidance in relation to Pillar Two.

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 I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024, as supplemented by the risks and uncertainties described in "Risk Factors" Item 1A. Risk Factors in Part II of 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 a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases - often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines, including leading therapies for sleep disorders and epilepsy, and a growing portfolio of cancer treatments. Our patient-focused and science-driven approach powers pioneering research and development advancements across our robust pipeline of innovative therapeutics in oncology and neuroscience.

Our strategy for growth is rooted in executing commercial launches and ongoing commercialization initiatives, advancing robust R&D programs and delivering impactful clinical results, effectively deploying capital to strengthen the prospects of achieving our short- and long-term goals through strategic corporate development, and delivering strong financial performance. We focus on patient populations with high unmet needs. We seek to identify and develop differentiated therapies for these patients that we expect will be long-lived assets and that we can support with an efficient commercialization model. In addition, we leverage our efficient, scalable operating model and integrated capabilities across our global infrastructure to effectively reach patients around the world.

Our strategy to deliver sustainable growth and enhanced value continues to be focused on:

- Strong commercial execution to drive diversified revenue growth and address unmet medical needs of our patients across our product portfolio, which focuses on neuroscience and oncology medicines;
- Expanding and advancing our pipeline to achieve a valuable portfolio of durable, highly differentiated products;
- Continuing to build a flexible, efficient and productive development engine for targeted therapeutic areas to identify and progress early-, mid- and late-stage assets;
- Identifying and acquiring novel product candidates and approved therapies to complement our existing pipeline and commercial portfolio;
- Investing in an efficient, scalable operating model and differentiated capabilities to enable growth; and
- Unlocking further value through indication expansion and entry into global markets.

In 2025, consistent with our strategy, we are continuing to focus on research and development activities within our neuroscience and oncology therapeutic areas.

Our lead marketed products, listed below, are approved in countries around the world to improve patient care.

Product	Indications	Initial Approval Date	Markets
NEUROSCIENCE			
Xywav® (calcium, magnesium, potassium, and sodium oxybates)	Treatment of cataplexy or EDS in patients seven years of age and older with narcolepsy.	July 2020	U.S.
	Treatment of IH in adults.	August 2021	U.S.
	Treatment of cataplexy in patients with narcolepsy.	May 2023	Canada
Epidiolex® (cannabidiol)	Treatment of seizures associated with LGS, DS, or TSC in patients 1 year of age and older.	June 2018	U.S., Israel
Epidyolex® (cannabidiol)	For adjunctive therapy of seizures associated with LGS or DS, in conjunction with clobazam, for patients 2 years of age and older.[1]	September 2019	EU, Great Britain, EEA, Switzerland, Australia, other markets
	For adjunctive therapy of seizures associated with TSC for patients 2 years of age and older.	April 2021	EU, Great Britain, EEA and Switzerland
Epidiolex® (cannabidiol)	For adjunctive therapy of seizures associated with LGS, DS or TSC for patients 2 years of age and older.	November 2023	Canada
ONCOLOGY			
Rylaze® (asparaginase erwinia chrysanthemi (recombinant)-rywn)	A component of a multi-agent chemotherapeutic regimen for the treatment of ALL, and LBL, in adult and pediatric patients 1 month or older who have developed hypersensitivity to E. coli-derived asparaginase.	June 2021	U.S.
Rylaze® (crisantaspase recombinant)	A component of a multi-agent chemotherapeutic regimen for the treatment of ALL and LBL, in adults and pediatric patients 1 year or older who have developed hypersensitivity to E. coli-derived asparaginase.	September 2022	Canada
Enrylaze® (recombinant crisantaspase)	A component of a multi-agent chemotherapeutic regimen for the treatment of ALL and LBL in adult and pediatric patients (1 month and older) who have developed hypersensitivity or silent inactivation to E. coli-derived asparaginase.	September 2023	EU, Great Britain, Switzerland, other markets
Zepzelca® (lurbinectedin)	Treatment of adult patients with metastatic SCLC, with disease progression on or after platinum-based chemotherapy.	June 2020	U.S. (licensed from PharmaMar)[2]
	Treatment of adults with Stage III or metastatic SCLC who have progressed on or after platinum-containing therapy.	September 2021	Canada (licensed from PharmaMar)[3]
Ziihera® (zanidatamab-hrii)	Treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC, as detected by an FDA-approved test.	November 2024	U.S. (licensed from Zymeworks)[2]
	Treatment of adults with unresectable locally advanced or metastatic HER2-positive (IHC3+) BTC previously treated with at least one prior line of systemic therapy.	June 2025	EU (licensed from Zymeworks)[4]

[1] The clobazam restriction limited to EU and Great Britain
[2] Accelerated approval received from FDA
[3] Conditional approval received from Health Canada
[4] Conditional marketing authorization granted by EC

Neuroscience

We are the global leader in the development and commercialization of oxybate therapy for patients with sleep disorders. Xyrem was approved by FDA in 2002, and is indicated for treating cataplexy and EDS in patients seven years of age or older with narcolepsy. In 2020, we received FDA approval for Xywav for the treatment of cataplexy or EDS in patients seven years of age and older with narcolepsy. In August 2021, Xywav became the first and only therapy approved by FDA for the treatment of IH in adults. Xywav is an oxybate therapy that contains 92% less sodium than Xyrem. Xywav has become a standard of care for patients with narcolepsy and IH.

Since there is no cure for narcolepsy and long-term disease management is needed, we believe that Xywav represents an important therapeutic option for patients with this sleep disorder. Our commercial efforts are focused on educating patients and physicians about the lifelong impact of high sodium intake, and how the use of Xywav enables them to address what is a modifiable risk factor for cardiovascular morbidity. We view the adoption of Xywav in narcolepsy as a positive indication that physicians and patients appreciate the benefits of a low-sodium oxybate option.

In June 2021, FDA recognized seven years of ODE for Xywav in narcolepsy. ODE extends through January 2028. Nevertheless, Lumryz, a fixed-dose, high-sodium oxybate, was approved by FDA on May 1, 2023, for the treatment of cataplexy or EDS in adults with narcolepsy and was launched in the U.S. market by Avadel. FDA continues to recognize seven years of ODE for Xywav in narcolepsy. In connection with granting ODE, FDA stated that "Xywav is clinically superior to Xyrem by means of greater safety because Xywav provides a greatly reduced chronic sodium burden compared to Xyrem." FDA's summary also stated that "the differences in the sodium content of the two products at the recommended doses will be clinically meaningful in reducing cardiovascular morbidity in a substantial proportion of patients for whom the drug is indicated." FDA has also recognized that the difference in sodium content between Xywav and Lumryz is likely to be clinically meaningful in all patients with narcolepsy and that Xywav is safer than Lumryz in all such patients. Lumryz has the same sodium content as Xyrem. Xywav is the only approved oxybate therapy that does not carry a warning and precaution related to high sodium intake.

On August 12, 2021, FDA approved Xywav for the treatment of IH in adults. Xywav remains the first and only FDA-approved therapy to treat IH. We initiated the U.S. commercial launch of Xywav for the treatment of IH in adults in November 2021. In January 2022, the company announced FDA recognized seven years of ODE for Xywav in IH that extends through August 2028. IH is a debilitating neurologic sleep disorder characterized by chronic EDS (the inability to stay awake and alert during the day resulting in the irrepressible need to sleep or unplanned lapses into sleep or drowsiness), severe sleep inertia, and prolonged and non-restorative nighttime sleep. An estimated 37,000 people in the U.S. have been diagnosed with IH and are actively seeking healthcare.

We have agreements in place for Xywav with all three major PBMs in the U.S. To date, we have entered into agreements with various entities and have achieved benefit coverage for Xywav in both narcolepsy and IH indications for approximately 90% of commercial lives.

We have seen strong adoption of Xywav in narcolepsy since its launch in November 2020, and increasing adoption in IH since its launch in November 2021. Exiting the second quarter of 2025, there were approximately 15,225 patients taking Xywav, including approximately 10,600 patients with narcolepsy and approximately 4,625 patients with IH.

We acquired Epidiolex (Epidyolex in certain markets outside the U.S.) in May 2021 as part of the GW Acquisition, which expanded our growing neuroscience business with a global, high-growth childhood-onset epilepsy franchise. Epidiolex was approved in the U.S. in June 2018 for the treatment of seizures associated with two rare and severe forms of epilepsy, LGS and DS, in patients two years of age and older, and subsequently approved in July 2020 for the treatment of seizures associated with TSC in patients one year of age and older. FDA also approved the expansion of all existing indications, LGS and DS, to patients one year of age and older. The rolling European launch of Epidyolex is also underway following EC approval in September 2019 for use as adjunctive therapy of seizures associated with LGS or DS, in conjunction with clobazam, for patients two years of age and older. The clobazam restriction is limited to the EU and Great Britain. Epidyolex is launched in all five key European markets: United Kingdom, Germany, Italy, Spain and France. Epidyolex was also approved for adjunctive therapy of seizures associated with TSC for patients 2 years of age and older in the EU in April 2021 and Great Britain in August 2021, and is approved or under review for this indication in other markets. Outside the U.S. and Europe, Epidiolex/Epidyolex is approved in Israel, Canada, Australia, New Zealand and Taiwan.

Oncology

Rylaze was approved by FDA in June 2021 under the Real-Time Oncology Review program, and was launched in the U.S. in July 2021 for use as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with ALL or LBL in pediatric and adult patients one month and older who have developed hypersensitivity to E. coli-derived asparaginase. Rylaze is the only recombinant erwinia asparaginase manufactured product approved in the U.S. that maintains a clinically meaningful level of asparaginase activity throughout the entire course of treatment. We developed Rylaze to address the needs of patients and health care providers for an innovative, high-quality erwinia asparaginase with reliable supply. The initial approved recommended dosage of Rylaze was for an IM administration of 25 mg/m2 every 48 hours. In November 2022, FDA approved an sBLA for a Monday/Wednesday/Friday 25/25/50 mg/m2 IM dosing schedule. In September 2023, the EC granted marketing authorization for JZP458 under the trade name Enrylaze®. This product has also been approved in Great Britain, Canada, Switzerland and Australia.

We acquired U.S. development and commercialization rights to Zepzelca in early 2020, and launched six months thereafter, with an indication for treatment of patients with SCLC with disease progression on or after platinum-based chemotherapy. Our education and promotional efforts are focused on SCLC-treating physicians. We are continuing to raise awareness of Zepzelca across academic and community cancer centers. In collaboration with Roche, we have an ongoing Phase 3 pivotal clinical trial of Zepzelca for use as maintenance therapy in first-line extensive-stage SCLC in combination with Tecentriq® (atezolizumab) following induction therapy with carboplatin, etoposide and Tecentriq. In October 2024, we announced positive top-line results from the trial showing a statistically significant and clinically meaningful benefit for Zepzelca and atezolizumab in combination in the first-line maintenance setting. In June 2025, we announced the FDA granted Priority Review of the sNDA to support this combination in the first-line maintenance setting with a PDUFA action date of October 7, 2025.

We acquired exclusive development and commercialization rights to Ziihera in 2022 through an exclusive licensing agreement with a subsidiary of Zymeworks providing development and commercialization rights to zanidatamab across all indications in the U.S., Europe, Japan and all other territories except for those Asia/Pacific territories previously licensed by Zymeworks. The term of the license agreement extends on a licensed product-by-licensed product and country-by-country basis until the expiration of the royalty term for such licensed product in such country. We have the right to terminate the amended license agreement at will upon a specified notice period, and either party can terminate the amended license agreement for the other party's uncured material breach or bankruptcy.

Ziihera is a bispecific HER2-directed antibody that binds to two extracellular sites on HER2. Binding of zanidatamab-hrii with HER2 results in internalization leading to a reduction of the receptor on the tumor cell surface. In the U.S., Ziihera was granted accelerated approval by FDA in November 2024 and is indicated for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC, as detected by an FDA-approved test. In June 2025, the EC granted conditional marketing authorization for Ziihera for the treatment of adults with unresectable locally advanced or metastatic HER2-positive (IHC3+) BTC previously treated with at least one prior line of systemic therapy.

Defitelio is the first and only approved treatment for patients with VOD, sVOD, or VOD with renal or pulmonary dysfunction following HSCT by regulatory authorities in the U.S., Europe, Japan and other markets. Utilization of Defitelio is in part driven by evolving treatment practices in HSCT, and we are continuing to educate healthcare professionals on the clinical profile of Defitelio and its role in treating VOD and/or sVOD following HSCT.

Vyxeos is a treatment for adults with newly-diagnosed t-AML, or AML-MRC. In March 2021, FDA approved a revised label to include a new indication to treat newly-diagnosed t-AML, or AML-MRC, in pediatric patients aged one year and older. We continue to expand into new markets internationally as the product receives approvals and reimbursement in relevant markets. In the U.S., with ongoing trends towards lower-intensity treatments and away from intensive chemotherapy regimens for AML, we have seen increasing competition from other therapeutic options.

Research and Development Progress

Our research and development activities encompass all stages of development and currently include clinical testing of new product candidates and activities related to clinical improvements of, or additional indications or new clinical data for, our existing marketed products. We also have active preclinical programs for novel therapies, including neuroscience and precision medicines in oncology. We are increasingly leveraging our growing internal research and development function, and we have also entered into collaborations with third parties for the research and development of innovative early-stage product candidates and have supported additional investigator-sponsored trials that are anticipated to generate additional data related to our products. We also seek out investment opportunities in support of the development of early- and mid-stage technologies in our therapeutic areas and adjacencies. We have a number of licensing and collaboration agreements with third parties, including biotechnology companies, academic institutions and research-based companies and institutions, related to preclinical and clinical research and development activities in hematology and in precision oncology, as well as in neuroscience.

Within our oncology R&D program, in October 2022, we announced an exclusive licensing and collaboration agreement with Zymeworks providing us the right to acquire development and commercialization rights to Zymeworks' zanidatamab across all indications in the U.S., Europe, Japan and all other territories except for those Asia/Pacific territories previously licensed by Zymeworks. In December 2022, we exercised the option to continue with the exclusive development and commercialization rights to zanidatamab. Under the terms of the agreement, Zymeworks received an upfront payment of $50.0 million, and following the exercise of our option to continue the collaboration, a second, one-time payment of $325.0 million. Zymeworks is also eligible to receive regulatory and commercial milestone payments of up to $1.4 billion, for total potential payments of $1.76 billion. Zymeworks is eligible to receive tiered royalties between 10% and 20% on our net sales. Zanidatamab is a bispecific HER2-directed antibody that binds to two extracellular sites on HER2. Zanidatamab is currently being evaluated in multiple clinical trials as a treatment for patients with HER2-expressing cancers. Following positive data from a pivotal Phase 2 clinical trial evaluating zanidatamab monotherapy in patients with previously treated advanced or metastatic HER2-amplified BTC, we completed a BLA submission in second-line BTC in March 2024. In May 2024, FDA granted Priority Review of the BLA; we received FDA approval for this BLA in November 2024. In April 2025, we announced that CHMP adopted a positive opinion recommending the conditional marketing authorization of zanidatamab in 2L BTC. In June 2025, the EC granted conditional marketing authorization for Ziihera for the treatment of adults with unresectable locally advanced or metastatic HER2-positive (IHC3+) BTC previously treated with at least one prior line of systemic therapy. In addition, we have an ongoing Phase 3 randomized clinical trial evaluating zanidatamab in combination with chemotherapy plus or minus tislelizumab as a first-line treatment for HER2-expressing GEA, an ongoing Phase 2 trial examining zanidatamab in combination with chemotherapy in first-line patients with HER2-expressing metastatic GEA and an ongoing Phase 3 trial examining zanidatamab in first-line patients with HER2-positive BTC. In July 2024, we announced the initiation of the Phase 3 EmpowHER-BC-303 to evaluate zanidatamab plus chemotherapy or trastuzumab plus chemotherapy in patients with HER2-positive breast cancer whose disease has progressed on previous T-DXd treatment. There are also multiple ongoing clinical trials exploring zanidatamab in breast cancer and other HER2-expressing tumor types.

Our development plan for Zepzelca continues to progress. We are collaborating with Roche on a pivotal Phase 3 clinical trial evaluating Zepzelca in combination with Tecentriq for use as maintenance therapy in first-line extensive-stage SCLC. In October 2024, we announced positive top-line results from the trial showing a statistically significant and clinically meaningful benefit for Zepzelca and atezolizumab in combination in the first-line maintenance setting. In April 2025, we announced the submission of an sNDA to support this combination in the first-line maintenance setting. In June 2025, we announced the FDA granted Priority Review of the sNDA to support this combination in the first-line maintenance setting with a PDUFA action date of October 7, 2025. In December 2021, our licensor PharmaMar initiated a confirmatory trial in second-line SCLC. This ongoing three-arm trial is comparing Zepzelca as either monotherapy or in combination with irinotecan to investigator's choice of irinotecan or topotecan. Data from either the first-line trial of Zepzelca in combination with Tecentriq or the PharmaMar trial could serve to confirm clinical benefit of Zepzelca and secure full approval in the U.S.

In addition, we have an ongoing Phase 4 observational study to collect real world safety and outcome data in adult Zepzelca monotherapy patients with SCLC who progress on or after prior platinum-containing chemotherapy. Preliminary findings from this study presented at the 2024 World Conference on Lung Cancer demonstrated Zepzelca provided clinical benefit when administered as second-line SCLC therapy. The safety and tolerability profile observed in this study was consistent with prior findings, with no new safety signals reported.

In June 2022, we announced FDA had cleared our Investigational New Drug application for JZP815 and, in October 2022, we enrolled the first patient in a Phase 1 trial. JZP815 is an investigational stage pan-RAF kinase inhibitor that targets specific components of the mitogen-activated protein kinase pathway that, when activated by oncogenic mutations, can be a frequent driver of human cancer.

In April 2022, we announced that we had entered into a licensing and collaboration agreement with Werewolf to acquire exclusive global development and commercialization rights to Werewolf's investigational WTX-613, now referred to as JZP898. Under the terms of the agreement, we made an upfront payment of $15.0 million to Werewolf, and Werewolf is eligible to receive development, regulatory and commercial milestone payments of up to $1.26 billion. If approved, Werewolf is eligible to receive a tiered, mid-single-digit percentage royalty on net sales of JZP898. This transaction underscores our commitment to enhancing our pipeline to deliver novel oncology therapies to patients, and also provides us with an opportunity to expand into immuno-oncology. JZP898 is a differentiated, conditionally-activated IFNα INDUKINE™ molecule. We initiated a Phase 1 clinical trial of JZP898 in late 2023.

In April 2025, we completed the acquisition of Chimerix, Inc. for $944.2 million in cash, and Chimerix is now a wholly owned subsidiary of Jazz. The lead clinical asset acquired from Chimerix is dordaviprone, a novel first-in-class small molecule treatment in development for H3 K27M-mutant diffuse glioma, a rare, high-grade brain tumor that most commonly affects children and young adults. An NDA for accelerated approval of dordaviprone in recurrent H3 K27M-mutant diffuse glioma was accepted and granted Priority Review by FDA. FDA has set a target PDUFA action date of August 18, 2025. If approved in the U.S., dordaviprone may be eligible for a Rare Pediatric Disease PRV. Separately, dordaviprone is being studied in the

ongoing Phase 3 ACTION trial, evaluating its use in newly diagnosed, non-recurrent H3 K27M-mutant diffuse glioma patients following radiation treatment, potentially extending this treatment option into the front-line setting.

Our neuroscience R&D efforts include an ongoing Phase 3 trial of Epidyolex for LGS, DS and TSC in Japan. In August 2024, we announced top-line results from the trial. The trial did not meet the primary efficacy endpoint of a pre-specified percentage change in indication-associated seizure frequency during the treatment period (up to 16 weeks) compared to baseline in Japanese pediatric patients; however, numeric improvements were observed in the primary and several secondary endpoints. No new safety signals were observed in the trial. We are continuing to collect data in Japanese patients and plan to engage with regulatory authorities in Japan regarding a potential NDA.

We are also pursuing early-stage activities related to the development of JZP324, an extended-release low sodium, oxybate formulation that we believe could provide a clinically meaningful option for narcolepsy patients.

In May 2022, we announced, that we had entered into a licensing agreement with Sumitomo to acquire exclusive development and commercialization rights in the U.S., Europe and other territories for JZP441, also known as DSP-0187, a potent, highly selective oral orexin-2 receptor agonist with potential application for the treatment of narcolepsy, IH and other sleep disorders. Under the terms of the agreement, we made an upfront payment of $50.0 million to Sumitomo, and Sumitomo is eligible to receive development, regulatory and commercial milestone payments of up to $1.09 billion. If approved, Sumitomo is eligible to receive a tiered, low double-digit royalty on our net sales of JZP441. In November 2023, we announced that we achieved initial proof-of-concept in our Phase 1 clinical trial program in healthy volunteers as demonstrated by the MWT. At that time, we also noted the program was being paused as we analyzed safety findings related to visual disturbances and cardiovascular effects; no liver toxicity signals were observed. Following additional review of the trial findings and input from FDA, we initiated a small Phase 1b trial of JZP441 in narcolepsy Type 1 patients in 2025. We expect data from this trial will further our understanding of JZP441 and orexin-2 receptor agonism, providing learnings that could inform future development efforts.

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

Product Candidates	**Description**
ONCOLOGY	
Regulatory	
Zepzelca	First-line maintenance for extensive-stage SCLC in combination with atezolizumab (sNDA under FDA review)
Dordaviprone	Recurrent H3 K27M-mutant diffuse glioma (NDA under FDA review)
Phase 3	
Zanidatamab	First-line HER2-positive GEA (ongoing trial)
Zanidatamab	First-line HER2-positive BTC (ongoing trial)
Zanidatamab	Previously treated HER2-positive breast cancer in patients whose disease has progressed on previous T-DXd treatment (EmpowHER-BC-303) (ongoing trial)
Dordaviprone	First-line H3 K27M-mutant diffuse glioma (ongoing trial)
Vyxeos	AML or high-risk MDS (AML18) (cooperative group studies) (ongoing trial) Newly diagnosed adults with standard- and high-risk AML (AML Study Group cooperative group study) (ongoing trial) Newly diagnosed pediatric patients with AML (COG cooperative group study) (ongoing trial)
Phase 2	
Zanidatamab	HER2-expressing GEA, BTC or colorectal cancer in combination with standard first-line chemotherapy (ongoing trial)
Zanidatamab	Basket trial including HER2-positive solid tumors (DiscovHER-Pan-206) (ongoing trial)
Zanidatamab	Neoadjuvant and adjuvant breast cancer (EmpowHER-BC-208)
Vyxeos	High-risk MDS (European Myelodysplastic Syndromes) (cooperative group study) (ongoing trial) Newly diagnosed untreated patients with intermediate- and high-risk AML (cooperative group study) (ongoing trial)
Vyxeos + other approved therapies	R/R AML or hypomethylating agent failure MDS (MD Anderson collaboration study) (ongoing trial) De novo or R/R AML (MD Anderson collaboration study) (ongoing trial)

Product Candidates	Description
Phase 2a	
Zanidatamab	Previously treated HER2+ HR+ breast cancer in combination with palbociclib (ongoing trial)
Phase 1b/2	
Zanidatamab	First-line breast cancer and GEA (BeiGene trial) (ongoing trial)
Zanidatamab	HER2-expressing breast cancer in combination with ALX148 (ongoing trial)
Phase 1	
JZP815	Raf and Ras mutant tumors (acquired from Redx) (ongoing trial)
Zanidatamab	Previously treated metastatic HER2-expressing cancers in combination with select antineoplastic therapies (cooperative group study) (ongoing trial)
JZP898	Conditionally-activated IFNα INDUKINE™ molecule in solid tumors (ongoing trial)
Vyxeos	Low intensity dosing for higher risk MDS (MD Anderson collaboration study) (ongoing trial)
JZP3507*	Primary central nervous system tumors (acquired from Chimerix) (ongoing trial)
Preclinical	
KRAS inhibitor targets	G12D selective and pan-KRAS molecules (acquired from Redx)
Undisclosed targets	Oncology
CombiPlex®	Hematology/oncology exploratory activities
NEUROSCIENCE	
Phase 3	
Epidyolex	LGS, TSC and DS (ongoing trial in Japan)
Phase 1	
JZP324	Oxybate extended-release formulation (planned trial)
JZP441**	Potent, highly selective oral orexin-2 receptor agonist (ongoing trial)
Preclinical	
Undisclosed targets	Sleep Epilepsy Other Neuroscience

*Also known as ONC206

**Also known as DSP-0187

Challenges, Risks and Trends Related to Our Business

Our operating plan assumes that Xywav, with 92% lower sodium compared to high-sodium oxybates (depending on the dose), a dosing titration option and an absence of a sodium warning, will remain the #1 branded oxybate treatment for narcolepsy; the position it held based on revenue in the second quarter of 2025. In June 2021, FDA recognized seven years of ODE for Xywav in narcolepsy through July 21, 2027 (which was subsequently extended to January 21, 2028), stating that Xywav is clinically superior to Xyrem by means of greater safety due to reduced chronic sodium burden. While we expect that our business will continue to meaningfully depend on oxybate revenues, there is no guarantee that oxybate revenues will remain at current levels.

Our ability to successfully commercialize Xywav depends on, among other things, our ability to maintain adequate payor coverage and reimbursement for Xywav and acceptance of Xywav by physicians and patients, including of Xywav for the treatment of IH in adults. In an effort to support strong adoption of Xywav and patient success, we are focused on facilitating payor coverage for Xywav and providing robust patient copay and savings programs.

Xywav and Xyrem face competition from Avadel's Lumryz, a branded product for treatment of cataplexy and/or EDS in narcolepsy, which was launched in the U.S. market in June 2023. In addition, in January 2023, our oxybate products began to face competition from an AG version of high-sodium oxybate pursuant to a settlement agreement we entered into with an ANDA filer. In July 2023, a volume-limited ANDA filer launched an additional AG version of high-sodium oxybate. These AG products have negatively impacted and are expected to continue to negatively impact Xyrem and Xywav sales for patients

with narcolepsy. Specifically, a wholly owned subsidiary of Hikma launched its AG version of sodium oxybate in January 2023 and Amneal launched its AG version of sodium oxybate in July 2023. Hikma has elected to continue to sell the Hikma AG product, with royalties to be paid to us, for a total of up to four years beginning in January 2024, which election may be terminated by Hikma in accordance with the notice provisions in the agreements between the parties. We have the right to receive a meaningful royalty from Hikma on net sales of the Hikma AG product; the royalty rate was fixed for the second half of 2023. There was a substantial increase in the royalty rate beginning in January 2024, which will remain fixed for the duration of the agreement's term. We are also paid for supply of the Hikma AG product and reimbursed by Hikma for a portion of the services costs associated with the operation of the Xywav and Xyrem REMS, and distribution of the Hikma AG product. We also granted Hikma a license to launch its own generic sodium oxybate product but, if it elects to launch its own generic product, Hikma will no longer have the right to sell the Hikma AG product. In addition, Hikma would need to set up its own REMS (or join an existing REMS operated by another company), which must be open to any other company seeking to commercialize a sodium oxybate product. In our settlements with Amneal, Lupin, and Par, we granted each party the right to sell a limited volume of an AG product in the U.S. beginning on July 1, 2023 and ending on December 31, 2025, with royalties to be paid to us. Amneal launched its AG version of high-sodium oxybate in July 2023. At this time, Amneal has rights to sell a low-single-digit percentage of historical Xyrem sales over each 6-month sales period. At this time, Lupin and Par have elected not to launch an AG product. AG products will be distributed through the same REMS as Xywav and Xyrem. We also granted each of Amneal, Lupin and Par a license to launch its own generic sodium oxybate product under its ANDA on or after December 31, 2025, or earlier under certain circumstances, including the circumstance where Hikma elects to launch its own generic product. If Amneal, Lupin or Par elects to launch its own generic product under such circumstance, it will no longer have the right to sell an AG product. In addition, any company commercializing a generic version of high-sodium oxybate would need to establish its own REMS, or join an existing REMS operated by another company.

In the future, we expect our oxybate products to continue to face competition from generic versions of high-sodium oxybate pursuant to settlement agreements we entered into with multiple ANDA filers. In addition, we received notices in June 2021 and February 2023 that Lupin and Teva, respectively, filed ANDAs for generic versions of Xywav. On October 13, 2023, Lupin announced that it has received tentative approval for its application to market a generic version of Xywav. Generic competition can decrease the net prices at which branded products, such as Xywav and Xyrem are sold, as can competition from other branded products. In addition, we have increasingly experienced pressure from third party payors to agree to discounts, rebates or restrictive pricing terms, and we cannot guarantee we will be able to agree to commercially reasonable terms with PBMs, or similar organizations and other third party payors, or that we will be able to ensure patient access and acceptance on formularies. Entering into agreements with PBMs or similar organizations and payors to ensure patient access has and may continue to result in decreased net prices for some of our products. Moreover, generic or AG high-sodium oxybate products or branded high-sodium oxybate entrants in narcolepsy, such as Avadel’s Lumryz, have had and may continue to have the effect of changing payor or formulary coverage of Xywav or Xyrem in favor of other products, and indirectly adversely affect sales of Xywav and Xyrem.

In any event, we expect that the approval and launch of AG products or other generic versions of Xyrem or Xywav and the approval and launch of any other sodium oxybate product, such as Avadel’s Lumryz, or alternative product that treats narcolepsy will continue to have a negative impact on, and could have a material adverse effect on, our sales of Xywav and Xyrem and on our business, financial condition, results of operations and growth prospects.

Our financial condition, results of operations and growth prospects are also dependent on our ability to maintain or increase sales of Epidiolex/Epidyolex in the U.S. and Europe, which is subject to many risks and there is no guarantee that we will be able to continue to successfully commercialize Epidiolex/Epidyolex for its approved indications. The commercial success of Epidiolex/Epidyolex depends on the extent to which patients and physicians accept and adopt Epidiolex/Epidyolex as a treatment for seizures associated with LGS, DS and TSC, and we do not know whether our or others’ estimates in this regard will be accurate. Physicians may not prescribe Epidiolex and patients may be unwilling to use Epidiolex/Epidyolex if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for Epidiolex/Epidyolex in the market, in clinical development for additional indications, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of Epidiolex/Epidyolex. Moreover, we expect that Epidiolex will face competition from generic products in the future. We have settled patent litigation with each of the ten companies seeking to market a generic version of Epidiolex in the U.S. by granting each of the Epidiolex ANDA Filers a license to manufacture, market, and sell its own generic version of Epidiolex beginning in the very late 2030s, or earlier under certain circumstances, including but not limited to the launch of another generic Epidiolex product or a final decision that all unexpired claims of the Epidiolex patents are not infringed, or are invalid and/or unenforceable. In addition, there are non-FDA approved cannabidiol preparations being made available from companies through the state-enabled medical marijuana industry, which might attempt to compete with Epidiolex. Thus, significant uncertainty remains regarding the commercial potential of Epidiolex/Epidyolex.

In addition to our neuroscience products and product candidates, we are commercializing a portfolio of oncology products, including Rylaze, Zepzelca, Ziihera, Defitelio and Vyxeos. An inability to effectively commercialize Rylaze,

Zepzelca, Ziihera, Defitelio and Vyxeos and to maximize their potential where possible through successful research and development activities could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

A key aspect of our growth strategy is our continued investment in our evolving and expanding R&D activities. If we are not successful in the clinical development of our product candidates, if we are unable to obtain regulatory approval for our product candidates in a timely manner, or at all, or if sales of an approved product do not reach the levels we expect, our anticipated revenue from our product candidates would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to continued investment in our R&D pipeline, we intend to continue to grow our business by acquiring or in-licensing, and developing, including with collaboration partners, additional products and product candidates that we believe are highly differentiated and have significant commercial potential. Failure to identify and acquire, in-license or develop additional products or product candidates, successfully manage the risks associated with integrating any products or product candidates into our portfolio or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing, such as the GW Acquisition and our recent acquisition of Chimerix, could have a material adverse effect on our business, results of operations and financial condition.

Our industry has been, and is expected to continue to be, subject to healthcare cost containment and drug pricing scrutiny by regulatory agencies in the U.S. and internationally. If new healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for our products may be affected, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted. For example, the Inflation Reduction Act of 2022 among other things, requires the U.S. Department of Health and Human Services Secretary to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologicals per year starting in 2026, penalizes manufacturers of certain Medicare Parts B and D drugs for price increases above inflation, and makes several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs and a change in manufacturer liability under the program, that could negatively affect our business and financial condition. In addition, under the Medicaid Drug Rebate Program, rebates owed by manufacturers are no longer subject to a cap on the rebate amount, which could adversely affect our rebate liability. Moreover, in May 2025, the White House issued an Executive Order directing federal agencies to pursue “most favored nation” pricing for certain prescription drugs, under which U.S. prices would be indexed to the lowest prices available in select OECD countries. The White House is currently seeking voluntary pricing concessions from manufacturers, with the potential for administrative action to follow if companies do not engage constructively, creating uncertainty around future pricing and reimbursement that could negatively impact our U.S. revenues and overall business performance. We are also subject to increasing pricing pressure and restrictions on reimbursement imposed by payors. If we fail to obtain and maintain adequate formulary positions and institutional access for our current products and future approved products, we will not be able to achieve a return on our investment and our business, financial condition, results of operations and growth prospects would be materially adversely affected.

While certain preparations of cannabis remain Schedule I controlled substances, if such products are approved by FDA for medical use in the U.S. they are rescheduled to Schedules II-V, since approval by FDA satisfies the “accepted medical use” requirement; or such products may be removed from control under the Controlled Substances Act entirely. If any of our product candidates receive FDA approval, the Department of Health and Human Services and the U.S. Drug Enforcement Administration will make a scheduling determination. U.S. or foreign regulatory agencies may request additional information regarding the abuse potential of our products which may require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost, delay the approval and/or delay the launch of that product.

In addition, business practices by pharmaceutical companies, including product formulation improvements, patent litigation settlements, and REMS programs, have increasingly drawn public scrutiny from legislators and regulatory agencies, with allegations that such programs are used as a means of improperly blocking or delaying competition. Government investigations with respect to our business practices, including as they relate to the Xywav and Xyrem REMS, the launch of Xywav, our Xyrem patent litigation settlement agreements or otherwise, could cause us to incur significant monetary charges to resolve these matters and could distract us from the operation of our business and execution of our strategy. In addition, from June 2020 to May 2022, a number of lawsuits were filed on behalf of purported direct and indirect Xyrem purchasers, alleging that the patent litigation settlement agreements we entered with certain generic companies violate state and federal antitrust and consumer protection laws. For additional information on these lawsuits, as well as a class settlement agreement with respect thereto and other legal matters, see Note 10, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part I, Item 1 of this Quarterly Report on Form 10-Q. It is possible that additional lawsuits will be filed against us making similar or related allegations. We cannot predict the outcome of these or potential additional lawsuits; however, if the plaintiffs were to be successful in their claims against us, they may be entitled to injunctive relief or

we may be required to pay significant monetary damages. Moreover, we are, and expect to continue to be, the subject of various claims, legal proceedings, and government investigations apart from those set forth above that have arisen in the ordinary course of business that have not yet been fully resolved and that could adversely affect our business and the execution of our strategy. Any of the foregoing risks and uncertainties could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Finally, the U.S. government has imposed and may seek to impose additional restrictions on international trade, such as tariffs on goods generally, and pharmaceutical and biological products in particular, imported into the U.S. In anticipation of the potential for increased tariffs on our products, we have increased inventory levels of our products in the U.S. We conduct our business globally and have third-party suppliers located outside the U.S., including in China. In addition, we have a manufacturing and development facility in Athlone, Ireland where we manufacture Xywav and Xyrem, a manufacturing and development facility in Kent Science Park, U.K. where we produce Epidiolex/Epidyolex, and a manufacturing plant in Villa Guardia, Italy where we produce defibrotide drug substance. While we cannot at this time predict the ultimate impact of such tariffs, we anticipate that our margins could be adversely affected beginning as early as fiscal 2026, depending on the ultimate scope and duration of tariffs imposed. However, given the volatility and uncertainty regarding the scope and duration of such tariffs and other aspects of U.S. and foreign government trade policies, the ultimate impact on our operations and financial results remains uncertain and could be significant. See “Global trade issues and changes in and uncertainties with respect to trade policies and export regulations, including import and export license requirements, trade sanctions, tariffs and international trade disputes, could increase our costs, reduce the competitiveness of our products and otherwise have a material adverse effect on our business, financial condition, results of operations and growth prospects” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

The foregoing risks and uncertainties are discussed in greater detail, along with other risks and uncertainties, in “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024, as supplemented by the risks and uncertainties described 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 June 30,		Increase/	Six Months Ended June 30,		Increase/
	2025	2024	(Decrease)	2025	2024	(Decrease)
Product sales, net	$ 985,571	$ 964,144	2 %	$ 1,824,989	$ 1,806,246	1 %
Royalties and contract revenues	60,141	59,681	1 %	118,564	119,562	(1)%
Cost of product sales (excluding amortization of acquired developed technologies)	116,268	109,902	6 %	220,888	205,389	8 %
Selling, general and administrative	358,399	338,523	6 %	872,412	690,235	26 %
Research and development	189,972	220,734	(14)%	370,624	443,581	(16)%
Intangible asset amortization	162,103	155,223	4 %	316,551	310,953	2 %
Acquired in-process research and development	905,362	—	—	905,362	10,000	N/A(1)
Interest expense, net	47,363	62,023	(24)%	101,069	128,139	(21)%
Foreign exchange (gain) loss	1,799	(507)	N/A(1)	2,012	1,186	70 %
Income tax benefit	(17,170)	(30,653)	(44)%	(34,982)	(18,984)	84 %
Equity in loss of investees	86	12	N/A(1)	628	1,359	(54)%

(1) Comparison to prior period not meaningful.

Revenues

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

	Three Months Ended June 30,		Increase/	Six Months Ended June 30,		Increase/
	2025	2024	(Decrease)	2025	2024	(Decrease)
Xywav	$ 415,321	$ 368,472	13 %	$ 760,125	$ 683,772	11 %
Xyrem	35,349	62,180	(43)%	72,590	126,412	(43)%
Epidiolex/Epidyolex	251,730	247,102	2 %	469,467	445,818	5 %
Sativex	4,615	6,383	(28)%	10,022	9,118	10 %
Total Neuroscience	707,015	684,137	3 %	1,312,204	1,265,120	4 %
Rylaze/Enrylaze	100,659	107,829	(7)%	194,892	210,579	(7)%
Zepzelca	74,541	81,047	(8)%	137,574	156,147	(12)%
Defitelio/defibrotide	48,106	45,421	6 %	88,768	93,097	(5)%
Vyxeos	44,851	43,012	4 %	74,395	75,035	(1)%
Ziihera	5,991	—	N/A(1)	7,966	—	N/A(1)
Total Oncology	274,148	277,309	(1)%	503,595	534,858	(6)%
Other	4,408	2,698	63 %	9,190	6,268	47 %
Product sales, net	985,571	964,144	2 %	1,824,989	1,806,246	1 %
High-sodium oxybate AG royalty revenue	54,138	54,164	— %	103,084	104,111	(1)%
Other royalty and contract revenues	6,003	5,517	9 %	15,480	15,451	— %
Total revenues	$ 1,045,712	$ 1,023,825	2 %	$ 1,943,553	$ 1,925,808	1 %

(1) Comparison to prior period not meaningful.

Total Revenues

Xywav product sales increased in the three and six months ended June 30, 2025, compared to the same periods in 2024, primarily due to increased sales volumes of 14% in both periods and, to a lesser extent, a higher selling price, partially offset by higher gross to net deductions. We continue to see Xywav adoption in patients with narcolepsy driven by educational initiatives around efficacy and the benefit of lowering sodium intake. In addition, Xywav product sales were positively impacted by adoption in IH; Xywav is the only oxybate therapy approved to treat IH and we see continued growth of new prescribers. Exiting the quarter, there were 10,600 patients taking Xywav for narcolepsy and 4,625 taking Xywav for IH, an increase of approximately 7% and 40%, respectively, compared to the same period in 2024. Xyrem product sales decreased in the three and six months ended June 30, 2025, compared to the same periods in 2024, primarily due to decreased sales volumes of 35% and 38% in the respective periods, due to high-sodium oxybate competition and adoption of Xywav by existing patients, and higher gross to net deductions, partially offset by a higher selling price. Epidiolex/Epidyolex product sales increased in the three and six months ended June 30, 2025, compared to the same periods in 2024, primarily due to increased sales volumes of 7% and 6% in the respective periods, due to increased demand, and a higher average selling price, partially offset by higher gross to net deductions. In the three months ended June 30, 2025, year-on-year growth was negatively affected by increases in U.S. inventory levels in the channel in the same period in 2024 and in the six months ended June 30, 2025, year-on-year growth was negatively affected by greater reductions in U.S. inventory levels in the channel in the current year's period.

Rylaze/Enrylaze product sales decreased in the three and six months ended June 30, 2025, compared to the same periods in 2024, primarily due to decreased sales volumes of 3% and 4% in the respective periods and higher gross to net deductions, partially offset by a higher average selling price. Following updates to pediatric treatment protocols for ALL which have been broadly adopted, pediatric asparaginase use as a class remains below levels seen prior to protocol implementation in the second half of 2024. Rylaze use within the asparaginase class remains broadly stable. Zepzelca product sales decreased in the three and six months ended June 30, 2025, compared to the same periods in 2024, primarily due to decreased sales volumes, driven by increased competition in second-line SCLC and treatment protocol updates delaying progression of first-line limited-stage SCLC patients to the second-line setting, offset by lower gross to net deductions and a higher selling price. Defitelio/defibrotide product sales increased in the three months ended June 30, 2025, compared to the same period in 2024, primarily due to increased sales volumes. Defitelio/defibrotide product sales decreased in the six months ended June 30, 2025, compared to the same period in 2024, primarily due to decreased sales volumes. Vyxeos product sales increased in the three months ended June 30, 2025, compared to the same period in 2024, primarily due to an increase in sales volumes, partially offset by a

lower average selling price due to regional mix. Vyxeos product sales decreased in the six months ended June 30, 2025, compared to the same period in 2024, primarily due to a lower average selling price due to regional mix, partially offset by an increase in sales volumes.

Royalties and contract revenues in the three and six months ended June 30, 2025 were in line with the same periods in 2024. We expect royalties and contract revenues to remain broadly in line with 2024.

We expect total revenues will increase in 2025 over 2024, primarily driven by growth across our commercial portfolio, offset by a decrease in sales of Xyrem due to the impact of high-sodium oxybate competition.

Cost of Product Sales

Cost of product sales increased in the three and six months ended June 30, 2025, compared to the same periods in 2024, primarily due to changes in product mix and higher fair value step-up expense of $3.9 million and $4.8 million in the respective periods. Gross margin as a percentage of net product sales was 88.2% and 87.9% for the three and six months ended June 30, 2025, compared to 88.6% for the same periods in 2024. We expect our cost of product sales to increase in 2025 compared to 2024, primarily driven by changes in product mix.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased in the three months ended June 30, 2025, compared to the same period in 2024, primarily due to an increase in compensation-related expenses of $21.7 million primarily driven by higher headcount in support of our commercial portfolio. Selling, general and administrative expenses increased in the six months ended June 30, 2025, compared to the same period in 2024, primarily due to certain Xyrem antitrust litigation settlements of $172.0 million.

We expect selling, general and administrative expenses in 2025 to increase compared to 2024, primarily due to Xyrem litigation settlement expenses, the inclusion of costs relating to Chimerix, investment in our commercial portfolio, including the launch of Ziihera, along with increased compensation-related expenses.

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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Clinical studies and outside services	$ 93,099	$ 134,118	$ 180,442	$ 265,584
Personnel expenses	75,439	68,305	149,798	141,301
Other	21,434	18,311	40,384	36,696
Total	$ 189,972	$ 220,734	$ 370,624	$ 443,581

Research and development expenses decreased by $30.8 million and $73.0 million in the three and six months ended June 30, 2025, compared to the same periods in 2024, driven by a reduction in clinical studies and outside services costs, primarily due to lower costs related to zanidatamab as a result of timing of clinical trial activities and JZP385 (essential tremor) following discontinuation of this program, partially offset by the addition of costs relating to dordaviprone following the Chimerix Acquisition.

For 2025, we expect that our research and development expenses will decrease compared to 2024, primarily driven by a reduction in clinical studies and outside services costs relating to zanidatamab, JZP385 and continued portfolio prioritization, partially offset by the inclusion of costs associated with the development of dordaviprone.

Intangible Asset Amortization

Intangible asset amortization in the three and six months ended June 30, 2025 was broadly in line with the same periods in 2024.

Acquired In-Process Research and Development

Acquired IPR&D expense in the three and six months ended June 30, 2025 represents the value allocated to dordaviprone in the Chimerix Acquisition.

Interest Expense, Net

Interest expense, net decreased by $14.7 million and $27.1 million in the three and six months ended June 30, 2025, respectively, compared to the same periods in 2024, primarily due to lower interest expense on the Tranche B-2 Dollar Term Loans, partially offset by the inclusion of interest expense on the 2030 Notes.

Income Tax Benefit

Our income tax benefit was $17.2 million and $35.0 million for the three and six months ended June 30, 2025, respectively, compared to an income tax benefit of $30.7 million and $19.0 million for the same periods in 2024, relating to tax arising on income or losses in Ireland, the U.K., the U.S. and certain other foreign jurisdictions and Pillar Two top-up taxes, offset by deductions on subsidiary equity, patent box and foreign derived intangible income benefits and tax credits. The income tax benefit in the six months ended June 30, 2025 was primarily due to the tax impact of certain Xyrem antitrust litigation settlements.

Liquidity and Capital Resources

As of June 30, 2025, we had cash, cash equivalents and investments of $1.7 billion, borrowing available under our Amended Revolving Credit Facility of $885.0 million and a long-term debt principal balance of $5.4 billion. Our long-term debt included $1.9 billion aggregate principal amount of the Tranche B-2 Dollar Term Loans, $1.5 billion in aggregate principal amount of the Secured Notes, $1.0 billion aggregate principal amount of the 2026 Notes, and $1.0 billion aggregate principal amount of the 2030 Notes. We generated cash flows from operations of $518.6 million during the six months ended June 30, 2025, and we expect to continue to generate positive cash flows from operations which will enable us to operate our business and de-lever our balance sheet over time.

Since the closing of the acquisition of GW in May 2021, we have fully repaid our Euro Term Loan. With respect to our Tranche B-2 Dollar Term Loans, we have made voluntary repayments of $1.1 billion, $300.0 million in September 2022 and $750.0 million in January 2025, along with mandatory repayments $124.0 million. In August 2024, we repaid the $575.0 million aggregate principal amount of our 2024 Notes.

We have a significant amount of debt outstanding on a consolidated basis. For further information, including details relating to our scheduled maturities with respect to our long-term debt, see Note 9, Debt, of the Notes to Condensed Consolidated Financial Statements, included in Part I, Item 1 of this Quarterly Report on Form 10-Q. This substantial level of debt could have important consequences to our business, including, but not limited to the factors set forth in “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2024, under the heading “We have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position, and our business would be adversely affected if we are unable to service our debt obligations.”

We believe that our existing cash, cash equivalents and investments balances, cash we expect to generate from operations and funds available under our Revolving Credit Facility will be sufficient to fund our operations and to meet our existing obligations for the foreseeable future. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses, as well as the other factors set forth in "Risk Factors" under the heading "Risks Related to our Lead Products and Product Candidates” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024, as supplemented by the risks described in “Risk Factors" under the heading “Delays or problems in the supply of our products for sale or for use in clinical trials, loss of our single source suppliers or failure to comply with manufacturing regulations could materially and adversely affect our business, financial condition, results of operations and growth prospects” in Part II, Item 1A of this Quarterly Report on Form 10-Q, as well as those factors set forth in

“Risk Factors" under the heading 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 and grow our business” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024.

Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources, and we may not be able to generate sufficient cash to service our debt obligations which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

To continue to grow our business over the longer term, we plan to commit substantial resources to product acquisition and in-licensing, product development, clinical trials of product candidates and expansion of our commercial, development, manufacturing and other operations. In this regard, we have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. We regularly evaluate the performance of our products and product candidates to ensure fit within our portfolio and support efficient allocation of capital. 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. However, our ability to raise additional capital may be adversely impacted by worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of inflationary pressures, potential future bank failures, or otherwise. Accordingly, we could experience an inability to access additional capital or our liquidity could otherwise be impacted, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. In addition, under Irish law we must have authority from our shareholders to issue any ordinary shares, including ordinary shares that are part of our authorized but unissued share capital, and we currently have such authorization. Moreover, as a matter of Irish law, when an Irish public limited company issues ordinary shares to new shareholders for cash, the company must first offer those shares on the same or more favorable terms to existing shareholders on a pro rata basis, unless this statutory pre-emption obligation is dis-applied, or opted-out of, by approval of its shareholders. At our annual general meeting of shareholders in July 2025, our shareholders voted to approve our proposal to dis-apply the statutory pre-emption obligation. This current pre-emption opt-out authority is due to expire in January 2027. If we are unable to obtain further pre-emption authorities from our shareholders in the future, or otherwise continue to be limited by the terms of new pre-emption authorities approved by our shareholders in the future, our ability to use our unissued share capital to fund in-licensing, acquisition or other business opportunities, or to otherwise raise capital, including at the time we are required to make repurchases of the 2026 Notes, the 2030 Notes and/or the Secured Notes, are required to repay outstanding amounts under the Amended Credit Agreement, or pay cash upon exchange of the 2026 Notes or the 2030 Notes, could likewise be adversely affected. In any event, an inability to borrow or raise additional capital in a timely manner and on attractive terms could prevent us from expanding our business or taking advantage of acquisition opportunities and could otherwise have a material adverse effect on our business and growth prospects. In addition, if we use a substantial amount of our funds to acquire or in-license products or product candidates, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose. Furthermore, any equity financing would be dilutive to our shareholders, and could require the consent of the lenders under the Amended Credit Agreement that provides for (i) the Tranche B-2 Dollar Term Loans and Amended Revolving Credit Facility, and the indenture for the Secured Notes for certain financings.

In July 2024, our board of directors authorized the New Repurchase Program, to repurchase ordinary shares having an aggregate purchase price of $500.0 million, exclusive of any brokerage commissions. Under the New Repurchase Program, which has no expiration date, we may repurchase ordinary shares from time to time by any methods and/or structures permitted by applicable law. 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 and the indenture for our Secured Notes, corporate and regulatory requirements and market conditions. The New Repurchase Program may be modified, suspended or discontinued at any time without our prior notice. The New Repurchase Program replaces and supersedes the Old Repurchase Program, a share repurchase program to repurchase ordinary shares having an aggregate purchase price of $1.5 billion, exclusive of any brokerage commissions. During the three and six months ended June 30, 2025, we spent a total of $125.0 million to repurchase 1.1 million of our ordinary shares, all under the New Repurchase Program, at a purchase price, including commissions, of $109.52 per share. During the three and six months ended June 30, 2024, we spent a total of $161.4 million to repurchase 1.5 million of our ordinary shares, all under the Old Repurchase Program, at a purchase price, including commissions, of $110.75 per share. As of June 30, 2025, the remaining amount authorized for repurchases under the New Repurchase Program was $225.0 million, exclusive of any brokerage commissions.

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

	Six Months Ended June 30,	
	2025	2024
Net cash provided by operating activities	$ 518,639	$ 598,581
Net cash used in investing activities	(809,951)	(528,995)
Net cash used in financing activities	(937,991)	(217,637)
Effect of exchange rates on cash and cash equivalents	6,319	(2,457)
Net decrease in cash and cash equivalents	$ (1,222,984)	$ (150,508)

Operating activities

Net cash provided by operating activities decreased by $79.9 million in the six months ended June 30, 2025, compared to the same period in 2024, primarily due to the payment of Xyrem antitrust litigation settlements of $172.0 million in the six months ended June 30, 2025, partially offset by the payment of accrued facility expenses of $52.2 million in the six months ended June 30, 2024.

Investing activities

Net cash used in investing activities increased by $281.0 million in the six months ended June 30, 2025, compared to the same period in 2024, primarily due to the following:

- $858.1 million outflow related to the net cash paid for the Chimerix Acquisition; and
- $25.0 million milestone payment to Zymeworks following FDA approval of Ziihera in BTC; partially offset by
- $605.0 million net increase in the proceeds from maturity of investments, driven by time deposits.

Financing activities

Net cash used in financing activities increased by $720.4 million in the six months ended June 30, 2025, compared to the same period in 2024, primarily due to:

- The $750.0 million voluntary repayment on the Tranche B-2 Dollar Term Loan in January 2025; and
- An increase of $17.3 million in payment of employee withholding taxes related to share-based awards; partially offset by
- A decrease of $36.4 million in share repurchases.

Debt

The summary of our outstanding indebtedness and scheduled maturities with respect to our long-term debt principal balances is included in Note 9, Debt, of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. In January 2025, we made a voluntary repayment on the Tranche B-2 Dollar Term Loans totaling $750.0 million.

During the six months ended June 30, 2025, there were no other changes to our financing arrangements, as set forth in Note 11, Debt, of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2024.

Contractual Obligations

During the six months ended June 30, 2025, there were no material changes to our contractual obligations as set forth in Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2024 other than the assumption of potential future milestone payments, totaling $340.0 million, and royalty obligations in the Chimerix Acquisition.

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 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 and also with respect to the acquisition and valuation of intangibles and income taxes. 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, 2024. 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, 2024.

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. These known and unknown risks, uncertainties and other factors include, without limitation:

- Our inability to maintain revenues from our oxybate franchise would have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products has adversely affected and may continue to adversely affect sales of our oxybate products.
- The distribution and sale of our oxybate products are subject to significant regulatory restrictions, including the requirements of a REMS and safety reporting requirements, and these regulatory and safety requirements subject us to risks and uncertainties, any of which could negatively impact sales of Xywav and Xyrem.
- Our inability to maintain or increase sales of Epidiolex/Epidyolex would have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- While we expect Xywav and Epidiolex/Epidyolex to remain our largest products, our success also depends on our ability to effectively commercialize our other existing products and potential future products.
- We face substantial competition from other companies, including companies with larger sales organizations and more experience working with large and diverse product portfolios, and competition from generic drugs.
- Adequate coverage and reimbursement from third party payors may not be available for our products and we may be unable to successfully contract for coverage from PBMs and other organizations; conversely, to secure coverage from these organizations, we may be required to pay rebates or other discounts or other restrictions to reimbursement, either of which could diminish our sales or adversely affect our ability to sell our products profitably.
- The pricing of pharmaceutical products has come under increasing scrutiny as part of a global trend toward healthcare cost containment and resulting changes in healthcare law and policy, including changes to Medicare, may impact our business in ways that we cannot currently predict, which could have a material adverse effect on our business and financial condition.
- In addition to access, coverage and reimbursement, the commercial success of our products depends upon their market acceptance by physicians, patients, third party payors and the medical community.
- Delays or problems in the supply of our products for sale or for use in clinical trials, loss of our single source suppliers or failure to comply with manufacturing regulations could materially and adversely affect our business, financial condition, results of operations and growth prospects.
- Global trade issues and changes in and uncertainties with respect to trade policies and export regulations, including import and export license requirements, trade sanctions, tariffs and international trade disputes, could increase our

costs, reduce the competitiveness of our products and otherwise have a material adverse effect on our business, financial condition, results of operations and growth prospects.

- We may not realize the anticipated benefits from our acquisition of Chimerix.
- Our future success depends on our ability to successfully obtain and maintain regulatory approvals for our late-stage product candidates and, if approved, to successfully launch and commercialize those product candidates.
- We may not be able to successfully identify and acquire or in-license additional products or product candidates to grow our business, and, even if we are able to do so, we may otherwise fail to realize the anticipated benefits of these transactions.
- 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.
- It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.
- We have incurred, and may in the future incur, substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, and we may be unable to protect our rights to, or commercialize, our products.
- Significant disruptions of information technology systems or data security incidents could adversely affect our business.
- We are subject to significant ongoing regulatory obligations and oversight, which may subject us to civil or criminal proceedings, investigations, or penalties and may result in significant additional expense and limit our ability to commercialize 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 have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position, and our business would be adversely affected if we are unable to service our debt obligations.
- To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate and grow our business.
- If we fail to attract, retain and motivate members of our executive management team and key personnel, our operations and our future growth may be adversely affected.

Additional discussion of the risks, uncertainties and other factors described above, as well as other risks material to our business, can be found under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024, as supplemented by the risks and uncertainties described in "Risk Factors" Part II, Item 1A. in 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

During the six months ended June 30, 2025, 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, 2024.

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) and 15d-15(e) of the Exchange Act) 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 June 30, 2025.

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 June 30, 2025, there were no changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

The information required to be set forth under this Item 1 is incorporated by reference to Note 10, Commitments and Contingencies—Legal Proceedings of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors

Below we are providing, in supplemental form, changes to our risk factors from those previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024. Our risk factors disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024, provide additional discussion regarding these supplemental risks and we encourage you to read and carefully consider all of the risk factors disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024, together with the below, for a more complete understanding of the risks and uncertainties material to our business.

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

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes, particularly given the current atmosphere of mounting criticism of prescription drug costs in the U.S. We expect there will continue to be legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably, as governmental oversight and scrutiny of biopharmaceutical companies is increasing. For example, we anticipate that the U.S. Congress, state legislatures, and federal and state regulators may adopt or accelerate adoption of new healthcare policies and reforms intended to curb healthcare costs, such as federal and state controls on reimbursement for drugs (including under Medicare, Medicaid and commercial health plans), new or increased requirements to pay prescription drug rebates and penalties to government health care programs, and additional pharmaceutical cost transparency policies that aim to require drug companies to justify their prices through required disclosures. This includes efforts by individual states in the U.S. to pass legislation and implement regulations designed to control pharmaceutical and biological product pricing, including by establishing Prescription Drug Affordability Boards (or similar entities) to review high-cost drugs and, in some cases, set upper payment limits and implementing marketing cost disclosure and transparency measures. Further, the IRA, among other things, requires the U.S. Department of Health and Human Services Secretary to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologicals per year starting in 2026, penalizes manufacturers of certain Medicare Parts B and D drugs for price increases above inflation, and makes several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs and a change in manufacturer liability under the program, which could negatively affect our business and financial condition. CMS has issued final guidance implementing the Drug Price Negotiation Program in which it finalized certain policies governing the selection of drugs for negotiation. Among other things, CMS finalized definitions of "qualifying single source drug" and "marketed" that, especially if they persist, could further disincentivize innovation. In addition, under the Medicaid Drug Rebate Program, rebates owed by manufacturers are no longer subject to a cap on the rebate amount effective January 1, 2024, which may adversely affect our rebate liability. The foregoing may negatively impact our overall rebate and discount liability, which would have a negative adverse effect on our revenues.

On July 4, 2025, President Trump signed into law H.R.1, a budget bill, which includes significant reforms to Medicaid, Medicare, and Affordable Care Act premium tax credits. Among other things, these reforms are anticipated to significantly decrease Medicaid spending, which could reduce access to and reimbursement for our products, which could have a negative adverse effect on our revenues.

Legislative and regulatory proposals that have recently been considered include, among other things, proposals to limit the terms of patent litigation settlements with generic sponsors, to define certain conduct around patenting and new product development as unfair competition, to address the scope of orphan drug exclusivity and to facilitate the importation of drugs into the U.S. from other countries. Moreover, on April 15, 2025, the White House issued an executive order announcing a number of initiatives seeking to lower drug pricing. In addition, there has been recent interest in incorporating so-called Most Favored Nation pricing into the U.S. healthcare system, under which prices for drugs in the United States could be tied to foreign reference prices through a mechanism that is not yet defined, announced in a second executive order dated May 12, 2025. Legislative and regulatory proposals to reform the regulation of the pharmaceutical industry and reimbursement for pharmaceutical drugs are continually changing, and all such considerations may adversely affect our business and industry in ways that we cannot accurately predict.

There is also ongoing activity related to health care coverage. The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers. These changes impacted previously existing government healthcare programs and have resulted in the development of new programs, including Medicare payment-for-performance initiatives. Further, federal and state policy makers have taken and may continue to try to take steps regarding health care coverage beyond the Affordable Care Act, which could have ramifications for the pharmaceutical industry. Additional legislative changes, regulatory changes, or guidance could be adopted, which may impact the marketing approvals and reimbursement for our products and product candidates. For example, there has been increasing legislative, regulatory, and enforcement interest in the U.S. with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products beyond the changes enacted by the IRA.

If new healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for our products may be affected, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted. We have periodically increased the price of our products, including Xywav and Xyrem most recently in January 2025, and there is no guarantee that we will not make similar price adjustments to our products in the future or that price adjustments we have taken or may take in the future will not negatively affect our sales volumes and revenues. There is no guarantee that such price adjustments will not negatively affect our reputation and our ability to secure and maintain reimbursement coverage for our products, which could limit the prices that we charge for our products, limit the commercial opportunities for our products and/or negatively impact revenues from sales of our products.

Government investigations or U.S. Congressional oversight with respect to drug pricing or our other business practices could cause us to incur significant expense and could distract us from the operation of our business and execution of our strategy. Any such investigation or hearing could also result in reduced market acceptance and demand for our products, could harm our reputation and our ability to market our products in the future, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. For more information, see the risk factor under the heading "*We are subject to significant ongoing regulatory obligations and oversight, which may subject us to civil or criminal proceedings, investigations, or penalties and may result in significant additional expense and limit our ability to commercialize our products*" in Part I, Item 1A of our Annual Report on Form 10-K for year ended December 31, 2024.

We expect that legislators, policymakers and healthcare insurance funds in Europe and other international markets will continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we will be able to charge for our products or the level of reimbursement available for these products from governmental authorities or third party payors as well as clawbacks and revenue caps. For example, in the U.K., the cap on NHS spending on branded medicines agreed between the U.K. government and industry for 2019 to 2023 has remained unaltered despite higher than expected growth in NHS use of branded medicines, resulting in significant increases to the industry level revenue clawback rate payable on sales of branded medicines to the NHS. In the EU, a trend in some EU member states is for medicinal products to be reimbursed based on the relative price of competitor products, which may undervalue newer innovative products. On April 26, 2023, the EC adopted proposals for a new Directive and a new Regulation, which revise and replace the existing EU general pharmaceutical legislation. This proposal includes increased transparency on research and development costs or public contributions to these costs with a view to strengthen the negotiating position of national competent authorities of the EU member states responsible for pricing and reimbursement, as well as reinforced cooperation with these authorities on pricing and reimbursement matters. The European Parliament and the Council of the European Union are currently engaged in interinstitutional negotiations to agree on the final version of the pharmaceutical legislation. Further, an increasing number of European and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Global trade issues and changes in and uncertainties with respect to trade policies and export regulations, including import and export license requirements, trade sanctions, tariffs and international trade disputes, could increase our costs, reduce the competitiveness of our products and otherwise have a material adverse effect on our business, financial condition, results of operations and growth prospects.

There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments and persons targeted by

U.S. sanctions. The U.S. and other countries have imposed and may continue to impose new trade restrictions and export regulations, have levied tariffs and taxes on certain goods, and could continue to significantly increase tariffs on a broad array of goods, including pharmaceutical and biological products.

While we are an Irish company headquartered in Dublin, Ireland, we derive the majority of our revenues from sales of our products in the U.S. We conduct business globally and our operations, including third-party suppliers, span numerous countries outside the U.S. In particular, we have a manufacturing and development facility in Athlone, Ireland where we manufacture Xywav and Xyrem, a manufacturing and development facility in Kent Science Park, U.K. where we produce Epidiolex/Epidyolex, and a manufacturing plant in Villa Guardia, Italy where we produce defibrotide drug substance. In addition, we rely on our supplier in China for the manufacture of Ziihera.

In 2025, President Trump signed a series of executive orders imposing various reciprocal tariffs. Most pharmaceutical products are currently exempt from the reciprocal tariffs. However, at President Trump's request, the U.S. Secretary of Commerce has initiated a Section 232 investigation that is expected to result in new tariffs on pharmaceutical products. Such tariffs will result in additional costs on our business, including costs with respect to APIs and other raw materials upon which our business depends and will generally increase our manufacturing costs. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Moreover, other governments have imposed and may continue to impose retaliatory tariffs, trade restrictions or trade barriers on our products, which may impose additional costs and complexity on our business.

While we cannot at this time predict the ultimate impact of such tariffs, we anticipate that that our margins could be adversely affected beginning as early as fiscal 2026, depending on the ultimate scope and duration of tariffs imposed. Additionally, it is possible that such tariffs could affect imports of APIs and other raw materials used in our products, or our business may be adversely impacted by retaliatory trade measures taken by other countries, including restricted access to APIs or other raw materials used in our products, further disrupting our supply chain and increasing our costs. Given the nature of our products, relocating the manufacturing supply in response to tariffs and other trade restrictions would be a complex, costly and time-consuming process making it difficult for us to react quickly to a rapidly changing environment. In this regard, it would take a significant amount of time and expense to implement and execute the necessary technology transfer to, and to qualify, new suppliers for our products. If there are delays in qualifying new suppliers or facilities or a new supplier is unable to meet FDA's or similar international regulatory body's requirements for approval, there could be a shortage of the affected products for the marketplace or for use in clinical studies, or both, which could negatively impact our anticipated revenues.

Further, the continued threats of new or increased tariffs, sanctions, trade restrictions and trade barriers as well as ongoing changes in U.S. and foreign government trade policies, including potential modifications to existing trade agreements, have had and may continue to have a generally disruptive impact on the global economy and, therefore, negatively impact revenues from sales of our products. Given the volatility and uncertainty regarding the scope and duration of such tariffs and other aspects of U.S. and foreign government trade policies, the ultimate impact on our operations and financial results is uncertain and could be significant. In any event, further trade restrictions and export regulations, or new or increased tariffs, including further retaliatory measures, could increase our supply chain complexity and our manufacturing costs, decrease our margins, reduce the competitiveness of our products, or restrict our ability to sell our products, provide services or purchase necessary equipment and supplies. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may not realize the anticipated benefits from our acquisition of Chimerix.

On April 21, 2025, we completed the acquisition of all the outstanding shares of Chimerix Common Stock. As a result of this, Chimerix became an indirect wholly owned subsidiary of the Company. The success of the acquisition will depend, in part, on our ability to realize the anticipated benefits from successfully combining our and Chimerix's operations and we plan on devoting management attention and resources to integrating our business practices and operations with Chimerix's so that we can fully realize the anticipated benefits of the acquisition. In addition, Chimerix's NDA for dordaviprone seeking accelerated approval for treatment of H3 K27M-mutant diffuse glioma in adult and pediatric patients with progressive disease following prior therapy may not be approved by FDA in a timely manner or at all. Moreover, dordaviprone, if approved, may not be successful or they may require significantly greater resources and investments than originally anticipated. The transaction could also result in the assumption of unknown or contingent liabilities. In addition, difficulties may arise during the process of combining the operations of our companies that could result in the failure to achieve revenue that we anticipate, the loss of key employees that may be difficult to replace in the very competitive pharmaceutical field, the failure to harmonize both companies' corporate cultures, the disruption of each company's ongoing businesses or inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with suppliers, collaboration partners, clinical trial investigators or managers of our clinical trials. As a result, the anticipated benefits of the acquisition may not be realized fully within the expected timeframe or at all or may take longer to realize or cost more than expected, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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

In addition to continued investment in our research and development pipeline, we intend to grow our business by acquiring or in-licensing, and developing, including with collaboration partners, additional products and product candidates that we believe are highly differentiated and have significant commercial potential. However, we may be unable to identify or consummate suitable acquisition or in-licensing opportunities, and this inability could impair our ability to grow our business. Other companies, many of which may have substantially greater financial, sales and marketing resources, compete with us for these opportunities. Even if appropriate opportunities are available, we may not be able to successfully identify them, or we may not have the financial resources necessary to pursue them.

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

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

As a result of these or other factors, products or product candidates we acquire, or obtain licenses to, may not produce the revenues, earnings or business synergies that we anticipated, may not result in regulatory approvals, and may not perform as expected. For example, in May 2021, we made a substantial investment in Epidiolex and certain other products and technologies acquired in our acquisition of GW. The total consideration paid by us for the entire issued share capital of GW was $7.2 billion. Additionally, in April 2025, we completed our acquisition of Chimerix, a biopharmaceutical company the lead clinical asset of which is dordaviprone, a novel first-in-class small molecule treatment in development for H3 K27M-mutant diffuse glioma, a rare, high-grade brain tumor that most commonly affects children and young adults. The total consideration paid by us for the outstanding shares of Chimerix Common Stock was $944.2 million. The success of our acquisition of GW and Chimerix will depend, in part, on our ability to realize the anticipated benefits from each of the acquisitions, which benefits may not be realized at the expected levels within the expected timeframe, or at all, or may take longer to realize or cost more than expected, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. In this regard, in the third quarter of 2022, we recorded a $133.6 million asset impairment charge as a result of the decision to discontinue the nabiximols program that we acquired as part of our acquisition of GW. In any event, failure to manage effectively our growth through acquisitions or in-licensing transactions could adversely affect our growth prospects, business, results of operations and financial condition.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

Our commercial success depends in part on obtaining, maintaining and defending intellectual property protection for our products and product candidates, including protection of their use and methods of manufacturing. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importation by third parties depends on the extent to which we have rights under valid and enforceable patents or have adequately protected trade secrets that cover these activities.

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

- our patent applications, or those of our licensors or partners, may not result in issued patents;
- others may independently develop similar or therapeutically equivalent products without infringing our patents, or those of our licensors, such as products that are not covered by the claims of our patents, or for which fall outside the exclusive rights granted under our license agreements;
- our issued patents, or those of our licensors or partners, may be held invalid or unenforceable as a result of legal challenges by third parties or may be vulnerable to legal challenges as a result of changes in applicable law;
- our patents covering certain aspects of our products or the use thereof could be delisted from FDA's Orange Book as a result of challenges by third parties before FDA or the courts;
- competitors may manufacture products in countries where we have not applied for patent protection or that have a different scope of patent protection or that do not respect our patents; or
- others may be issued patents that prevent the sale of our products or require licensing and the payment of significant fees or royalties.

Patent enforcement generally must be sought on a country-by-country basis, and patent validity and infringement may be judged differently in different countries. The legal systems of certain countries, particularly certain developing countries, may lack maturity or consistency when it comes to the enforcement of patents and other intellectual property rights, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property portfolio. Any patent may be challenged, and potentially invalidated or held unenforceable, including through patent litigation or through administrative procedures that permit challenges to patent validity. Patents can also be designed around by an ANDA or Section 505(b)(2) NDA that avoids infringement of our intellectual property.

In June 2021, we received notice from Lupin that it has filed with FDA an ANDA for a generic version of Xywav. The notice from Lupin included a “paragraph IV certification” with respect to ten of our patents listed in FDA’s Orange Book for Xywav on the date of our receipt of the notice. A paragraph IV certification is a certification by a generic applicant that patents covering the branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product. In April 2022, we received notice from Lupin that it had filed a paragraph IV certification regarding a newly-issued patent listed in the Orange Book for Xywav. In February 2023, we received notice from Teva that it had filed an ANDA seeking approval to market a generic version of Xywav, which notice included a paragraph IV certification with respect to certain of our patents listed in FDA’s Orange Book for Xywav. For additional information on litigation involving these matters, see Note 10, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part I of this Quarterly Report on Form 10-Q.

We have settled patent litigation with each of the ten companies seeking to introduce generic versions of Xyrem in the U.S. by granting those companies licenses to launch their generic products (and in certain cases, an AG version of Xyrem) in advance of the expiration of the last of our patents. Notwithstanding our Xyrem patents and settlement agreements, additional third parties may also attempt to introduce generic versions of Xyrem, Xywav or other sodium oxybate products for treatment of cataplexy and/or EDS in narcolepsy that design around our patents or assert that our patents are invalid or otherwise unenforceable. Such third parties could launch a generic or 505(b)(2) product referencing Xyrem before the dates provided in our patents or settlement agreements. For example, we have several methods of use patents listed in the Orange Book, that expire in 2033 that cover treatment methods included in the Xyrem label related to a DDI with divalproex sodium. Although FDA has stated, in granting a Citizen Petition we submitted in 2016, that it would not approve any sodium oxybate ANDA referencing Xyrem that does not include the portions of the currently approved Xyrem label related to the DDI patents, we cannot predict whether a future ANDA filer, or a company that files a Section 505(b)(2) application for a drug referencing Xyrem, may pursue regulatory strategies to avoid infringing our DDI patents notwithstanding FDA’s response to the Citizen

Petition, or whether any such strategy would be successful. Likewise, we cannot predict whether we will be able to maintain the validity of these patents or will otherwise obtain a judicial determination that a generic or other sodium oxybate product, its package insert or the generic sodium oxybate REMS or another separate REMS will infringe any of our patents or, if we prevail in proving infringement, whether a court will grant an injunction that prevents a future ANDA filer or other company introducing a different sodium oxybate product from marketing its product, or instead require that party to pay damages in the form of lost profits or a reasonable royalty.

Since Xyrem's regulatory exclusivity has expired in the EU, we are aware that generic or hybrid generic applications have been approved by various EU regulatory authorities, and additional generic or hybrid generic applications may be submitted and approved.

We have settled patent litigation with each of the ten companies seeking to market a generic version of Epidiolex in the U.S. by granting each of the Epidiolex ANDA Filers a license to manufacture, market, and sell its own generic version of Epidiolex beginning in the very late 2030s, or earlier under certain circumstances, including but not limited to the launch of another generic Epidiolex product or a final decision that all unexpired claims of the Epidiolex patents are not infringed, or are invalid and/or unenforceable. Notwithstanding our patents listed in FDA's Orange Book for Epidiolex and settlement agreements, additional third parties may also attempt to introduce generic versions of Epidiolex that design around our patents or assert that our patents are invalid or otherwise unenforceable.

In March 2025, we received a notice from Almaject that it had filed with FDA an ANDA for a generic version of Defitelio (defibrotide sodium). The notice from Almaject included a paragraph IV certification respect to certain of our patents listed in FDA's Orange Book for Defitelio on the date of the notice. The listed patents relate generally to the Defitelio drug product and its approved use. For additional information on litigation involving this matter, see Note 10, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part I of this Quarterly Report on Form 10-Q.

On May 13, 2021, we filed a patent infringement suit against Avadel and several of its corporate affiliates in the United States District Court for the District of Delaware. The suit alleges that Avadel's product candidate FT218 will infringe five of our patents related to controlled release formulations of oxybate and the safe and effective distribution of oxybate. In March 2024, the jury upheld the validity of both of our asserted patents and awarded us damages for infringement for past sales of Lumryz in the U.S. For additional information on litigation involving this matter, see "*Avadel Litigation*" in Note 10, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part I of this Quarterly Report on Form 10-Q.

In July and August 2024, Zepzelca ANDA filers sent us notices that they had filed ANDAs seeking approval to market a generic version of Zepzelca (lurbinectedin), which notices each included a paragraph IV certification with respect to our Orange Book listed patent for Zepzelca on the date of the receipt of the applicable notice. In September 2024, we filed patent infringement suits against these ANDA filers. For additional information on litigation involving this matter, see "*Zepzelca Patent Litigation*" in Note 10, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part I of this Quarterly Report on Form 10-Q.

We also currently rely in part on trade secret protection for several of our products, including Defitelio, and product candidates. Trade secret protection does not protect information or inventions if another party develops that information or invention independently and establishing that a competitor developed a product through trade secret misappropriation rather than through legitimate means may be difficult to prove. We seek to protect our trade secrets and other unpatented proprietary information in part through confidentiality and invention agreements with our employees, consultants, advisors and partners. Nevertheless, our employees, consultants, advisors and partners may unintentionally or willfully disclose our proprietary information to competitors, and we may not have adequate remedies for such disclosures. Moreover, if a dispute arises with our employees, consultants, advisors or partners over the ownership of rights to inventions, including jointly developed intellectual property, we could lose patent protection or the confidentiality of our proprietary information, and possibly also lose the ability to pursue the development of certain new products or product candidates.

Disruptions at FDA, including due to a reduction in FDA's workforce and/or inadequate funding for FDA, could prevent FDA from performing normal functions on which our business relies, which could negatively impact our business.

The ability of FDA to review and approve new products or review other regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget and funding levels, a reduction in FDA's workforce and its ability to hire and retain key personnel. Disruptions at FDA and other agencies may also increase the time to meet with and receive agency feedback, review and/or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to FDA and other related government agencies. For example, the current President Trump administration recently established the Department of Government Efficiency, which implemented a federal government hiring freeze and

announced certain additional efforts to reduce federal government employee headcount, including by attempting to eliminate 3,500 employees from FDA. It is unclear how these executive actions or other potential actions by the Trump Administration or other parts of the federal government will impact FDA or other regulatory authorities that oversee our business. The reductions in FDA's workforce and budgetary pressures could significantly impact the ability of FDA to timely review and process our regulatory submissions or take other actions critical to the marketing of our products which could have a material adverse effect on our business. For example, our recently acquired product candidate dordaviprone has a target PDUFA action date of August 18, 2025. If approval of the dordaviprone NDA is granted by FDA, the approval may not happen on or prior to the target PDUFA action date, including as a result of recent reductions in FDA's workforce. Any delay in obtaining, or inability to obtain, regulatory approval of the dordaviprone NDA would delay or prevent commercialization of the resulting product and could increase our costs. As a result, the anticipated benefits of the Chimerix acquisition may not be realized fully within the expected timeframe or at all or may take longer to realize or cost more than expected, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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

The U.S. Congress, the EU, the OECD, and other government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations. As a result of the focus on the taxation of multinational corporations, the tax laws in Ireland, the U.S. and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could adversely affect us.

One example is the OECD's initiative in the area of "base erosion and profit shifting," including the 15% global minimum tax under Pillar Two. In December 2022, the EU agreed to implement this global minimum tax rate for EU member states by the start of 2024. In accordance with the EU directive, Ireland adopted legislation implementing Pillar Two on December 18, 2023, with effect from the start of 2024. Other jurisdictions in which we do business have also adopted legislation implementing Pillar Two. Pillar Two legislation could have an adverse impact on our effective tax rate, tax liabilities, and cash tax.

Further, the IRA, among other things, introduced new tax provisions, including a 15% corporate alternative minimum tax for certain large corporations, and a one percent excise tax on certain share repurchases by publicly traded corporations, including certain repurchases by specified domestic affiliates of publicly traded foreign corporations. These provisions became effective in 2023. The IRS has issued limited guidance on the corporate alternative minimum tax, the excise tax and the other tax provisions in the IRA, and much of this guidance has yet to be finalized. Final guidance under the IRA could adversely affect our tax provision, cash tax liability and effective tax rate.

The U.S. and other jurisdictions in which we operate continue to consider other changes in tax laws and regulations that apply to multinationals, including proposed legislation and guidance with respect to research and development expenditures and other guidance under the 2017 Tax Cuts and Jobs Act. On July 4, 2025, the U.S. adopted legislation that extended certain provisions of the 2017 Tax Cuts and Jobs Act, which would otherwise have expired on December 31, 2025, and introduced a number of other changes to U.S. tax laws, including immediate expensing of domestic research and experimentation expenditures. The new legislation also amended the foreign-derived intangible income provisions, increasing the effective tax rate for foreign-derived intangible income from the current rate of approximately 13% to approximately 14% and excluding research and experimentation expenditures and interest expense from the deductions allocated to gross income for purposes of the foreign derived deduction eligible income calculation. We are still evaluating the effect of the new legislation on our tax provision, cash tax liability and effective tax rate.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

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 June 30, 2025:

	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)
April 1 - April 30, 2025	—	$ —	—	$ 349,999,951
May 1 - May 31, 2025	1,141,570	$ 109.52	1,141,570	$ 224,999,972
June 1 - June 30, 2025	—	$ —	—	$ 224,999,972
Total	1,141,570	$ 109.52	1,141,570	

1. This table does not include ordinary shares that we withheld in order to satisfy tax withholding requirements in connection with the vesting and release of restricted stock units. All the ordinary shares reported in this column were purchased pursuant to our publicly announced share repurchase program.
2. Average price paid per ordinary share includes brokerage commissions.
3. On July 31, 2024, we announced that our board of directors had authorized the use of up to $500.0 million to repurchase our ordinary shares under the New Repurchase Program. Under the New Repurchase Program, which has no expiration date, we may repurchase ordinary shares from time to time by any methods and/or structures permitted by applicable law. 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 outstanding credit agreement and the indenture for our Secured Notes, corporate and regulatory requirements and market conditions. The New Repurchase Program may be modified, suspended or discontinued at any time without our prior notice. The ordinary shares reported in the table above were purchased pursuant to the New Repurchase Program. As of June 30, 2025, the remaining amount authorized for repurchases under the New Repurchase Program was $225.0 million, exclusive of any brokerage commissions.
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 the New Repurchase Program, exclusive of any brokerage commissions.

Item 6. Exhibits

Exhibit Number	Description of Document
2.1+	Transaction Agreement, dated as of February 3, 2021, by and among Jazz Pharmaceuticals UK Holdings Limited, Jazz Pharmaceuticals Public Limited Company and GW 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 February 4, 2021).
2.2+	Agreement and Plan of Merger, dated as of March 4, 2025, by and among Chimerix, Inc, Jazz Pharmaceuticals Public Limited Company, and Pinetree Acquisition Sub, Inc. (incorporated 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 5, 2025).
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).
10.1A#	License and Option Agreement, dated July 27, 2016, by and between Pfenex Inc. and Jazz Pharmaceuticals Ireland Limited.
10.1B#	Amended and Restated License and Option Agreement, dated December 18, 2017, by and between Pfenex Inc. and Jazz Pharmaceuticals Ireland Limited.
10.2†	Letter Agreement, dated as of July 30, 2025, by and between Jazz Pharmaceuticals, Inc. and Renee Gala.
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 - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

+ Certain portions of this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K.

Portions of this document have been omitted pursuant to Item 601(b)(10) of Regulations S-K because they are both not material and are the type that the Company treats as private and confidential.

† Indicates management contract or compensatory plan.

* The certification attached as Exhibit 32.1 accompanies 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: August 6, 2025

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY
(Registrant)

/s/ Bruce C. Cozadd

Bruce C. Cozadd

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

/s/ Philip L. Johnson

Philip L. Johnson

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

/s/ Patricia Carr

Patricia Carr

Senior Vice President, Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 10.1A

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Execution Version

CONFIDENTIAL

LICENSE AND OPTION AGREEMENT

This **LICENSE AND OPTION AGREEMENT** (the "**Agreement**") is entered into as of July 27, 2016 (the "**Effective Date**") by and between **PFENEX INC.**, a Delaware corporation, with its principal place of business at 10790 Roselle Street, San Diego, CA 92121 ("**Pfenex**"), and **JAZZ PHARMACEUTICALS IRELAND LIMITED**, a limited liability company incorporated under the laws of Ireland, with a registered office at Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland ("**Jazz**"). Pfenex and Jazz are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, Jazz is a specialty biopharmaceutical company with expertise in the development, marketing, and commercialization of pharmaceutical products; and

WHEREAS, Pfenex possesses certain intellectual property, materials and expertise related to its proprietary *P. fluorescens* manufacturing platform;

WHEREAS, the Parties desire to establish a collaboration regarding certain [***] products and for Jazz to receive an option to certain [***] products using Pfenex's *P. fluorescens* manufacturing platform all in accordance with the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.1 "[***] **ROFN Product**" has the meaning set forth in Section 2.5(c)(i).

1.2 "**Acquired Party**" has the meaning set forth in Section 13.7.

1.3 "**Acquiring Entity**" has the meaning set forth in Section 1.15.

1.4 "**Additional Amounts**" has the meaning set forth in Section 6.10(c).

1.5 "**Affiliate**" means, with respect to a particular Party or other entity, a person, corporation, partnership, or other entity (any, a "**Person**") that controls, is controlled by or is under common control with such Party or other entity. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Person, whether by the ownership of fifty percent (50%) or more of the voting stock of such Person, or by contract or otherwise. For clarity, a Person shall be deemed an Affiliate only for so long as this definition is satisfied with respect to such Person.

1.6 "**Agreement**" has the meaning set forth in the Preamble.

1.7 "**Alternative Product**" has the meaning set forth in Section 11.4(a)(ii)(B).

1.8 "**Assessment Materials**" has the meaning set forth in Section 2.1(a).

1.9 "**Assessment Period**" means, with respect to each HemOnc Product, a period of [***] after [***] for such HemOnc Product.

1.10 "**Bankrupt Party**" has the meaning set forth in Section 13.2(a).

1.11 "[***] **ROFN Product**" has the meaning set forth in Section 2.5(c)(ii).

1.12 "**Biosimilar Product**" has the meaning set forth in Section 7.4(a).

1.13 "**BLA**" means a Biologics License Application, as defined in Section 351(a) or (k) of the Public Health Service Act, 42 U.S.C. Section 262, as amended, and applicable regulations and guidance promulgated thereunder by the FDA or an equivalent application for Regulatory Approval outside of the United States.

1.14 "**Business Day**" means a day other than Saturday, Sunday or any day that banks in Dublin, Ireland or New York City, U.S. are required or permitted to be closed.

1.15 "**Change of Control**" of a Party means (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's business to which the subject matter of this Agreement relates, except in connection with the issuance of equity securities for financing purposes or to change the domicile of a Party (in each case (a)–(c), inclusive, such Third Party, the "**Acquiring Entity**").

1.16 "**Claims**" has the meaning set forth in Section 9.1.

1.17 "**CMC**" means the chemistry, manufacturing and controls of the Product, as specified by the FDA, or other applicable Regulatory Authorities.

1.18 "**COGS**" means, with respect to a particular Product, the fully burdened manufacturing cost in Dollars, as defined by JPP's consistent application of GAAP, of producing or obtaining supply of finished, packaged and labeled product, which cost shall include labor and material costs, quality assurance and control expenses, allocable facilities costs (e.g., insurance, water, waste, other utilities and depreciation) [***].

1.19 "**COGS Improvement**" has the meaning set forth on **Exhibit 1.19**.

1.20 "**COGS Variance**" has the meaning set forth on **Exhibit D**.

1.21 "**Combination Product**" has the meaning set forth in Section 1.90.

1.22 "**Commercialization**" means, with respect to a Product, the marketing, promotion, sale and/or distribution of such Product in the Territory. Commercialization shall include commercial activities conducted in preparation for Product launch. "**Commercialize**" has a correlative meaning.

1.23 "**Commercially Reasonable Efforts**" means, with respect to each Party's obligations under this Agreement to Develop, manufacture, or Commercialize a Product, the carrying out of such obligations or tasks with a level of efforts and resources that are consistent with the efforts and resources normally used by such Party in the performance of such activity for other pharmaceutical products, in each case owned by it or to which it has exclusive rights, at a similar stage of development or commercialization and with similar commercial and market potential as the Product, taking into account all relevant factors, including patent coverage, safety and efficacy, product profile, competitiveness of the marketplace and other products, proprietary position and profitability (including pricing and reimbursement). Without limiting the foregoing, such efforts shall include: (a) assigning responsibilities for activities for which such Party is responsible to specific employee(s) who are held accountable for the progress, monitoring and completion of such activities, (b) setting and seeking to reasonably achieve meaningful objectives for carrying out such activities, and (c) making and implementing reasonable decisions and allocating resources reasonably necessary or appropriate to advance progress with respect to and complete such objectives in an expeditious manner, in each case, consistent with the efforts and resources normally used by such Party in the performance of such activity for other pharmaceutical products, in each case owned by it or to which it has exclusive rights, at a similar stage of development or commercialization and with similar commercial and market potential as the Product, taking into account all relevant factors, including patent coverage, safety and efficacy, product profile, competitiveness of the marketplace and other products, proprietary position and profitability (including pricing and reimbursement).

1.24 "**Competing Program**" has the meaning set forth in Section 2.6(e).

1.25 "**Confidential Information**" of a Party means any and all Information of such Party that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, or electronic form. In addition, all Information disclosed by Pfenex pursuant to the Mutual Confidentiality Agreement between Pfenex and Jazz Pharmaceuticals plc ("**JPP**"), an Affiliate of Jazz, dated October 30, 2015 or the Mutual Confidentiality Agreement between Pfenex and JPP dated June 23, 2016 (collectively, the "**Confidentiality Agreements**") shall be deemed to be Pfenex's Confidential Information disclosed hereunder, and all Information disclosed by JPP pursuant to the Confidentiality Agreements shall be deemed to be Jazz's Confidential Information disclosed hereunder.

1.26 "**Confidentiality Agreements**" has the meaning set forth in Section 1.25.

1.27 "**Conjugated Protein**" has the meaning set forth in **Exhibit E**.

1.28 "**Conjugation Election**" has the meaning set forth in Section 2.1(a).

1.29 "**Control**" means, with respect to any material, Information, or intellectual property right, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement) to such material, Information, or intellectual property right and, in each case (a) and (b), has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other legally enforceable arrangement with any Third Party. Notwithstanding anything to the contrary in this Agreement, in the event of a Change of Control of a Party, (i) any subject matter owned or controlled by any Acquiring Entity (and not Controlled by such Party or its Affiliates) immediately prior to the effective date of such Change of Control and (ii) any subject matter independently developed or acquired by or on behalf of any Acquiring Entity without access to or use of any subject matter used or made available under this Agreement, in each case (i) and (ii) shall not be deemed to be Controlled by such Party or its Affiliates after the effective date of such Change of Control for purposes of this Agreement.

1.30 "**Cover**" means, with respect to a claim of a Patent and a Product, that such claim would be infringed, absent a license, by the manufacture, use, offer for sale, sale or importation of such Product (considering claims of patent applications to be issued as pending).

1.31 "**Declination Notice**" has the meaning set forth in Section 2.1(a).

1.32 "**Develop**" or "**Development**" means, with respect to a Product, all activities that relate to the development of such Product, including (a) obtaining, maintaining or expanding Regulatory Approvals for such Product, or (b) developing the ability to manufacture clinical and commercial quantities of such Product. Development includes: (i) the conduct of preclinical testing, toxicology, and clinical trials; (ii) preparation, submission, review, and development of Information for the purpose of submission to a Governmental Authority to obtain, maintain or expand Regulatory Approvals for such Product; and (iii) manufacturing process development and scale-up, bulk production, and fill/finish work associated with the supply of such Product for preclinical testing, toxicology and clinical trials, and related quality assurance and technical support activities.

1.33 "**Development Plan**" has the meaning set forth in Section 4.2(a).

1.34 "**Development Program**" has the meaning set forth in Section 4.2(a).

1.35 "**Disclosed Platform**" has the meaning set forth in Section 7.1(c).

1.36 "**Dispute**" has the meaning set forth in Section 12.1.

1.37 "**Divestiture**" has the meaning set forth in Section 2.6(e)(ii).

1.38 "**Dollar**" means a U.S. dollar, and "**$**" shall be interpreted accordingly.

1.39 "**Effective Date**" has the meaning set forth in the Preamble.

1.40 "**EMA**" means the European Medicines Agency or any successor entity.

1.41 "**EU**" or "**European Union**" means the European Union member states as of the Effective Date or as may be added or subtracted from time to time during the Term. As of the Effective Date, the European Union member states are Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. Notwithstanding the foregoing, the EU shall include the United Kingdom for purposes of this definition regardless of whether such country officially exits the EU during the Term.

1.42 "**EU Approval**" has the meaning set forth in Section 6.3(b).

1.43 "**Executive Officer**" means, with respect to Pfenex, its Chief Executive Officer, and with respect to Jazz, its Chief Executive Officer, or, in each case, a designee with senior decision-making authority.

1.44 "**Expression Feasibility Data Package**" means, with respect to each HemOnc Product, the data with respect to such HemOnc Product generated by Pfenex in the performance of the Pfenex Expression Feasibility Activities as described in **Exhibit 1.44**.

1.45 "**FD&C Act**" means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

1.46 "**FDA**" means the U.S. Food and Drug Administration or any successor entity.

1.47 "**Federal Arbitration Act**" has the meaning set forth in Section 12.2(a).

1.48 "**Field**" means the diagnosis, prevention and treatment of any and all diseases and conditions.

1.49 "**First Commercial Sale**" means, with respect to a Product, the first sale to a Third Party of such Product in a given regulatory jurisdiction after Regulatory Approval has been obtained in such jurisdiction for such Product.

1.50 "**Fused Protein**" has the meaning set forth in **Exhibit E**.

1.51 "**Fusion Election**" has the meaning set forth in Section 2.1(a).

1.52 "**GAAP**" means United States generally accepted accounting principles consistently applied.

1.53 "**GCP**" or "**Good Clinical Practices**" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

1.54 "**GLP**" or "**Good Laboratory Practices**" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

1.55 "**GMP**" or "**Good Manufacturing Practices**" means the then-current good manufacturing practices required by the FDA, as set forth in the FD&C Act and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable laws and regulations applicable to the manufacture and testing of pharmaceutical materials promulgated by other Regulatory Authorities, as they may be updated from time to time.

1.56 "**Governmental Authority**" means any multi-national, national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.57 "**Half-Life Extension Component**" means a component that may be included as part of a pharmaceutical product that has been incorporated by chemical conjugation, or by fusion with another protein or other genetic means, with the intended purpose of extending the time it takes for such pharmaceutical product to lose half of its pharmacologic activity when administered to humans.

1.58 "**HemOnc-NextGen**" has the meaning set forth in **Exhibit E**.

1.59 "**HemOnc-Pf**" has the meaning set forth in **Exhibit E**.

1.60 "**HemOnc Products**" means HemOnc-Pf and HemOnc-NextGen.

1.61 "**ICH**" means International Conference on Harmonisation.

1.62 "**IND**" means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, or (b) the equivalent application to a Governmental Authority in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

1.63 "**Indemnified Party**" has the meaning set forth in Section 9.3.

1.64 "**Indemnifying Party**" has the meaning set forth in Section 9.3.

1.65 "**Indication**" means a separately defined, well-categorized class of human disease or condition for which a separate MAA (including any extensions or supplements) may be filed with a Regulatory Authority. For clarity, if an MAA is approved for a Product in a particular Indication and patient population, a label expansion for such Product to include such Indication in a different patient population shall not be considered a separate Indication. For further clarity, all subtypes of a particular tumor type and all treatments thereof, including all lines of treatment shall be deemed the same Indication.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

1.66 "**Information**" means any data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical and clinical test data and data resulting from non-clinical studies), CMC information, stability data and other study data and procedures.

1.67 "**Invention**" shall mean any Information, process, method, composition of matter, article of manufacture, discovery or finding, patentable or otherwise, that is invented, made or generated as a result of a Party (acting solely or jointly with the other Party) exercising its rights or carrying out its obligations under this Agreement, whether directly or via its Affiliates, agents or independent contractors, including all rights, title and interest in and to the intellectual property rights therein.

1.68 "**JAMS Rules**" has the meaning set forth in Section 12.2(a).

1.69 "**Jazz**" has the meaning set forth in the Preamble.

1.70 "**Jazz Assessment Activities**" means, with respect to each HemOnc Product, such testing of the Assessment Materials as performed by Jazz for purposes of evaluating whether to terminate its license hereunder with respect to such HemOnc Product.

1.71 "**Jazz HemOnc-NextGen Data**" has the meaning set forth in Section 11.4(b)(i).

1.72 "**Jazz HemOnc-Pf Data**" has the meaning set forth in Section 11.4(a)(i).

1.73 "**Jazz Extension IP**" means the data, technical information, and Patents (a) Controlled by Jazz or its Affiliates as of the Effective Date or any time during the Term, and (b) relating to or Covering the Half-Life Extension Component for HemOnc-NextGen selected by Jazz, in its sole discretion. For clarity, Jazz Extension IP includes Jazz Improvements.

1.74 "**Jazz Improvements**" has the meaning set forth in Section 7.1(d).

1.75 "**Jazz Indemnitees**" has the meaning set forth in Section 9.1.

1.76 "**Jazz Retained Data Rights**" has the meaning set forth in Section 11.4(a)(i).

1.77 "**Jazz Sole Patents**" has the meaning set forth in Section 7.3(a).

1.78 "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 3.1(a).

1.79 "**Joint Inventions**" has the meaning set forth in Section 7.1(b).

1.80 "**Joint Management Team**" or "**JMT**" has the meaning set forth in Section 3.2(a).

1.81 "**Joint Patents**" has the meaning set forth in Section 7.1(b).

1.82 "**JPP**" has the meaning set forth in Section 1.25.

1.83 "**Laws**" means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

1.84 "**Lead Indication**" has the meaning set forth in **Exhibit E**.

1.85 "**Major European Country**" means any one of the United Kingdom, Germany, France, Italy and Spain.

1.86 "**Manufacturing Process Transfer**" has the meaning set forth in Section 4.7(b).

1.87 "**Manufacturing Process Transfer Criteria**" has the meaning set forth in Section 4.7(a).

1.88 "**Marketing Authorization Application**" or "**MAA**" means an application to the appropriate Regulatory Authority for approval to market a Product (but excluding Pricing Approval) in any particular jurisdiction, including a BLA.

1.89 "**Marketing Partner**" means a Third Party that has received from Jazz or its Affiliate a sublicense, under Section 2.1(d), of the rights granted to Jazz either: (a) to develop and sell a Product, provided that Jazz or its Affiliates receives payment based upon sales of such Product by or on behalf of such Third Party (e.g., such Third Party pays Jazz or its Affiliates a royalty, milestone, profit share or other payment with respect to the sale of such Product by or on behalf of such Third Party); or (b) to make (to the extent Jazz is so permitted to make or sublicense such right to a Third Party to make as described in Section 2.1(d)) Product and sell Product.

1.90 "**Net Sales**" means, with respect to any Product, the gross amounts invoiced by Jazz and its Affiliates, sublicensees and Marketing Partners (each, a "**Selling Party**") for sales of such Product in the Field to unaffiliated Third Parties, less the following deductions provided to unaffiliated entities to the extent actually taken, paid, accrued, allowed, included or allocated:

(a) cash, trade, quantity or other discounts, coupons, or co-pay expenditures, charge-back payments, and rebates to trade customers, retail pharmacy chains, wholesalers, managed health care organizations, pharmaceutical benefit managers, insurers, group purchasing organizations and national, state, or local government, including any Medicaid or other rebate payments or other price reductions provided based on sales to any Governmental Authority or Regulatory Authority in respect of any state or federal Medicare, Medicaid or similar programs;

(b) credits, rebates or allowances related to prompt payment or on account of damaged goods, rejections or returns of Products, including in connection with recalls, and the actual amount of any write-offs for bad debt (provided that any amount subsequently recovered will be added back as Net Sales);

(c) reasonable distributors', wholesalers' and dispensing fees in connection with Products;

(d) freight, postage, shipping, transportation and insurance charges; and

(e) taxes (other than income taxes), duties, tariffs, mandated contributions or other governmental charges levied on the manufacture or sale of Products, including VAT, excise taxes and sales taxes.

Notwithstanding the foregoing, sales among Selling Parties shall not be included in the computation of Net Sales hereunder (except where such Selling Party is an end user). Net Sales shall be accounted for in accordance with the Selling Party's standard practices in the relevant country in the Territory, applied consistently with respect to all of such Selling Party's products in such country. For clarity, the gross invoiced price for sale of a Product to any wholesaler or distributor (i.e., a Third Party to whom a Selling Party sells units of such Product for resale in a particular market or country) shall be included in Net Sales as sales of such Selling Party, but amounts received by such a wholesaler or distributor for subsequent sale of the Product shall not be included in Net Sales.

Notwithstanding the foregoing, "Net Sales" shall not include any amounts invoiced for sales of Products supplied for use in clinical trials of Products, or under early access, compassionate use, named patient, indigent access, patient assistance or other reduced pricing programs, in each case provided that the gross amount invoiced is at or below the Selling Party's COGS for the applicable Product.

If the Product (a) contains any active pharmaceutical ingredient in addition to any active pharmaceutical ingredient specified in the applicable Product definition, or (b) is sold in combination with another pharmaceutical product that contains any active pharmaceutical ingredient other than [***], in each case (a) and (b) for a single price, such Product shall be referred to as a "**Combination Product**", and the other active pharmaceutical ingredient(s) in clause (a) and the other pharmaceutical product(s) in clause (b) are each referred to as the "**Other Product(s)**".

Net Sales for a Combination Product in a particular country shall be calculated as follows:

(i) If the Product and Other Product(s) each are sold separately in such country, Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction A/(A+B), where A is the price in such country of the Product sold separately, and B is the (sum of the) price(s) in such country of the Other Product(s) sold separately.

(ii) If the Product, but not the Other Product(s), is sold separately in such country, Net Sales will be calculated by multiplying the total Net Sales (as described above) of such Combination Product by the fraction A/C, where A is the price in such country of the Product sold separately, and C is the price in such country of the Combination Product.

(iii) If the Other Product(s), but not the Product, is sold separately in such country, Net Sales will be calculated by multiplying the total Net Sales (as described above) of such Combination Product by the fraction 1-B/C, where B is the (sum of the) price(s) in such country of the Other Product(s) and C is the price in such country of the Combination Product.

(iv) If the Product and the Other Product(s) are not sold separately in such country, Net Sales shall be determined by mutual written agreement of the Parties based on the relative value of such Product and such Other Product(s).

1.91 "**Option**" has the meaning set forth in Section 2.4(a).

1.92 "**Option Data Package 1**" means the data and materials generated in the performance of Pfenex's Development of the Pegaspargase Product as described in **Exhibit 1.92**.

1.93 "**Option Data Package 2**" means [***].

1.94 "**Option Exercise**" means the entry by the Parties into an Option Exercise Agreement pursuant to Section 2.4(d).

1.95 "**Option Exercise Agreement**" has the meaning set forth in Section 2.4(d).

1.96 "**Option Exercise Notice**" has the meaning set forth in Section 2.4(c).

1.97 "**Other Product(s)**" has the meaning set forth in Section 1.90.

1.98 "**Party**" or "**Parties**" has the meaning set forth in the Preamble.

1.99 "**Patents**" means (a) pending patent applications, issued patents, utility models and designs anywhere in the world; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; (c) patents that issue with respect to any of the foregoing applications; and (d) extensions, renewals or restorations of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

1.100 "**Pegaspargase Product**" means the product described on **Exhibit 1.100** as may be agreed to be amended by the Parties.

1.101 "**Person**" has the meaning set forth in Section 1.5.

1.102 "**Pfenex**" has the meaning set forth in the Preamble.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

1.103 "**Pfenex Expression Feasibility Activities**" means, with respect to each HemOnc Product, the protein expression activities performed by Pfenex as set forth in the Development Plan for such HemOnc Product.

1.104 "**Pfenex General Product Patent**" means a Pfenex Sole Patent that (a) claims an Invention and (b) is not a Pfenex Product- Specific Patent.

1.105 "**Pfenex Improvements**" has the meaning set forth in Section 7.1(c).

1.106 "**Pfenex Indemnitees**" has the meaning set forth in Section 9.2.

1.107 "**Pfenex IP**" means the Pfenex Know-How and Pfenex Patents.

1.108 "**Pfenex Know-How**" means all data and technical information (a) Controlled by Pfenex or its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize any HemOnc Product. Pfenex Know-How includes Pfenex Improvements, Sole Inventions owned by Pfenex, and Pfenex's interest in Joint Inventions, in each case to the extent that the foregoing are necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize any HemOnc Product.

1.109 "**Pfenex Patent**" means any Patent (a) Controlled by Pfenex or its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize any HemOnc Product, including any and all Patents claiming any Pfenex Know-How, Patents listed on **Exhibit A**, Patents claiming Pfenex Improvements and Sole Inventions owned by Pfenex, and Pfenex's interest in any Joint Patents, in each case to the extent that the foregoing are necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize any HemOnc Product.

1.110 "**Pfenex Pegaspargase Product IP**" means the Pfenex Pegaspargase Product Know-How and Pfenex Pegaspargase Product Patents.

1.111 "**Pfenex Pegaspargase Product Know-How**" means all data and technical information (a) Controlled by Pfenex or its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize the Pegaspargase Product. Pfenex Know-How includes Pfenex Improvements, Sole Inventions owned by Pfenex, and Pfenex's interest in Joint Inventions, in each case to the extent that the foregoing are necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize the Pegaspargase Product.

1.112 "**Pfenex Pegaspargase Product Patent**" means any Patent (a) Controlled by Pfenex or its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize the Pegaspargase Product, including any and all Patents claiming any Pfenex Pegaspargase Product Know-How, Patents listed on **Exhibit A**, Patents claiming Pfenex Improvements and Sole Inventions owned by Pfenex, and Pfenex's interest in any Joint Patents, in each case to the extent that the foregoing are necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize the Pegaspargase Product.

1.113 "**Pfenex Product-Specific Patent**" means a Pfenex Sole Patent that claims only a Product (including the composition of matter, manufacture or use thereof) and no other subject matter.

1.114 "**Pfenex ROFN Product IP**" means, with respect to a particular ROFN Product, the Pfenex ROFN Product Know-How and Pfenex ROFN Product Patents.

1.115 "**Pfenex ROFN Product Know-How**" means, with respect to a particular ROFN Product, all data and technical information (a) Controlled by Pfenex or its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or useful to develop, manufacture, use, offer for sale, sell, import or otherwise commercialize such ROFN Product. Pfenex Know-How includes Pfenex Improvements, Sole Inventions owned by Pfenex, and Pfenex's interest in Joint Inventions, in each case to the extent that the foregoing are necessary or useful to develop, manufacture, use, offer for sale, sell, import or otherwise commercialize such ROFN Product.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

1.116 "**Pfenex ROFN Product Patent**" means, with respect to a particular ROFN Product, any Patent (a) Controlled by Pfenex or its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or useful to develop, manufacture, use, offer for sale, sell, import or otherwise commercialize such ROFN Product, including any and all Patents claiming any Pfenex ROFN Product Know-How, Patents listed on **Exhibit A**, Patents claiming Pfenex Improvements and Sole Inventions owned by Pfenex, and Pfenex's interest in any Joint Patents, in each case to the extent that the foregoing are necessary or useful to develop, manufacture, use, offer for sale, sell, import or otherwise commercialize such ROFN Product.

1.117 "**Pfenex Sole Patent**" means a Pfenex Patent that is not a Joint Patent.

1.118 "**Post-Primary Recovery Inventions**" has the meaning set forth in Section 7.1(g).

1.119 "**Pricing Approval**" means such governmental approval, agreement, determination or decision establishing prices for a Product that can be charged and/or reimbursed in regulatory jurisdictions where it is required by applicable Laws or customary for the applicable Governmental Authorities to approve or determine the price and/or reimbursement of pharmaceutical products prior to the commencement of commercial sales of such Product in the applicable regulatory jurisdiction.

1.120 "**Product**" means HemOnc-Pf, HemOnc-NextGen, and/or the Pegaspargase Product, excluding (a) any such Product in the event that this Agreement is terminated with respect to such Product and (b) the Pegaspargase Product in the event that the Option expires without Option Exercise.

1.121 "**Product A**" has the meaning set forth in **Exhibit E**.

1.122 "**Product B**" has the meaning set forth in **Exhibit E**.

1.123 "**Product Infringement**" has the meaning set forth in Section 7.4(a).

1.124 "**Product Marks**" has the meaning set forth in Section 7.8.

1.125 "**Production Techniques Patents**" has the meaning set forth in the Technology Licensing Agreement among Dow Global Technologies Inc., The Dow Chemical Company and Pfenex dated November 30, 2009.

1.126 "**Proposals**" has the meaning set forth in Section 12.2(b).

1.127 "[***]" has the meaning set forth in **Exhibit E**.

1.128 "[***]" has the meaning set forth in **Exhibit E**.

1.129 "[***]" has the meaning set forth in **Exhibit E**.

1.130 "**Regulatory Approval**" means all approvals, including, if applicable, Pricing Approvals, that are necessary for the commercial sale of a Product in the Field in a given country or regulatory jurisdiction.

1.131 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

1.132 "**Regulatory Materials**" means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, manufacture, market, sell or otherwise Commercialize a Product in a particular country or jurisdiction, including INDs.

1.133 "**ROFN**" has the meaning set forth in Section 2.5(a).

1.134 "**ROFN Data Package**" means, with respect to a particular ROFN Product, (a) the data that [***] for such ROFN Product and (b) any additional data that [***], prior to filing an IND for such ROFN Product, to further develop and commercialize such ROFN Product.

1.135 "**ROFN Exercise**" means, with respect to a particular ROFN Product, the entry by the Parties into a ROFN Exercise Agreement pursuant to Section 2.5(c).

1.136 "**ROFN Exercise Agreement**" has the meaning set forth in Section 2.5(c).

1.137 "**ROFN Exercise Notice**" has the meaning set forth in Section 2.5(a).

1.138 "**ROFN Product**" means a product (other than a Product) that contains [***] and for which Pfenex conducts any research or development activities, excluding any such product comprising a Competing Program.

1.139 "**ROFN Third Party Notice**" has the meaning set forth in Section 2.5(c)(ii).

1.140 "**Royalty Term**" has the meaning set forth in Section 6.5(b).

1.141 "**Selling Party**" has the meaning set forth in Section 1.90.

1.142 "**Sole Inventions**" has the meaning set forth in Section 7.1(a).

1.143 "**Successful Expression**" has the meaning set forth on **Exhibit 1.143**.

1.144 "**Term**" has the meaning set forth in Section 11.1.

1.145 "**Territory**" means all countries of the world.

1.146 "**Third Party**" means any entity other than Pfenex or Jazz or an Affiliate thereof.

1.147 "**Third Party Agreements**" means the agreements listed on **Exhibit 1.147**.

1.148 "**Title 11**" has the meaning set forth in Section 13.2(a).

1.149 "**United States**" or "**U.S.**" means the United States of America, including all possessions and territories thereof.

1.150 "**Upfront Payments**" has the meaning set forth in Section 6.1.

1.151 "**VAT**" means value-added tax, consumption taxes and other similar taxes required by Law to be disclosed on an invoice.

1.152 "**Withholding Tax Action**" has the meaning set forth in Section 6.10(c).

1.153 "**Working Group**" has the meaning set forth in Section 3.4.

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ARTICLE 2
LICENSES AND EXCLUSIVITY

2.1 License to Jazz for HemOnc Products.

(a) Election for HemOnc Products. Pfenex shall use Commercially Reasonable Efforts to perform the Pfenex Expression Feasibility Activities for each of HemOnc-Pf and the Fused Protein. Pfenex shall promptly notify Jazz in writing if Pfenex reasonably believes, after using Commercially Reasonable Efforts, that it will not be able to achieve Successful Expression for either HemOnc-Pf or the Fused Protein. Promptly following completion of the Pfenex Expression Feasibility Activities for each HemOnc Product, Pfenex shall promptly provide Jazz with the Expression Feasibility Data Package for such HemOnc Product. Pfenex shall, within ten (10) Business Days following Jazz's written request, provide Jazz with any additional information reasonably requested by Jazz with respect to the Expression Feasibility Data Package (provided that such additional information is in Pfenex's possession and does not require the expenditure of additional funds or the performance of additional studies to generate), or Pfenex shall notify Jazz in writing during such period that Pfenex does not have such additional information in its possession, as the case may be. Following the mutual agreement of the Parties with respect to the achievement of Successful Expression for each HemOnc Product, Pfenex shall provide Jazz with the amount of such HemOnc Product set forth in **Exhibit 1.143** meeting the specifications as described in **Exhibit 1.143** (with respect to each HemOnc Product, the "**Assessment Materials**"). The data contained in the Expression Feasibility Data Package shall be the Confidential Information of Jazz, and Jazz shall have all right, title, and interest in and to the data contained in the Expression Feasibility Data Package and the Assessment Materials. Notwithstanding anything to the contrary in this Agreement, as between the Parties, Pfenex shall retain all right, title and interest in and to any Pfenex IP (including any Information disclosed by Pfenex to Jazz in connection with such Assessment Materials or otherwise under this Agreement) and all Pfenex Improvements assigned to Pfenex pursuant to Section 7.1(c). Commencing upon receipt of the Assessment Materials for each HemOnc Product, Jazz shall use Commercially Reasonable Efforts to conduct the Jazz Assessment Activities with respect to such HemOnc Product. Prior to expiration of the Assessment Period for the applicable HemOnc Product, Jazz may provide Pfenex with written notice that Jazz elects to terminate its license hereunder with respect to such HemOnc Product (with respect to such HemOnc Product, the "**Declination Notice**"). If Jazz provides Pfenex with a Declination Notice for a HemOnc Product, then Jazz shall be deemed to have terminated this Agreement with respect to such HemOnc Product pursuant to Section 11.2, and such termination shall be deemed to be effective as of immediately prior to expiration of the applicable Assessment Period for purposes of Section 11.4. If Jazz does not provide Pfenex with a Declination Notice during the Assessment Period with respect to either HemOnc Product, Jazz will retain its license hereunder and be obligated to commence its obligations with respect to such HemOnc Product, and such HemOnc Product will remain a Product for the purposes of this Agreement. [***].

(b) License to Jazz. Pfenex hereby grants Jazz an exclusive (even as to Pfenex except as provided in Section 2.1(c) below), royalty-bearing and sublicenseable (subject to Section 2.1(d)) license, under the Pfenex IP to research, Develop, make, have made, use, sell, have sold, offer for sale, import, and otherwise Commercialize the HemOnc Products in the Field in the Territory. Notwithstanding anything to the contrary in this Agreement, all licenses granted to Jazz pursuant to this Agreement under the Production Techniques Patents shall be non-exclusive. Pfenex shall not grant a license under the Production Techniques Patents to any Third Parties to research, Develop, make, have made, use, sell, have sold, offer for sale, import, or otherwise Commercialize any HemOnc Product in the Field in the Territory.

(c) Pfenex Retained Rights. Notwithstanding the rights granted to Jazz in Section 2.1(b), Pfenex retains the non-exclusive right to practice the Pfenex IP in the Territory solely as necessary to (i) conduct the activities assigned to Pfenex under the Development Plans in accordance with the terms of this Agreement; and (ii) manufacture the HemOnc Products solely for supply to Jazz, its Affiliates or its/their sublicensees and Marketing Partners.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential..

(d) Sublicenses. Jazz shall have the right to grant sublicenses through multiple tiers, under any or all of the rights granted in Section 2.1(b), to its Affiliates and/or to Third Parties. Each agreement in which Jazz grants a sublicense under the Pfenex IP shall be consistent with the terms and conditions of this Agreement relevant to such sublicense. Jazz shall be liable to Pfenex for the performance of its direct and indirect sublicensees, including their compliance with the applicable provisions of this Agreement. Jazz shall ensure that the efforts of each Third Party sublicensee to Develop and Commercialize a Product shall be at least equivalent to Jazz's Commercially Reasonable Efforts in accordance with Sections 4.4 and 5.2.

2.2 License to Pfenex. Effective on commencement of the Pfenex Expression Feasibility Activities for HemOnc-NextGen, Jazz shall, and hereby does, grant to Pfenex a non-exclusive, royalty-free, non-sublicenseable and non-transferable license or sublicense, under the Jazz Extension IP, solely as necessary (i) to conduct the Pfenex activities for HemOnc-NextGen as specified in the Development Plan for such Product, and (ii) subject to the Parties' agreement in accordance with Section 4.7, to manufacture HemOnc- NextGen for supply to Jazz or its designees. Jazz shall disclose to Pfenex the potential Half-Life Extension Component(s) within the Jazz Extension IP (and any changes thereto) to be evaluated and/or used in the Development of HemOnc-NextGen under this Agreement to the extent necessary for Pfenex to perform such activities.

2.3 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party. All rights not otherwise expressly granted hereunder by a Party shall be retained.

2.4 Option for Pegaspargase Product.

(a) Option Grant. Pfenex hereby grants Jazz an exclusive option (the "**Option**") to obtain an exclusive, sublicenseable (through multiple tiers) license from Pfenex under the Pfenex Pegaspargase Product IP to Develop, make, have made, use, sell, have sold, offer for sale and import and otherwise Commercialize the Pegaspargase Product in the Field in the Territory, subject to payment of such amounts as may be agreed in any Option Exercise Agreement. The foregoing license shall permit Pfenex to retain the right to perform any Development or manufacturing activities that the Parties agree to allocate to Pfenex in the Option Exercise Agreement.

(b) Development of Pegaspargase Product. Pfenex shall Develop the Pegaspargase Product only in accordance with the mutually agreed Development Plan for such Product and with a primary objective for the Pegaspargase Product to have enzyme activity comparable to that of Oncaspar®. Pfenex shall keep Jazz informed of its Development of the Pegaspargase Product through the JDC or more frequently upon Jazz's reasonable request, including the timeline, data and results of such Development activities. Pfenex shall notify Jazz through the JDC if Pfenex proposes to amend the then-current Development Plan for the Pegaspargase Product. Promptly following completion of the corresponding activities under the Development Plan for the Pegaspargase Product, Pfenex shall provide Jazz with Option Data Package 1 and, if Jazz has not previously delivered to Pfenex an Option Exercise Notice or if Jazz delivered an Option Exercise Notice but the Parties were unable to negotiate and enter into an Option Exercise Agreement pursuant to
Section 2.4(d), Option Data Package 2. Pfenex shall, within ten (10) Business Days following Jazz's written request, provide Jazz with any additional information reasonably requested by Jazz with respect to Option Data Package 1 or Option Data Package 2, as applicable (provided that such additional information is in Pfenex's possession and does not require the expenditure of additional funds or the performance of additional studies to generate), or Pfenex shall notify Jazz in writing during such period that Pfenex does not have such additional information in its possession, as the case may be.

(c) Option Exercise. Jazz may exercise the Option by providing written notice (an "**Option Exercise Notice**") to Pfenex either:

(i) during the twenty-five (25) Business Day period commencing upon Jazz's receipt of Option Data Package 1; or

(ii) to the extent that an Option Exercise Notice has not previously been delivered by Jazz to Pfenex in connection with Option Data Package 1 or if Jazz delivered an Option Exercise Notice but the Parties were unable to negotiate and enter into an Option Exercise Agreement pursuant to Section 2.4(d), during the twenty-five (25) Business Day period commencing upon Jazz's receipt of Option Data Package 2.

If Jazz does not provide an Option Exercise Notice before the expiration of the period referenced in subsection (ii) above, then the Option shall lapse for the Pegaspargase Product and this Agreement shall be deemed terminated with respect to the Pegaspargase Product, and Pfenex may decide, in its sole discretion, whether to terminate or continue the Development and Commercialization of the Pegaspargase Product, itself or in collaboration with one or more Third Parties, and the terms of Section 2.6(c)(iii) shall apply with respect to such Product.

(d) Negotiation. Following Jazz's delivery of an Option Exercise Notice, the Parties shall use good faith efforts to negotiate the terms and conditions of a definitive agreement regarding the Pegaspargase Product (an "**Option Exercise Agreement**") on an exclusive basis, meaning that Pfenex and its representatives shall not engage in discussions with any Third Party regarding a potential grant of rights to such Third Party with respect to the Pegaspargase Product during the negotiation period. The terms of such Option Exercise Agreement shall be commercially reasonable and all applicable non-financial terms and conditions shall be substantially the same as those in this Agreement, including decision-making, diligence, exclusivity (as applicable to the Pegaspargase Product), development, commercialization, manufacture, rights and obligations of the Parties, risk-allocation, intellectual property-related matters, dispute resolution, and general agreement structure, but excluding any rights of first negotiation or other rights except solely with respect to the Pegaspargase Product. Notwithstanding the foregoing, under the Option Exercise Agreement, Pfenex may opt-in to contribute to the Development costs of the Pegaspargase Product, and upon such opt-in, shall be responsible for between [***] and [***] of the Development costs in Pfenex's discretion. The Option Exercise Agreement will also set forth usual and customary economic terms similar to those of this Agreement, including an upfront payment, clinical developmental and commercial milestone payments, and royalty payments, which payments shall take into account Pfenex's level of contribution to the Development costs of the Pegaspargase Product. Without limiting the foregoing, the economic terms of the Option Exercise Agreement will reflect the level of development or commercial funding and risk assumed by each Party (taking into account Pfenex's investment and risk prior to the Option Exercise Notice) and include the period over which royalties would be paid, as well as applicable deductions from royalty payments based upon royalty stacking for third party intellectual property (substantially the same as Section 6.5(c) herein) and generic competition.

(e) If the Parties are unable to reach agreement upon and do not enter into a mutually acceptable Option Exercise Agreement within three (3) months from Jazz's delivery of the Option Exercise Notice, then either Party shall have the right to refer the matter for at least one in-person meeting (or telephone call if an in-person meeting is impractical) between the Parties' respective Executive Officers. If the Parties are unable to reach mutual agreement on the terms of the Option Exercise Agreement within such three (3)-month period, Jazz may have the terms and conditions of the Option Exercise Agreement determined by baseball arbitration in accordance with Section 12.2(b), and the Parties shall promptly enter into the Option Exercise Agreement on such terms decided by such arbitration; provided that Jazz initiates such arbitration within sixty (60) days after such three (3)-month negotiation period. With respect to the arbitration process, the Parties shall work with the arbitrator, who will determine a reasonable framework for resolving the issues in dispute between the Parties. This framework shall address a means to evaluate the overall economic value proposed by each party, the relative investments and risks assumed by each Party, the underlying assumptions in valuation models and the time-weighted allocation of overall economic value through the combination of milestone and royalty payments.

2.5 ROFN Products.

(a) ROFN. With respect to each ROFN Product, Pfenex hereby grants Jazz an exclusive right of first negotiation (the "**ROFN**") to obtain an exclusive, sublicenseable (through multiple tiers) license from Pfenex under the Pfenex ROFN Product IP for such ROFN Product to Develop, make, have made, use, sell, have sold, offer for sale and import and otherwise Commercialize such ROFN Product in the Field in the Territory under a definitive agreement as negotiated by the Parties pursuant to Section 2.5(c) for such ROFN Product. Jazz shall have the right to exercise the ROFN for each ROFN Product by delivery of written notice to Pfenex (a "**ROFN Exercise Notice**") within sixty (60) days of Jazz's receipt of the ROFN Data Package for such ROFN Product in accordance with the terms of this Section 2.5. If Jazz does not provide a ROFN Exercise Notice to Pfenex within sixty (60) days after Jazz's receipt of the applicable ROFN Data Package, then Jazz's ROFN shall lapse only with respect to such ROFN Product.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

(b) ROFN Data Package. Pfenex shall keep Jazz reasonably informed of material research and development activities with respect to each ROFN Product through the regular meetings of the JDC, including by providing summaries in reasonable detail of any material data generated in connection with such activities. Following the completion of IND-enabling toxicology studies for a ROFN Product and in all events prior to the filing of an IND for such ROFN Product, Pfenex shall provide to Jazz the ROFN Data Package for such ROFN Product. Pfenex shall, within ten (10) Business Days following Jazz's written request, provide Jazz with any additional information reasonably requested by Jazz with respect to such ROFN Data Package (provided that such additional information is in Pfenex's possession and does not require the expenditure of additional funds or the performance of additional studies to generate), or Pfenex shall notify Jazz in writing during such period that Pfenex does not have such additional information in its possession, as the case may be.

(c) Negotiation. Following Jazz's delivery of a ROFN Exercise Notice for a particular ROFN Product, the Parties shall use good faith efforts to negotiate the terms and conditions of a definitive agreement regarding the ROFN Product (a "**ROFN Exercise Agreement**") on an exclusive basis, meaning that Pfenex and its representatives shall not engage in discussions with any Third Party regarding a potential grant of rights to such Third Party with respect to such ROFN Product during the negotiation period. The terms of such ROFN Exercise Agreement shall be commercially reasonable and provide usual and customary terms for such arrangements. If the Parties are unable to reach agreement upon and do not enter into a mutually acceptable ROFN Exercise Agreement within three (3) months from Jazz's delivery of the applicable ROFN Exercise Notice, then the Parties shall refer the matter for at least one in-person meeting (or telephone call if an in-person meeting is impractical) between the Parties' respective Executive Officers.

(i) With respect to any ROFN Product [***] (in each case, prior to the effect of any Half-Life Extension Component) (a "[***] **ROFN Product**"), if the Parties are unable to reach mutual agreement on the terms of the ROFN Exercise Agreement within the three (3)-month period, Jazz may have the terms of the ROFN Exercise Agreement determined by baseball arbitration in accordance with Section 12.2(b), and the Parties shall promptly execute the ROFN Exercise Agreement on terms and conditions decided by such arbitration; provided that Jazz initiates such arbitration within sixty (60) days after such three (3)-month negotiation period. The arbitrator shall determine the terms and conditions of such ROFN Exercise Agreement generally taking into consideration the factors described in Section 2.4(d) for the Option Exercise Agreement.

(ii) With respect to any ROFN Product [***] (in each case, prior to the effect of any Half-Life Extension Component) (a "[***] **ROFN Product**"), if the Parties are unable to reach mutual agreement on the terms of the ROFN Exercise Agreement within the three (3)-month period, then the ROFN shall lapse for such [***] ROFN Product, and Pfenex may decide, in its sole discretion, whether to terminate or continue the development and commercialization of such [***] ROFN Product, itself or in collaboration with one or more Third Parties; *provided* that Pfenex shall notify Jazz within thirty (30) days after a Third Party first communicates in writing to Pfenex the general terms applicable to the development and commercialization of (or granting an option to develop and commercialize) such [***] ROFN Product as contained in a term sheet or proposed definitive agreement, [***]. Jazz further acknowledges and agrees that Pfenex has no obligation to conduct or continue any research or development of any ROFN Product.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

2.6 Exclusivity.

(a) Pfenex. Subject to the terms of this Section 2.6, during the Term, Pfenex shall not research, develop, manufacture or commercialize, itself or with or through any Affiliate or Third Party (including by performing any services on a contract basis or activities on a Third Party product), any product containing [***] except for (i) the manufacture of HemOnc Products for supply to Jazz and its Affiliates under this Agreement; (ii) the Development of the Pegaspargase Product under the corresponding Development Plan and any activities agreed to be conducted by Pfenex for such Pegaspargase Product under any Option Exercise Agreement; (iii) the development of the applicable ROFN Product for purposes of developing the ROFN Data Package for such ROFN Product; (iv) if the Parties enter into a ROFN Exercise Agreement for a particular ROFN Product, the manufacture of such ROFN Product for supply to Jazz and its Affiliates to the extent set forth in the applicable ROFN Exercise Agreement; and (v) as provided in Sections 2.6(d)(i) and 2.6(e) below.

(b) Jazz. Subject to the terms of this Section 2.6, from and after the expiration of the last Assessment Period and thereafter during the Term, Jazz shall not research, develop, manufacture or commercialize, itself or with or through any Affiliate or Third Party (including by performing any services on a contract basis or activities on a Third Party product), any product containing [***] for such product; (iii) Development, manufacture and Commercialization of HemOnc-Pf under this Agreement, HemOnc-NextGen under this Agreement, if Jazz exercises the Option, the Pegaspargase Product in accordance with the Option Exercise Agreement, or if Jazz exercises its ROFN for a particular ROFN Product, such ROFN Product in accordance with the applicable ROFN Exercise Agreement and (iv) as provided in subsection(e) below.

(c) Termination of Exclusivity. The exclusivity obligations set forth in Section 2.6(a) and (b) shall terminate as follows:

(i) If this Agreement is terminated with respect to HemOnc-Pf, the exclusivity obligations set forth in Section 2.6(a) and (b) shall thereafter no longer apply with respect to products containing [***].

(ii) If this Agreement is terminated with respect to HemOnc-NextGen, the exclusivity obligations set forth in Section 2.6(a) and (b) shall thereafter no longer apply with respect to products containing [***].

(iii) If either this Agreement is terminated with respect to the Pegaspargase Product or the Option expires without Option Exercise, the exclusivity obligations set forth in Section 2.6(a) and (b) shall no longer apply with respect to products containing or comprising [***]; provided that the ROFN in Section 2.5 shall continue to apply.

For clarity, clauses (i), (ii) and (iii) above are cumulative (i.e., more than one clause may apply).

(d) ROFN Products.

(i) In the event that, with respect to a particular [***] ROFN Product, Jazz declines its ROFN, Jazz's ROFN expires without delivery by Jazz to Pfenex of a ROFN Exercise Notice or the Parties do not enter into a ROFN Exercise Agreement for such ROFN Product in accordance with the terms of Section 2.5, then Sections 2.6(a) shall no longer apply to such ROFN Product. Pfenex may not file an IND for a [***] ROFN Product until Jazz declines its ROFN, Jazz's ROFN expires without delivery by Jazz to Pfenex of a ROFN Exercise Notice, or the Parties fail to enter into a ROFN Exercise Agreement for such ROFN Product in accordance with the terms of Section 2.5.

(ii) Pfenex's obligations under Section 2.6(a) shall continue to apply to any [***] ROFN Product, regardless of whether Jazz declines its ROFN, Jazz's ROFN expires without delivery by Jazz to Pfenex of a ROFN Exercise Notice, or the Parties fail to enter into a definitive ROFN Exercise Agreement.

(e) Acquisition of Competing Product. In the event that a Third Party becomes an Affiliate of a Party after the Effective Date through merger, acquisition, consolidation or other similar transaction, and as of the closing date of such transaction, such Third Party is engaged in the research, development, manufacture or commercialization of a product that, if conducted by such Party, would cause such Party to be in breach of its exclusivity obligations set forth above (a "**Competing Program**"), then:

(i) if such transaction results in a Change of Control of such Party, then such new Affiliate shall have the right to continue such Competing Program and such continuation shall not constitute a breach of such Party's exclusivity obligations set forth in Section 2.6(a) or 2.6(b), respectively; provided that such new Affiliate conducts such Competing Program independently of the activities of this Agreement and does not use any of the other Party's intellectual property rights or Confidential Information (except as may be separately licensed by such other Party to such new Affiliate) in the conduct of such Competing Program; and

(ii) if such transaction does not result in a Change of Control of such Party, then such Party and its new Affiliate shall have twelve (12) months from the closing date of such transaction to wind down or complete the divestiture of such Competing Program, and its new Affiliate's conduct of such Competing Program during such twelve (12)-month period shall not be deemed a breach of such Party's exclusivity obligations set forth above; provided that such new Affiliate conducts such Competing Program during such twelve (12)-month period independently of the activities of this Agreement and does not use any of the other Party's intellectual property or Confidential Information (except as may be separately licensed by such other Party to such new Affiliate) in the conduct of such Competing Program. "**Divestiture**", as used in this Section 2.6(e)(ii), means the sale or transfer of rights to the Competing Program to a Third Party without receiving a continuing share of profit, royalty payment or other economic interest in the success of such Competing Program.

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ARTICLE 3
GOVERNANCE

3.1 Joint Development Committee and Joint Management Team and.

(a) Formation and Role. Promptly, and in any event within thirty (30) days after the Effective Date, the Parties shall establish a joint development committee (the "**Joint Development Committee**" or "**JDC**") and such JDC will:

(i) coordinate the activities of the Parties under the Development Plans, including facilitating information exchange and discussions between the Parties with respect to the Development of Products, the progress and results (whether preliminary or final) under the Development Plans and ROFN Products;

(ii) review and discuss any proposed amendments or revisions to the Development Plans;

(iii) review and discuss any cost to be shared by the Parties;

(iv) oversee all activities relating to the manufacturing-related activities, including Product supply, process development/optimization and any related procedures;

(v) oversee technology transfer from Pfenex to Jazz's Third Party manufacturer, if applicable;

(vi) establish such Working Groups as it deems necessary to achieve the objectives and intent of this Agreement; and

(vii) perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as agreed by the Parties in writing.

It is the expectation of the Parties that the JDC will set forth the general principles and strategies upon which the Parties will perform their activities under the Development Plans. The JDC shall have only the powers expressly assigned to it in this Section 3.1 and all other matters are expressly excluded. In no event shall the JDC have the right to amend, modify, or waive compliance with this Agreement.

(b) Members. Each Party shall initially appoint up to three (3) representatives to the JDC. Each Party may change the number of its representatives and may replace its representatives at any time upon written notice to the other Party; provided that neither Party shall have more than three (3) representatives in the JDC and each representative shall be an officer or employee of the applicable Party or its Affiliate having sufficient experience and responsibility within such Party to make decisions arising within the scope of the JDC's responsibilities. The JDC shall have a chairperson selected by Jazz. The role of the chairperson shall be to convene and preside at the meetings of the JDC and to ensure the preparation of meeting minutes, but the chairperson shall have no additional powers or rights beyond those held by other JDC representatives.

(c) Meetings. The JDC shall meet at least one (1) time per calendar quarter, unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the JDC (by videoconference or teleconference) by at least ten (10) Business Days' prior written notice to the other Party, and such Party shall provide the JDC, no later than ten (10) Business Days prior to the special meeting, with materials reasonably adequate to enable informed discussion or decision-making, as applicable. No later than ten (10) Business Days prior to any meeting of the JDC, the chairperson of the JDC shall prepare and circulate an agenda for such meeting; provided, however, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. The JDC may meet in person, by videoconference or by teleconference, as the Parties agree. Each Party shall bear the expense of its respective JDC members' participation in JDC meetings. Meetings of the JDC shall be effective only if at least one (1) representative of each Party is present or participating in such meeting. The chairperson of the JDC shall be responsible for preparing written minutes of all JDC meetings that reflect, without limitation, all material actions taken at such meeting and further issues to be considered. The JDC chairperson shall send draft meeting minutes to each member of the JDC for review and approval within ten (10) Business Days after each JDC meeting. Such minutes shall be deemed approved unless one or more members of the JDC object to the accuracy of such minutes within ten (10) Business Days of receipt. The JDC may be disbanded at any time by the mutual agreement of the Parties, it being understood that matters previously to be considered by the JDC shall be considered directly by the Parties in good faith with the decision making allocation as described below in the event of any dispute on such matters.

3.2 Joint Management Team

(a) Formation. Promptly, and in any event within thirty (30) days after the Effective Date, the Parties shall establish a joint management team (the "**Joint Management Team**" or "**JMT**") and such JMT will:

(i) Manage and coordinate the strategic relationship of the Parties in the performance of the obligations under this Agreement; and

(ii) Address and resolve any disputes of the JDC.

(b) Members. Each Party shall appoint one senior executive to the JMT. Each Party may replace its representative at any time upon written notice to the other Party; provided that each representative shall be an executive of the applicable Party or its Affiliate having sufficient experience and responsibility within such Party to make decisions arising within the scope of the JMT's responsibilities.

(c) Meetings. The JMT shall meet at least one (1) time per calendar year. Either Party may also call a special meeting of the JMT (by videoconference or teleconference) by at least ten (10) Business Days' prior written notice to the other Party, and such Party shall provide the other member, no later than ten (10) Business Days prior to the special meeting, with materials reasonably adequate to enable informed discussion or decision-making, as applicable. The JMT may meet in person, by videoconference or by teleconference, as the Parties agree. Each Party shall bear the expense of its respective JMT members' participation in JMT meetings. Meetings of the JMT shall be effective only if both representatives are present or participating in such meeting.

3.3 Decision Making. The JDC and JMT each shall strive to act by consensus. The representatives from each Party on the JDC will have, collectively, one (1) vote on behalf of that Party; each Party will have one vote on the JMT. If the JDC is unable to reach consensus on any matter within the JDC's authority within thirty (30) days after first considering such matter, then such matter shall be referred to the JMT for resolution. If the JMT, after good faith efforts and consideration of the other party's position, cannot resolve such matter within thirty (30) days after such matter has been referred to the JMT, then:

(a) Jazz shall have the final decision making authority with respect to all matters relating to the HemOnc Products; provided that such final decision making authority shall not apply with respect to (i) the prosecution and enforcement of Pfenex Patents (for which decisions shall be made as set forth in Sections 7.3 and 7.4), and (ii) material changes to the Pfenex Expression Feasibility Activities;

(b) prior to Option Exercise, Pfenex shall have the final decision making authority with respect to all matters relating to the development of the Pegaspargase Product; provided that Pfenex may not materially change any of its development obligations outlined in the applicable Development Plan with respect to the Pegaspargase Product without Jazz's prior written consent; and

(c) prior to ROFN Exercise with respect to the applicable ROFN Product, Pfenex shall have the final decision making authority with respect to all matters relating to the development of such ROFN Product.

Notwithstanding the foregoing, a Party may not exercise such final decision making authority in a manner that would increase the financial obligations of the other Party.

3.4 Working Groups. From time to time, the JDC may establish and delegate duties to other committees, sub-committees or directed teams (each, a "**Working Group**") on an "as-needed" basis to oversee particular projects or activities, which delegation shall be reflected in the minutes of the meetings of the JDC. For illustrative purposes only, the JDC may establish a Working Group focused on CMC matters and a Working Group focused on intellectual property matters. Each Working Group shall be constituted and shall operate as the JDC determines and shall report to the JDC. Each Working Group and its activities shall be subject to the oversight, review and approval of the JDC. In no event shall the authority of the Working Group exceed that specified for the JDC in Section 3.1(a). Any disagreement between the designees of Pfenex and of Jazz on a Working Group shall be referred to the JDC for resolution.

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ARTICLE 4
DEVELOPMENT; MANUFACTURE; REGULATORY

4.1 Overview. The Parties agree to conduct Development of Products as provided in this Article 4.

4.2 Development Programs.

(a) General. The Parties shall undertake, using Commercially Reasonable Efforts, a development program to Develop each Product (with respect to each Product, the "**Development Program**") in accordance with the terms of this Article 4. Development of each Product under this Agreement by the Parties will be conducted pursuant to a development plan (with respect to each Product, the "**Development Plan**") that describes all Development activities to be conducted by the Parties in an initial twelve (12)-month period and, after expiry of the applicable Assessment Period, in a twenty-four (24)-month period, including to the extent applicable for the period included under such plan: (i) the proposed overall program of Development for such Product in the Territory, including preclinical studies, toxicology, formulation, process development, supply, manufacturing technology transfer, clinical studies, regulatory plans and other elements of obtaining Regulatory Approval(s) of such Product, and (ii) the tasks allocated to each Party under the Development Program and estimated timelines for such tasks and responsibilities. The Development Plan for each HemOnc Product shall also set forth the scope and timeline for completion of the Pfenex Expression Feasibility Activities and the Jazz Assessment Activities. In the event of any inconsistency between a Development Plan and this Agreement, the terms of this Agreement shall prevail.

(b) Initial Development Plans and Amendments. The Parties have set forth the initial Development Plan for each of the Development Programs as **Exhibit C**. From time to time (at least on an annual basis), Jazz shall prepare proposed amendments, as appropriate, to the then-current Development Plans for the HemOnc Products and, prior to Option Exercise, Pfenex shall prepare proposed amendments, as appropriate, to the then-current Development Plan for the Pegaspargase Product for review and discussion at the JDC. Following Option Exercise, the Development Plan for the Pegaspargase Product shall be prepared and amended by the Parties as set forth in the Option Exercise Agreement. Once discussed by the JDC (and as amended based on such discussion), each amended Development Plan shall become effective and supersede the previous Development Plan as of the date of approval by the applicable Party.

4.3 Allocation of Development Responsibilities.

(a) HemOnc Products. Subject to Pfenex's performance of the Pfenex Expression Feasibility Activities and Section 4.7, Jazz shall be responsible for conducting the Jazz Assessment Activities and all Development (other than manufacturing process development) of the HemOnc Products, including all activities during the applicable Assessment Period and all pre-clinical and clinical studies in accordance with the terms of this Agreement.

(b) Pegaspargase Product. Prior to Option Exercise, Pfenex shall be solely responsible, at its expense, for all Development of the Pegaspargase Product, including the manufacturing and supply of the Pegaspargase Product for Development use. Following Option Exercise, the responsibilities for the Development of the Pegaspargase Product shall be allocated between the Parties as agreed by the Parties under the Option Exercise Agreement.

4.4 Development Standards of Conduct. After the expiration of the applicable Assessment Period, Jazz shall use Commercially Reasonable Efforts to Develop the HemOnc Products for the Lead Indication in the United States and to achieve the Development milestones numbered 5 and 6 referenced in **Exhibit 6.3** that specifically relate to the Lead Indication in the United States. For clarity, Jazz's Development obligations under this Section 4.4 do not require Jazz to Develop the HemOnc Products in more than one subtype, subgroup, or line of treatment for the Lead Indication. Pfenex shall use Commercially Reasonable Efforts to Develop the manufacturing process for the HemOnc Products as set forth in the Development Plans for such Products and to Develop the Pegaspargase Product for the United States. Without limiting the foregoing, each Party shall use Commercially Reasonable Efforts to carry out the tasks assigned to it under the respective Development Plans, and each Party shall conduct its activities under the Development Plans in a good scientific manner.

4.5 Development Records and Reports. Each Party shall maintain complete, current and accurate records of all Development activities conducted by it hereunder, and all Information resulting from such activities. Such records shall accurately and completely reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes.

4.6 Development Reports. Each Party shall keep the JDC reasonably informed on the Development activities performed by such Party under this Agreement. Without limiting the foregoing, at each regularly scheduled JDC meeting, each Party shall provide the JDC with a summary report of the Development or manufacturing activity performed by it since the last JDC meeting and the results thereof. The JDC shall discuss the progress and results of the Parties' Development or manufacturing activity and each Party shall promptly respond to the other Party's reasonable questions or requests for additional information relating to such Development. Notwithstanding the foregoing, during the applicable Assessment Period, Jazz shall only be obligated to share with Pfenex a high level plan for its activities with respect to such HemOnc Product during such time period.

4.7 Process Development; Manufacture of Products

(a) Process Development. Each Party shall be responsible, at its expense, for manufacturing process development in accordance with the applicable Development Plan. The Development Plan for each HemOnc Product shall set forth the timeline and the Parties' respective activities for the development of the manufacturing process for each such HemOnc Product, to be generally assigned to each Party consistent with the table below for each such HemOnc Product. In addition, manufacturing process development activities shall include technology transfer to Third Party manufacturers or Third Party research organizations for scale up and production of materials for clinical trials, and all other such activities related to development and validation of a commercial manufacturing process. Further, the Development Plan for each HemOnc Product shall set forth the criteria with respect to the manufacturing process for such HemOnc Product that must be satisfied prior to the transfer of such manufacturing process pursuant to Section 4.7(b) (with respect to such HemOnc Product, the "**Manufacturing Process Transfer Criteria**"). Each Party shall provide periodic written reports on its Development of the applicable manufacturing process.

Pfenex Activity	**Jazz Activity**
[***]	[***]
[***]	[***]
[***]	
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

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(b) Manufacturing Process Transfer.

(i) At Jazz's request after achievement of the Manufacturing Process Transfer Criteria with respect to the applicable HemOnc Product, Pfenex shall transfer, at its expense, Pfenex's manufacturing process for such HemOnc Product to Jazz, its Affiliate, or a Third Party manufacturer, in Jazz's sole discretion (with respect to such HemOnc Product, the "**Manufacturing Process Transfer**"). For clarity, Pfenex shall not be required to perform more than a maximum of two (2) Manufacturing Process Transfers (i.e., one for each HemOnc Product). If the Manufacturing Process Transfer is to a Third Party manufacturer for commercial supply of the applicable Product, then the Parties shall negotiate in good faith to agree on the Third Party manufacturer, but if the Parties are unable to agree, Jazz may select the Third Party manufacturer; *provided* that Pfenex may reasonably object to any proposed Third Party manufacturer on the basis of reasonable concerns regarding the protection of Pfenex's Confidential Information or intellectual property rights based on the Third Party manufacturer's history of patent infringement or misappropriation or specific geographic concerns. Notwithstanding anything to the contrary in this Agreement, if Jazz requests that Pfenex perform the Manufacturing Process Transfer with respect to the applicable HemOnc Product prior to achievement of the Manufacturing Process Transfer Criteria for such HemOnc Product, then, provided that the Parties agree in writing (such agreement not to be unreasonably withheld) with respect to alternative criteria for such Manufacturing Process Transfer following discussion of any risk factors reasonably identified by Pfenex in response to such request, Pfenex shall perform such Manufacturing Process Transfer, at its expense, pursuant to such alternative criteria. Notwithstanding the foregoing, Pfenex shall perform a Manufacturing Process Transfer for an applicable Product at Jazz's request (A) not later than the applicable time set forth in the Development Plan and/or (B) if after good faith discussions with Pfenex with an opportunity for Pfenex to take corrective action, Jazz reasonably determines that Pfenex will be unable achieve the Manufacturing Process Transfer Criteria by the applicable time set forth in the Development Plan.

(ii) The Parties shall conduct the applicable Manufacturing Process Transfer in accordance with this Section 4.7 and in accordance with a written Manufacturing Process Transfer plan to be mutually and reasonably agreed by the Parties prior to such Manufacturing Process Transfer. The Manufacturing Process Transfer shall include the transfer of all data, technical information, documents, and materials necessary or useful to enable Jazz or such Affiliate or Third Party manufacturer, as applicable, to manufacture and supply the applicable HemOnc Product in compliance with the applicable specifications for Development and Commercialization use and the generally accepted practices and principles for such technology transfer. The Manufacturing Process Transfer also includes reasonable and customary on-site support by Pfenex at the Third Party manufacturer's facilities during the Manufacturing Process Transfer, including participation by Pfenex in technical exchange meetings, review by Pfenex of draft batch records, and provision by Pfenex of technical supervision during any batches necessary to demonstrate that the Manufacturing Process Transfer is complete. Following the Manufacturing Process Transfer for each HemOnc Product and upon Jazz's reasonable request, Pfenex [***], as applicable, to implement the manufacturing process and analytical methods for such HemOnc Product developed by Pfenex without additional compensation and (B) such additional technical assistance (including access to its technical personnel) as may be requested by Jazz for compensation at Pfenex's then applicable hourly rates, in each case (A) and (B) subject to reimbursement of Pfenex's documented travel and other out-of-pocket expenses incurred in performing providing such assistance within thirty (30) days of invoice therefor. Jazz may use any unused portion of Pfenex's [***] with respect to the [***] following Manufacturing Process Transfer.

(c) Product Supply. Prior to Manufacturing Process Transfer under Section 4.7(b) (if applicable), Pfenex shall use reasonable efforts to manufacture and supply to Jazz all non-GMP HemOnc Products reasonably required for pre-clinical and process development studies in accordance with the specifications, quantities and timeline set forth in the applicable Development Plan. After the completion of a Manufacturing Process Transfer for a HemOnc Product, Jazz shall be responsible, at its expense and through Jazz, its Affiliates or a designated Third Party manufacturer, for the manufacture and supply of all HemOnc Product required for use in the remaining clinical Development and the Commercialization of such HemOnc Product. Upon Jazz's request, at a reasonable time during the manufacturing development process, the Parties shall negotiate in good faith for a reasonable period of time, not to exceed ninety (90) days or such longer period as mutually agreed by the Parties, the terms and conditions of a supply agreement pursuant to which Pfenex will be Jazz's supplier of one or both GMP HemOnc Products for use in clinical Development and Commercialization, on a non-exclusive or exclusive basis as agreed by the Parties. For clarity, neither Party shall be required to enter into such an agreement except on such terms as are acceptable to such Party in its sole and absolute discretion.

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4.8 Regulatory Matters for HemOnc Products.

(a) Jazz Responsibilities. Except as expressly set forth herein, Jazz shall be responsible, at its expense, for all regulatory activities required to obtain and maintain Regulatory Approval for the HemOnc Products, including the preparation of all Regulatory Materials and all communications and interactions with Regulatory Authorities with respect to the HemOnc Products and pharmacovigilance reporting. Jazz shall own all Regulatory Materials (including all INDs, BLAs, MAAs and Regulatory Approvals) for the HemOnc Products. Pfenex shall not submit any Regulatory Materials for the HemOnc Products without the prior written consent of Jazz. Except as expressly requested by Jazz in writing, Pfenex shall not communicate with any Regulatory Authority with respect to the HemOnc Products, unless so required to comply with applicable Laws, in which case Pfenex shall promptly notify Jazz of such requirement under applicable Laws and, to the extent practicable and permitted under applicable Laws, shall submit any proposed communication to Jazz for prior approval or, if not practicable or permitted, shall provide Jazz with a copy or summary thereof as soon as reasonably practicable thereafter.

(b) Regulatory Collaboration. Upon Jazz's request, Pfenex shall provide reasonable support with respect to CMC (including writing applicable M3 modules of the International Conference on Harmonisation Common Technical Document specifically related to the production strains with respect to the applicable Product), pharmacovigilance, and other matters for the HemOnc Products in connection with Jazz's regulatory activities. Without limiting the foregoing, at the direction of Jazz, the Parties shall collaborate and work together to prepare CMC related Regulatory Materials for the HemOnc Products and the JDC may establish a Working Group to coordinate and oversee such regulatory work.

(c) Regulatory Information Sharing. Jazz shall lead all interactions with Regulatory Authorities with respect to the HemOnc Products and shall keep Pfenex reasonably informed on the regulatory development for the HemOnc Products through the JDC. Jazz shall provide Pfenex with drafts of all Regulatory Materials prepared by Jazz for the HemOnc Products reasonably in advance of filing where practicable for Pfenex's review and comment. Jazz will consider in good faith any such comments where practicable. Jazz shall also promptly provide Pfenex with copies of any material Regulatory Materials submitted or received by Jazz for the HemOnc Products.

(d) Regulatory Meetings. At each regularly scheduled JDC meeting, Jazz shall provide Pfenex with a list and schedule of any in-person meetings or teleconferences with Regulatory Authorities planned for the next calendar quarter that relate to the HemOnc Products. In addition, Jazz shall notify Pfenex as soon as reasonably possible if Jazz becomes aware of any additional such meetings or teleconferences that become scheduled for such calendar quarter. Pfenex shall provide all reasonable assistance requested by Jazz to prepare for any such meeting or teleconference. Upon either Party's request and to the extent permitted by applicable Laws, Pfenex shall have the right to have a representative present in all such meetings and teleconferences; provided, however, Pfenex may only actively participate in such meeting with respect to topics that pertain to activities performed by Pfenex under the applicable Development Plan and the content of such participation is subject to the prior agreement of the Parties.

(e) Regulatory Inspection.

(i) Pfenex shall promptly (and in any event within one (1) Business Day of becoming aware thereof) notify Jazz of any Regulatory Authority inspections relating to any HemOnc Product or related activities under the applicable Development Plan. Jazz shall have the right to be present at any such inspections and shall have the opportunity to provide, review and comment on any responses that may be required. Pfenex shall provide Jazz with copies of all materials, correspondence, statements, forms and records received or generated pursuant to any such inspection. In addition to such obligations with respect to Regulatory Authority inspections, Pfenex shall promptly (and in any event within one (1) Business Day following receipt thereof) notify Jazz of any information it receives regarding any threatened or pending action or communication by or from any Third Party, including a Regulatory Authority, that may materially affect the Development, manufacturing, Commercialization or regulatory status of HemOnc Products.

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(ii) Jazz shall promptly (and in any event within one (1) Business Day of becoming aware thereof) notify Pfenex of any Regulatory Authority inspections relating specifically to the manufacturing process developed by Pfenex for any HemOnc Product (or any modified version of such manufacturing process for such HemOnc Product) and conducted by Jazz, its Affiliate or any Third Party manufacturer. Jazz shall provide Pfenex with copies of all materials, correspondence, statements, forms and records received or generated pursuant to any such inspection to which it has access and authority to disclose; provided that Jazz shall only provide Pfenex with any such materials received by a Third Party to the extent permitted under Jazz's agreement with such Third Party. In addition to such obligations with respect to Regulatory Authority inspections, Jazz shall promptly (and in any event within one (1) Business Day following receipt thereof) notify Pfenex of any information it receives regarding any threatened or pending action or communication by or from any Third Party, including a Regulatory Authority, that may materially affect the manufacturing or regulatory status of HemOnc Products; provided that Jazz shall only provide Pfenex with any such information received by a Third Party to the extent permitted under Jazz's agreement with such Third Party.

4.9 Regulatory Matters for Pegaspargase Product. Prior to Option Exercise, Pfenex shall be solely responsible for all regulatory activities for the Pegaspargase Product, shall be solely responsible for all interactions with Regulatory Authorities with respect to the Pegaspargase Product and shall keep Jazz reasonably informed on regulatory developments for the Pegaspargase Product through the JDC. After Option Exercise, the responsibilities for the regulatory activities required to obtain and maintain Regulatory Approval of the Pegaspargase Product shall be allocated between the Parties as agreed by the Parties under the Option Exercise Agreement.

4.10 Subcontracts. Each Party may perform its Development Program obligations under this Agreement through one or more subcontractors, provided that (a) Pfenex's subcontractors shall be subject to Jazz's prior written approval (except that, in the case of the Development Program for the Pegaspargase Product prior to Option Exercise, Pfenex may engage subcontractors without such approval), (b) the subcontracting Party shall remain responsible for the work delegated to, and payment to (subject to Section 6.2(b)), its subcontractors to the same extent it would if it had done such work itself and (c) the subcontracting Party shall enter into a written agreement with the subcontractor that is consistent with this Agreement, including provisions relating to confidentiality and intellectual property rights that are at least as restrictive as those in this Agreement. The subcontracting Party shall enforce any breach by a subcontractor under such subcontracting agreement for the non-subcontracting Party's benefit and on its behalf.

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ARTICLE 5
COMMERCIALIZATION

5.1 Commercialization Responsibilities. Subject to the terms hereof, Jazz will have the exclusive right to conduct, and will be solely responsible for all aspects of, the Commercialization of HemOnc Products and, subject to Option Exercise, the Pegaspargase Product in the Field in the Territory, including: (a) developing and executing a commercial launch and pre-launch plan; (b) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of Products; (c) marketing and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; (g) conforming its practices and procedures to applicable Laws relating to the marketing, detailing and promotion of Products in the Territory; and (h) manufacturing of Products for commercial use (subject to the terms of any definitive manufacturing agreement between the Parties). As between the Parties, Jazz shall bear all of its costs and expenses incurred in connection with the Commercialization activities for the HemOnc Products.

5.2 Commercial Diligence; Report. After Jazz has obtained Regulatory Approval for a HemOnc Product, Jazz shall use Commercially Reasonable Efforts to Commercialize such HemOnc Product for the Lead Indication in the United States. For clarity, Jazz's Commercialization obligations under this Section 5.2 do not require Jazz to Commercialize the applicable HemOnc Product in more than one subtype, subgroup, or line of treatment of the Lead Indication. In addition, subject to Option Exercise, Jazz will use Commercially Reasonable Efforts to Commercialize the Pegaspargase Product following Regulatory Approval in the United States. On an annual basis, Jazz shall provide Pfenex with a summary of Jazz's significant Commercialization activities with respect to each Product in the Territory since the last such report.

ARTICLE 6
COMPENSATION

6.1 Upfront Payments. Within two (2) Business Days after the Effective Date, Jazz shall pay to Pfenex a one-time, non- refundable (i) upfront payment of [***] Dollars ($[***]) in consideration of the licenses and related rights granted under this Agreement for HemOnc-NextGen; and (ii) option payment of [***] Dollars ($[***]) in consideration of the Option granted under Section 2.4 (together, such amounts, the "**Upfront Payments**").

6.2 Development Costs.

(a) General. Except as expressly set forth herein, each Party shall be responsible for the cost and expenses it incurs to carry out the Development work under the Development Plans, including in the case of Pfenex, the cost and expense of the manufacturing technology transfer under Section 4.7(b).

(b) HemOnc Products. If Pfenex is required to perform any Development activities for the HemOnc Products under the applicable Development Plan or at Jazz's request, the Parties shall promptly agree on a budget for such activities either in the applicable Development Plan or otherwise prior to the commencement of the applicable activity.

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(i) If Pfenex engages a Third Party to perform such activities because Pfenex does not have the capability to perform such Development activities, then Jazz shall reimburse Pfenex for its reasonable and documented actual expenses paid by Pfenex to Third Parties to perform such Development activities, without markup, to the extent such expenses do not exceed a mutually agreed written budget for such activities or an amount otherwise approved in advance and in writing by Jazz. Within five (5) Business Days after the end of each month during which Pfenex incurred any such expenses, Pfenex shall provide Jazz with a good faith estimate of all amounts paid to Third Parties in such month, without markup, to engage such Third Party to conduct such Development activities. Within thirty (30) days after the end of each month during which Pfenex incurred any such expenses, Pfenex shall provide Jazz with an invoice and reasonable supporting documentation for all amounts paid to Third Parties in such month, without markup, to engage such Third Party to conduct such Development activities (up to the amount budgeted for such Development activities or otherwise approved in writing by Jazz). Jazz shall pay each such invoice within forty-five (45) days after receipt thereof, except to the extent disputed by Jazz in good faith. Jazz shall notify Pfenex if it disputes any portion of any such invoice prior to the due date for payment. For clarity, Jazz shall not be required to pay any invoiced amount for a particular Development activity that exceeds the amount budgeted or approved for such activity. Jazz shall notify Pfenex if it disputes any portion of any such invoice within ten (10) Business Days from receipt of the invoice.

(ii) Pfenex shall perform any Development activities for the HemOnc Products pursuant to the applicable Development Plan at its sole cost and expense; *provided*, that Jazz shall reimburse Pfenex for documented internal expenses, at the rate of [***], in excess of [***] actually incurred by Pfenex to generate the Assessment Materials for HemOnc-NextGen that are within the approved budget in the Development Plan for such activities.

(c) Pegaspargase Product. Prior to Option Exercise, Pfenex shall be solely responsible for all cost and expenses it incurs for the Development of the Pegaspargase Product. After Option Exercise, the Parties will allocate the Development cost for the Pegaspargase Product as agreed by the Parties under the Option Exercise Agreement.

6.3 Development Milestone Payments for HemOnc Products. Jazz shall notify Pfenex within ten (10) days after the achievement by the applicable Party or its Affiliates or sublicensees of the development milestone events set forth on **Exhibit 6.3**. Thereafter, Pfenex shall invoice Jazz for the corresponding milestone payment set forth on **Exhibit 6.3**, and Jazz shall pay each such invoice within forty-five (45) days after receipt thereof. Notwithstanding the preceding sentence, concurrently with the delivery of materials set forth in milestone payments numbered 1 and 2 listed on **Exhibit 6.3**, Pfenex shall invoice Jazz for the corresponding milestone payment, and Jazz shall pay each invoice within five (5) Business Days after receipt thereof. Each payment set forth in this Section 6.3 shall be non-refundable and non-creditable.

(a) Each milestone payment is payable one time only, regardless of the number of times the corresponding event is achieved by a Product and regardless of the number of Products to achieve such event. Under no circumstances shall Jazz be obligated to pay Pfenex more than forty-six million Dollars ($46,000,000) pursuant to this Section 6.3.

(b) "**EU Approval**" means the later of (i) first achievement of MAA approval in the European Union by the centralized procedure or in at least three of the five Major European Countries; and (b) first receipt of Pricing Approval in at least three Major European Countries, provided that Jazz uses Commercially Reasonable Efforts to obtain such Pricing Approvals after the corresponding MAA approval.

(c) For clarity, in the case of development milestone events numbered 1 through 4 listed on **Exhibit 6.3** only, if any such higher numbered development milestone event for a particular HemOnc Product is achieved and any such lower numbered development milestone event for such HemOnc Product has not yet been achieved for any reason, notwithstanding anything herein to the contrary, such lower numbered development milestone event shall be deemed to have been achieved and the corresponding development milestone payment listed on **Exhibit 6.3** shall be payable simultaneously with the development milestone payment for achievement of such higher numbered development milestone event.

6.4 Sales Milestones for HemOnc-NextGen. Jazz shall notify Pfenex, concurrently with the delivery of the royalty report under Section 6.5(d), after the end of the calendar quarter in which the aggregate annual Net Sales of HemOnc-NextGen by Jazz and its Affiliates and sublicensees first reaches each of the amounts specified on **Exhibit 6.4**. Thereafter, Pfenex shall invoice Jazz for the corresponding milestone payment set forth on **Exhibit 6.4**, and Jazz shall pay each such invoice within thirty (30) days after receipt thereof. Each such sales milestone payment shall be payable one time only. For clarity, the milestone payments in **Exhibit 6.4** shall be additive such that if more than one milestone below is met in the same calendar year, Jazz shall pay all applicable payments to Pfenex for that calendar year in accordance with this Section 6.4.

6.5 Royalties on HemOnc Products.

(a) Royalty Rates. Subject to Sections 6.5(b) and 6.5(c), Jazz shall pay to Pfenex royalties on aggregate annual Net Sales of HemOnc-Pf and HemOnc-NextGen, as calculated by multiplying the applicable royalty rate by the corresponding amount of Net Sales of HemOnc-Pf and HemOnc-NextGen in each calendar year as set forth on **Exhibit 6.5(a)**. For clarity, Net Sales and the applicable royalty rate shall be determined separately for each of HemOnc-Pf and HemOnc-NextGen.

(b) Royalty Term. Royalties shall be paid under this Section 6.5, on a Product-by-Product basis, for so long as Jazz or any other Selling Party is Commercializing or having Commercialized the HemOnc Products (with respect to each Product, the "**Royalty Term**").

(c) Third Party Royalty Stacking. If Jazz obtains a license from a Third Party to any intellectual property right in order to manufacture, import, sell or Commercialize a HemOnc Product, Jazz shall have the right to deduct, from the royalty payment that would otherwise have been due pursuant to this Section 6.5 with respect to Net Sales of such HemOnc Product in the applicable country in a particular calendar quarter, an amount equal to [***] of the royalties paid by Jazz to such Third Party pursuant to such license on account of the sale of such HemOnc Product in such country during such calendar quarter; [***]. Jazz shall not be entitled to any reduction for any Third Party payments made under any intellectual property licensed by Jazz from any Third Party as of the Effective Date or for any Jazz Extension IP.

(d) Royalty Reports and Payments. Within forty-five (45) days after the end of each calendar quarter (or sixty (60) days for the last calendar quarter of the calendar year) after the First Commercial Sale of any HemOnc Product, Jazz shall deliver to Pfenex a statement, on a country-by-country and Product-by-Product basis, of the amount of gross sales and Net Sales of the HemOnc Products during the applicable calendar quarter and a calculation of the amount of royalty payment due on such sales for such calendar quarter, including royalty reduction under Section 6.5(c), if applicable. Following receipt of each royalty report, Pfenex shall invoice Jazz for the royalty payment, and Jazz shall pay each such invoice within fifteen (15) days after receipt thereof.

(e) Third Party Payments. Pfenex will be solely responsible for all amounts owed to Third Parties pursuant to agreements between Pfenex and Third Parties with respect to HemOnc Products.

6.6 HemOnc-Pf COGS Improvement Sharing. In addition to amounts payable under Section 6.5, for HemOnc-Pf sold by Jazz and other Selling Parties in a particular calendar year, Jazz shall pay to Pfenex an amount equal to the COGS Improvement. Within sixty (60) days after the end of each calendar year after the First Commercial Sale of HemOnc-Pf, Jazz shall deliver to Pfenex a statement of the calculation of COGS Variance in accordance with **Exhibit D** and amount of COGS Improvement sharing payment due for such calendar year.

Following receipt of each such report, Pfenex shall invoice Jazz for the COGS Improvement sharing payment, and Jazz shall pay each such invoice within forty-five (45) days after receipt thereof.

6.7 Foreign Exchange. The rate of exchange to be used in computing the amount of currency equivalent in Dollars of Net Sales invoiced in other currencies shall be the rate used by Jazz in its financial reporting in accordance with applicable GAAP or other standard as then-used by Jazz.

6.8 Manner and Place of Payment. All payments owed by Jazz under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Pfenex.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

6.9 Records; Audits. Jazz agrees that it and all other Selling Parties will maintain complete and accurate records in reasonably sufficient detail to permit Pfenex to confirm the accuracy of the calculation of royalty payments and COGS Improvement sharing payments, and the achievement of sales milestone events. Upon reasonable prior notice, such records shall be available during regular business hours for a period of three (3) years from the end of the calendar year to which they pertain for examination, not more often than once each calendar year, by an independent certified public accountant selected by Pfenex and reasonably acceptable to Jazz, for the sole purpose of verifying the accuracy of the financial reports furnished by Jazz pursuant to this Agreement. Any such auditor shall enter into a confidentiality agreement with Jazz and shall not disclose Jazz's Confidential Information to Pfenex or to any Third Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Jazz or the amount of payments due by Jazz to Pfenex under this Agreement. Any amounts shown to be owed but unpaid shall be paid by Jazz to Pfenex, and any amounts showed to be overpaid will be refunded by Pfenex to Jazz, within forty-five (45) days from the accountant's report. Pfenex shall bear the full cost of such audit unless such audit discloses an underpayment by Jazz of more than ten percent (10%) of the amount due, in which case Jazz shall bear the full cost of such audit.

6.10 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Jazz to Pfenex under this Agreement. To the extent Jazz is required to deduct and withhold taxes on any payment to Pfenex, Jazz shall deduct the amounts of such taxes from the payment to Pfenex, pay such amounts to the proper Governmental Authority in a timely manner and promptly transmit to Pfenex an official tax certificate or other evidence of such withholding sufficient to enable Pfenex to claim such payment of taxes. Pfenex shall provide Jazz any tax forms that may be reasonably necessary in order for Jazz not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

(c) Withholding Tax Action. If either Party (or its Affiliates or successors) is required to make a payment to the other Party subject to a deduction or withholding of tax, then (A) if such deduction or withholding of tax obligation arises as a result of any action by the first Party, such as a Change of Control, change of domicile, or assignment by such first Party and such action has the effect of increasing the amount of tax deducted or withheld (a "**Withholding Tax Action**"), then the amount payable by the Party taking such Withholding Tax Action (in respect of which such increased deduction or withholding is required to be made) shall be increased by the amount necessary (the "**Additional Amounts**") to ensure that the other Party receives the same amount that it would have received had no such Withholding Tax Action occurred, and (B) the Additional Amounts shall be deducted and withheld by the Party paying the Additional Amounts. The Additional Amounts, along with any other tax deducted and withheld from the payment made by such Party, shall be timely remitted to the proper Governmental Authority for the account of the other Party in accordance with applicable Law. Notwithstanding the foregoing, any sublicense or assignment in contravention of Sections 2.1(d) or 13.6, respectively, of this Agreement will not constitute a Withholding Tax Action.

(d) Refund of Additional Amounts. In the event a Party actually receives a credit against any tax on its income for any Additional Amounts paid to a Governmental Authority on its behalf (whether for the taxable year with respect to which such Additional Amounts are deducted and withheld, or in any prior or subsequent taxable year), the Party obtaining such credit shall refund and pay to the other Party an amount equal to the lesser of the credit obtained and such Additional Amounts. Whether a credit is obtained for Additional Amounts or for other taxes paid by a Party shall be determined in a manner consistent with applicable Laws.

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ARTICLE 7
INTELLECTUAL PROPERTY MATTERS

7.1 Ownership of Inventions.

(a) Sole Inventions. Each Party shall solely own any Inventions made solely by it or its Affiliates' employees, agents, or independent contractors that are not Pfenex Improvements, Jazz Improvements or Post-Primary Recovery Inventions ("**Sole Inventions**").

(b) Joint Inventions. The Parties shall jointly own: (i) any Inventions that (A) are made jointly by employees, agents, or independent contractors of one Party or its Affiliates together with employees, agents, or independent contractors of the other Party or its Affiliates and (B) are not Pfenex Improvements or Jazz Improvements; and (ii) Post-Primary Recovery Inventions ((i) and (ii) together, "**Joint Inventions**"). All Patents claiming Joint Inventions shall be referred to herein as "**Joint Patents**." Except to the extent a Party is expressly limited by the terms of this Agreement, including 7.1(g), each Party shall be entitled to practice, license, assign and otherwise exploit the Joint Inventions and Joint Patents without the duty of accounting or seeking consent from the other Party. Inventorship shall be determined in accordance with U.S. patent laws.

(c) Pfenex Improvements. Notwithstanding Sections 7.1(a) and 7.1(b) and subject to Section 7.1(g), Pfenex shall solely own all Inventions (developed solely by or on behalf of a Party or jointly by or on behalf of the Parties) that constitute an improvement, modification or enhancement of Pfenex's proprietary *P. fluorescens* protein expression and manufacturing technology that has been disclosed by Pfenex to Jazz in writing (the "**Disclosed Platform**"), where such improvement, modification, and enhancement is applicable to the manufacture of drug substance for products in addition to the Products, including (i) improvements, modifications and enhancements to the Disclosed Platform generated under this Agreement (excluding, for clarity, any protein sequence), and (ii) growth media and conditions generally applicable to *P. fluorescens* and products that do not contain [***], but excluding (A) Post-Primary Recovery Inventions and (B) any Inventions, Information, or improvements relating to the process of formulating a Product or the formulated Product (the "**Pfenex Improvements**"). To the extent any Pfenex Improvement is made by Jazz's or its Affiliates' employees, agents, or independent contractors (whether solely or jointly with Pfenex), Jazz hereby assigns to Pfenex all of the right, title and interest in and to such Pfenex Improvement.

(d) Jazz Improvements. Notwithstanding Sections 7.1(a) and 7.1(b), Jazz shall solely own all Inventions (developed solely by or on behalf of a Party or jointly by or on behalf of the Parties) that constitute an improvement, modification or enhancement of the Half-Life Extension Component for HemOnc-NextGen selected by Jazz, in its sole discretion, including any fusion protein comprised of [***] together with a Half-Life Extension Component (the "**Jazz Improvements**"). To the extent any Jazz Improvement is made by Pfenex's or its Affiliates' employees, agents, or independent contractors (whether solely or jointly with Jazz), Pfenex hereby assigns to Jazz all of the right, title and interest in and to such Jazz Improvement.

(e) Product Licenses. Pfenex Improvements, Sole Inventions owned by Pfenex, and Pfenex's interest in Joint Inventions shall be included in Pfenex IP and automatically licensed to Jazz under Section 2.1. Jazz Improvements shall be included in Jazz Extension IP and automatically licensed to Pfenex under Section 2.2.

(f) Improvement Licenses. In addition to the license grant contained in Section 7.1(e), Pfenex hereby grants to Jazz a non-exclusive, worldwide, transferrable, fully paid, perpetual, irrevocable, sublicenseable license (through multiple tiers) under Pfenex Improvements assigned by Jazz to Pfenex under Section 7.1(c) solely to manufacture any product that contains [***] or includes a Half-Life Extension Component. In addition to the license grant contained in Section 7.1(e), Jazz hereby grants to Pfenex a non- exclusive, worldwide, transferrable, fully paid, perpetual, irrevocable, sublicenseable (through multiple tiers) license under Jazz Improvements Controlled by Jazz assigned by Pfenex to Jazz under Section 7.1(d) solely to use with Pfenex's proprietary *P. fluorescens* manufacturing platform to manufacture biological products. For clarity, the foregoing licenses granted by each Party expressly exclude (by implication or otherwise) any license or other right to practice any other intellectual property right Controlled by a Party that may be necessary or useful to practice the subject Jazz Improvement or Pfenex Improvement, as applicable.

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(g) Post-Primary Recovery Inventions. Notwithstanding Sections 7.1(a), 7.1(b), and 7.1(c), the Parties shall jointly own all Inventions (developed solely by or on behalf of a Party or jointly by or on behalf of the Parties) made prior to completion of the applicable Manufacturing Process Transfer that constitute a process, or an improvement, modification, or enhancement of a process, used in the manufacture of proteins following the primary recovery of such proteins, excluding any Inventions, Information, or improvements relating to the process of formulating a Product or the formulated Product (the "**Post-Primary Recovery Inventions**"). To the extent any Post-Primary Recovery Invention is made solely by the employees, agents, or independent contractors of a Party or its Affiliates, such Party hereby assigns to the other Party a joint ownership interest in and to such Post-Primary Recovery Invention such that the Parties shall jointly own such Post-Primary Recovery Invention. For clarity, after completion of the applicable Manufacturing Process Transfer, Sections 7.1(a) and 7.1(b) shall govern ownership of Inventions that constitute a process, or an improvement, modification, or enhancement of a process, used in the manufacture of proteins following the primary recovery of such proteins. Neither Party may file a Patent on Post-Primary Recovery Inventions without the consent of the other Party, such consent not to be unreasonably withheld, conditioned, or delayed.

7.2 Disclosure of Inventions. Each Party shall promptly disclose to the other Party, subject to any Third Party obligations, all Inventions made by such Party to which the other Party has rights hereunder, including any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing such Inventions, and shall promptly respond to reasonable requests from the other Party for additional Information relating to such Inventions.

7.3 Patent Prosecution.

(a) Jazz Sole Patents. As between the Parties, Jazz shall have the sole and exclusive right to file, prosecute and maintain all Patents contained in Jazz Extension IP (including Jazz Improvements) and Patents claiming Jazz's Sole Inventions (collectively, the "**Jazz Sole Patents**"), at its own cost and expense. Jazz shall periodically provide Pfenex with updates on the status of the Jazz Sole Patents. For the purpose of this Article 7, "prosecution" shall include conducting any *inter partes* review, post-grant review, or any other post-grant proceeding including any patent interference proceeding, opposition proceeding and reexamination.

(b) Pfenex Sole Patents. As between the Parties, Pfenex shall have the first right to file, prosecute and maintain all Pfenex Sole Patents, at its own cost and expense. Pfenex shall consult with Jazz and keep Jazz reasonably informed of the status of the Pfenex Sole Patents and shall promptly provide Jazz with all material correspondence received from any patent authority in connection therewith. In addition, Pfenex shall promptly provide Jazz with drafts of all proposed material filings and correspondence to any patent authority with respect to the Pfenex Sole Patents for Jazz's review and comment prior to the submission of such proposed filings and correspondence. Pfenex shall confer with Jazz and shall (i) accept Jazz's comments to any Pfenex Product-Specific Patent and
(ii) consider in good faith Jazz's comments to any other Pfenex Sole Patent (including Pfenex General Product Patent), in each case prior to submitting such filings and correspondence. Each Party shall have the right to refer any such matters for further discussion to the JDC or to any Working Group focused on intellectual property as may be established by the JDC. Pfenex shall file patents covering Sole Inventions owned by Pfenex in a manner to separate the claims specifically related to a Product from other subject matter to the extent possible and in consultation with Jazz, if doing so does not, in Pfenex's reasonable, good faith determination, cause a material adverse effect on Pfenex's intellectual property rights covering products other than a Product. If Pfenex decides to no longer prosecute or maintain any Pfenex Product-Specific Patent in any jurisdiction in the Territory, it shall notify Jazz in writing. Thereafter, Jazz shall have the right to prosecute and maintain such Pfenex Product-Specific Patent in such jurisdiction at its own cost and expense. If Pfenex decides to no longer prosecute or maintain any Pfenex General Product Patent, it shall notify Jazz in writing. Thereafter, Jazz shall have the right to prosecute and maintain such Pfenex General Product Patent in such jurisdiction at its own cost and expense if doing so does not, in Pfenex's reasonable, good faith determination, cause a material adverse effect on Pfenex's intellectual property rights covering products other than a Product.

(c) Joint Patents. As between the Parties, Jazz shall have the first right to file, prosecute and maintain all Joint Patents, at its own cost and expense. Jazz shall consult with Pfenex and keep Pfenex reasonably informed of the status of the Joint Patents and shall promptly provide Pfenex with all material correspondence received from any patent authority in connection therewith. In addition, Jazz shall promptly provide Pfenex with drafts of all proposed material filings and correspondence to any patent authority with respect to the Joint Patents for Pfenex's review and comment prior to the submission of such proposed filings and correspondences. Jazz shall confer with Pfenex and consider in good faith Pfenex's comments prior to submitting such filings and correspondences. If Jazz decides to no longer prosecute or maintain any Joint Patent in any jurisdiction in the Territory, it shall notify Pfenex in writing. Thereafter, Pfenex shall have the right to prosecute and maintain such Joint Patent in such jurisdiction at its own cost and expense.

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(d) Cooperation. Each Party shall provide the other Party all reasonable assistance and cooperation, at the other Party's request and expense, in the patent prosecution efforts provided above in this Section 7.3, including providing any necessary powers of attorney, executing any other required documents or instruments for such prosecution, and making its personnel with appropriate scientific expertise available to assist in such efforts.

7.4 Patent Enforcement.

(a) Notification. If either Party becomes aware of (i) any existing or threatened infringement of any Pfenex Patent in the Territory, which infringing activity involves the using, making, importing, exporting, offering for sale or selling Products or products that otherwise are competitive with Products, (ii) a declaratory judgment action asserting the invalidity, unenforceability or non- infringement of any Pfenex Patent in the Territory in connection with any infringement described in clause (i), or (iii) an application for a Biosimilar Product (defined below) referencing a Product submitted to a Party or a Regulatory Authority for Regulatory Approval (each of (i), (ii), and (iii) a "**Product Infringement**"), it shall promptly notify the other Party in writing to that effect, and the Parties will consult with each other regarding any actions to be taken with respect to such Product Infringement. For purpose of this definition, "**Biosimilar Product**" means, with respect to a particular Product in a particular country in the Territory, any pharmaceutical product that is claimed to be biosimilar to or interchangeable with such Product (including a product that is the subject of an application submitted under Section 351(k) of the Public Health Service Act as set forth at 42 U.S.C. Chapter 6A, as amended, citing the Product as the reference product) or for which the BLA otherwise references or relies on such Product or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval.

(b) Enforcement Rights. For any Product Infringement, each Party shall share with the other Party all information available to it that may be shared subject to Third Party obligations regarding such alleged infringement, pursuant to a mutually agreeable "common interest agreement" executed by the Parties under which the Parties agree to their shared, mutual interest in the outcome of any suit to enforce the Pfenex Patents against such Product Infringement.

(i) Jazz shall have the first right, but not the obligation, to bring an appropriate suit or take other action against any person or entity engaged in, or to defend against, a Product Infringement to the extent involving infringement of (A) any Pfenex Product-Specific Patent and (B) any Pfenex General Product Patent. Jazz shall consult with Pfenex and keep Pfenex reasonably informed of the status of the enforcement of such Pfenex Product-Specific Patent or Pfenex General Product Patent, as the case may be. Jazz shall consider Pfenex's comments with respect to the enforcement of such Pfenex General Product Patent in good faith. Jazz shall not settle any such suit or action without providing Pfenex an opportunity to review and comment on such proposed settlement. Jazz shall not settle any such suit or action with respect to a Pfenex General Product Patent if Pfenex promptly notifies Jazz that it reasonably and in good faith believes that doing so would cause a material adverse effect on Pfenex's intellectual property rights covering products other than a Product.

(ii) If Jazz does not, within one hundred eighty (180) days after its receipt or delivery of notice under Section 7.4(a), commence a suit to enforce an applicable Pfenex Sole Patent, take other action to terminate such Product Infringement with respect to an applicable Pfenex Sole Patent, or initiate a defense against such Product Infringement with respect to an applicable Pfenex Sole Patent, then upon Jazz's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, Pfenex shall have the right, but not the obligation, to commence such a suit or take such an action to enforce the applicable Pfenex Sole Patent. In such event, Jazz shall take appropriate actions in order to enable Pfenex to commence a suit or take the actions set forth in the preceding sentence. Pfenex shall not settle any such suit or action in any manner that would negatively impact the applicable Pfenex Sole Patent or that would limit or restrict the ability of Jazz to sell Products anywhere in the Territory without the prior written consent of Jazz.

(c) Collaboration. Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff to ensure legal standing if required by applicable Laws to pursue such action or if requested by the enforcing Party. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any such efforts. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) Expenses and Recoveries. The Party bringing or defending a claim, suit or action under Section 7.4(b) shall be solely responsible for any expenses incurred by such Party as a result of such claim, suit or action. If such enforcing Party recovers monetary damages in such claim, suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel), and any remaining amounts shall be allocated as follows: (i) if Jazz is the enforcing or defending Party, the remaining amounts will be retained by Jazz, except that any imputed lost sales upon which such amounts were calculated shall be included in Net Sales subject to the royalty payment by Jazz to Pfenex pursuant to Section 6.5, and (ii) if Pfenex is the enforcing or defending Party, the remaining amounts will be shared equally by Pfenex and by Jazz.

7.5 Enforcement of Jazz Sole Patents and Joint Patents. Jazz shall have the sole right, but not the obligation, in the case of the Jazz Sole Patents and the first right, but not the obligation, in the case of the Joint Patents to bring an appropriate suit or other action against any person or entity allegedly infringing any Jazz Sole Patents or Joint Patents, as the case may be, and to defend against any declaratory judgment action against any Jazz Sole Patents or Joint Patents, as the case may be. In the case of any existing or threatened infringement of any Joint Patent in the Territory that does not involve the using, making, importing, exporting, offering for sale or selling Products or products that otherwise are competitive with Products, if Jazz does not, within one hundred eighty (180) days after written request by Pfenex, commence a suit to enforce an applicable Joint Patent or take other action to terminate such infringement with respect to an applicable Joint Patent, then Pfenex shall have the right, but not the obligation, to commence such a suit or take such other action to enforce the applicable Joint Patent. Each Party shall provide reasonable assistance to the enforcing Party in such enforcement or defense, at such enforcing Party's request and expense, including joining such action as a party plaintiff to ensure legal standing if required by applicable Laws to pursue such action or if requested by such enforcing Party. If such enforcing Party recovers monetary damages in such claim, suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel), and any remaining amounts shall be retained by such enforcing Party.

7.6 Patent Term Extensions. Pfenex shall cooperate with Jazz, at Jazz's request, in seeking and obtaining patent term extensions (including any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country with respect to any Pfenex Product-Specific Patents and Products. If elections with respect to obtaining such patent term extensions are to be made, Jazz shall consider in good faith any comments provided by Pfenex in regard to such elections, provided that Jazz have the sole right to make such elections with respect to any Pfenex Product-Specific Patents. Pfenex shall further cooperate with Jazz, at Jazz's request, in seeking and obtaining patent term extensions (including any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country with respect to any Pfenex General Product Patents and Products, which Pfenex shall file and manage in good faith unless Pfenex has previously extended the applicable Pfenex General Product Patent in connection with any product other than the applicable Product.

7.7 Personnel Obligations. Prior to beginning work under this Agreement relating to any Development of a Product, each employee, agent or independent contractor of a Party or its Affiliates shall be bound by invention assignment obligations that are consistent with the obligations of such Party in this Article 7, including: (a) promptly reporting any invention, discovery, process or other intellectual property right; (b) assigning to such Party all of the right, title and interest in and to any invention, discovery, process or other intellectual property right; (c) cooperating in the preparation, filing, prosecution, maintenance and enforcement of any Patent; (d) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement; and (e) complying with obligations of confidentiality and non-use consistent with those contained in this Agreement.

7.8 Trademarks. Jazz and its Affiliates and sublicensees shall have the right to brand the Products in the Territory using any trademarks it determines appropriate for the Products, which may vary by country or within a country (the "**Product Marks**"), provided that Jazz shall not, and shall ensure that its Affiliates and sublicensees will not make any use of the trademarks or house marks of Pfenex (including Pfenex's corporate name) or any trademark confusingly similar thereto (except to the extent required by applicable Laws (e.g., to indicate the manufacturer of the Product)). As between the Parties, Jazz shall own all rights in the Product Marks and shall register and maintain, in its discretion and at its own cost and expense, the Product Marks in the countries and regions in the Territory that it determines to be appropriate. Jazz shall have the sole right, in its discretion and at its expense, to defend and enforce the Product Marks. Pfenex shall not, and shall ensure that its Affiliates and sublicensees will not, file or use any trademark confusingly similar to the Product Marks.

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ARTICLE 8
REPRESENTATIONS AND WARRANTIES; COVENANTS

8.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows:

(a) Corporate Existence. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated or otherwise formed.

(b) Corporate Power, Authority and Binding Agreement. As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) No Conflicts. It has not entered, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted by it under this Agreement, and has not taken and shall not take any action that would in any way prevent it from granting the rights granted to, or contemplated to be granted to, the other Party under this Agreement, or that would otherwise materially conflict with or adversely affect such other Party's rights under this Agreement.

(d) No Debarment. As of the Effective Date, none of its employees, consultants or contractors is debarred by any Regulatory Authority or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

8.2 Additional Representations and Warranties of Pfenex. Pfenex represents and warrants and, as applicable, covenants to Jazz as follows, as of the Effective Date:

(a) Title; Encumbrances. Pfenex Controls the Patents listed on **Exhibit A** and other intellectual property rights within the Pfenex IP, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreements, and, to Pfenex's knowledge, other encumbrances, charges or claims of any kind, subject to the terms and conditions of the Third Party Agreements. Pfenex has the full and legal rights and authority to license to Jazz the Pfenex IP for the purposes expressly provided in this Agreement.

(b) Patent Matters. **Exhibit A** is an accurate listing by owner, inventor(s), serial number, filing date, country, and status of all patents and patent applications Controlled by Pfenex as of the Effective Date that may be necessary or useful for the development, manufacture, use, offer for sale, sale or import of the Products as contemplated herein.

(c) Control. Pfenex Controls and shall Control throughout the Term (i) all Patents listed on **Exhibit A**, and (ii) all data and technical information owned, generated or licensed by Pfenex that is related to any Product, in each case subject to the terms and conditions of the Third Party Agreements.

(d) Validity. There is no fact or circumstance known to Pfenex that would cause Pfenex to reasonably conclude that any of the issued patents in the Pfenex Patents is invalid or unenforceable.

(e) Inventorship. To Pfenex's knowledge, the inventorship of each Pfenex Patent is properly identified on the corresponding patent or patent application.

(f) Good Standing. All official fees, maintenance fees and annuities for the Pfenex Patents have been paid and all administrative procedures with Governmental Authorities are in process or have been completed for the Pfenex Patents such that the Pfenex Patents are pending, subsisting or in good standing.

(g) Duty of Disclosure. Pfenex has complied with the U.S. PTO duty of disclosure with respect to the prosecution of all of the Pfenex Patents for which Pfenex controls the prosecution. To Pfenex's knowledge, all Third Parties that control the prosecution of a Pfenex Patent have complied with the U.S. PTO duty of disclosure.

(h) Notice of Infringement. Pfenex has not received any written notice or written threat from any Third Party asserting or alleging, nor does Pfenex have any knowledge of any basis for any assertion or allegation, that any use of any Pfenex IP by Pfenex prior to the Effective Date infringed or would infringe the issued Patents of such Third Party.

(i) Notice of Misappropriation. Pfenex has not received any written notice or written threat from any Third Party asserting or alleging, nor does Pfenex have any knowledge of any basis for any assertion or allegation, that any use or creation of Pfenex IP by Pfenex prior to the Effective Date misappropriated the intellectual property rights of such Third Party.

(j) Third Party Technology. To Pfenex's knowledge, the manufacture, Development, and Commercialization of Products (excluding any Half-Life Extension Component incorporated into any Product), and the use of Pfenex's proprietary *P. fluorescens* expression technology, in each case as contemplated herein, does not infringe any valid and enforceable issued Patent of a Third Party.

(k) Third Party Infringement. To Pfenex's knowledge, no Third Party is infringing or has infringed any issued Pfenex Patent or has misappropriated any Pfenex Know-How.

(l) No Proceeding. There are no pending, and to Pfenex's knowledge, no threatened, adverse actions, suits or proceedings (including interferences, reissues, reexaminations, cancellations, oppositions, nullity actions, invalidation actions or post-grant reviews) against Pfenex involving the Pfenex IP or Products.

(m) Contracts. Pfenex has irrevocably terminated all rights granted to Agila Biotech Private Limited with respect to the Pegaspargase Product, and a copy of the documentation effecting such termination has been provided to Jazz.

8.3 Mutual Covenants.

(a) No Debarment. In the course of the Development of the Products, neither Party shall use any employee or consultant who has been debarred by any Regulatory Authority or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority. Each Party shall notify the other Party in writing promptly upon becoming aware that any of its employees or consultants has been debarred or is the subject of debarment proceedings by any Regulatory Authority.

(b) Compliance. Each Party and its Affiliates (and, in the case of Jazz, other Selling Parties) shall comply in all material respects with all Laws applicable to the Development, manufacture and Commercialization of Products and performance of its obligations under this Agreement, including, to the extent applicable, the statutes, regulations and written directives of the FDA (including GCP, GLP, and GMP), the EMA and any Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law, 42 U.S.C. § 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other health care programs, as defined in 42 U.S.C. § 1320a-7b(f), and the Foreign Corrupt Practices Act of 1977, each as may be amended from time to time.

8.4 Disclaimer. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

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ARTICLE 9
INDEMNIFICATION

9.1 Indemnification by Pfenex. Pfenex shall defend, indemnify, and hold harmless Jazz and its Affiliates and their respective officers, directors, employees, and agents (the "**Jazz Indemnitees**") from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such Jazz Indemnitees, resulting from any claims, suits, proceedings or causes of action brought by such Third Party (collectively, "**Claims**") against such Jazz Indemnitee to the extent arising from or based on (a) the Development or manufacture of Products by or on behalf of Pfenex or its Affiliates or sublicensees prior to the Effective Date, (b) Pfenex's and its Affiliates' performance of the activities allocated to Pfenex under the applicable Development Plan, including the manufacture of Products, (c) the breach of any of Pfenex's obligations, representations or warranties under this Agreement, or (d) the willful misconduct or negligent acts of Pfenex, its Affiliates, or the officers, directors, employees, or agents of Pfenex or its Affiliates in connection with this Agreement. The foregoing indemnity obligation shall not apply to the extent that (i) the Jazz Indemnitees fail to comply with the indemnification procedures set forth in Section 9.3 and Pfenex's defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from or is based on any activity set forth in Section 9.2 for which Jazz is obligated to indemnify the Pfenex Indemnitees under Section 9.2.

9.2 Indemnification by Jazz. Jazz shall defend, indemnify, and hold harmless Pfenex and its Affiliates and their respective officers, directors, employees, and agents (the "**Pfenex Indemnitees**") from and against damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such Pfenex Indemnitees, resulting from any Claims against such Pfenex Indemnitee to the extent arising from or based on (a) the Development, manufacture or Commercialization of Products by or on behalf of Jazz or its Affiliates or sublicensees (in each case other than by Pfenex), (b) the breach of any of Jazz's obligations, representations or warranties under this Agreement, or (c) the willful misconduct or negligent acts of Jazz, its Affiliates, or the officers, directors, employees, or agents of Jazz or its Affiliates in connection with this Agreement. The foregoing indemnity obligation shall not apply to the extent that (i) the Pfenex Indemnitees fail to comply with the indemnification procedures set forth in Section 9.3 and Jazz's defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from or is based on any activity set forth in Section 9.1 for which Pfenex is obligated to indemnify the Jazz Indemnitees under Section 9.1.

9.3 Indemnification Procedures. The Party claiming indemnity under this Article 9 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. Unless the settlement involves only the payment of money, the Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, such consent not to be unreasonably withheld, conditioned or delayed. So long as the Indemnifying Party is conducting the defense of the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 9.

9.4 Insurance. Each Party shall procure and maintain product liability insurance of at least [***] at all times during which any Product is being clinically tested in human subjects and of at least [***] at all times during which any Product is being commercially distributed or sold by such Party and for the five (5)-year period thereafter. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 9. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation or non-renewal of such insurance.

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ARTICLE 10
CONFIDENTIALITY

10.1 Confidentiality. Each Party agrees that, during the Term and for a period of ten (10) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it by the other Party pursuant to this Agreement, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application or use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

As between the Parties, each Party shall own its Confidential Information.

10.2 Authorized Disclosure. Notwithstanding the obligations set forth in Section 10.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary to its employees, agents, consultants, contractors, licensees or sublicensees on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement; or

(b) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, licensee, sublicensee, or other financial or commercial partner for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; provided that in connection with such disclosure, such Party shall use all reasonable efforts to inform each disclosee of the confidential nature of such Confidential Information and, in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement; or

(c) such disclosure is reasonably necessary to comply with applicable Laws, rules or regulations promulgated by Governmental Authorities or applicable securities exchanges, court order, or administrative subpoena or order; provided that the Party subject to such Laws, rules, regulations, court order, or administrative subpoena or order shall (i) promptly notify the other Party prior to making such required disclosure; (ii) provide reasonable prior advance notice of the proposed text of such disclosure to the other Party for its prior review; (iii) use good faith efforts to incorporate the reviewing Party's reasonable comments thereon and (iv) use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

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10.3 Technical Publication. Pfenex may not publish peer reviewed manuscripts, or provide other forms of public disclosure including abstracts and presentations, of results of studies carried out under the Development Plans, or otherwise pertaining to a Product, without the prior written consent of Jazz. Commencing upon (a) the end of the Assessment Period for a HemOnc Product for which Jazz has not provided a Declination Notice in the case of each HemOnc Product and (b) Option Exercise in the case of the Pegaspargase Product, Jazz shall have the right to publish and otherwise publicly disclose peer reviewed manuscripts, or provide other forms of public disclosure including abstracts and presentations, of results of studies carried out by or on behalf of Jazz under the Development Plan for the applicable Product concerning the Development and Commercialization of such Product, including on clinicaltrials.gov, subject to compliance with this Section 10.3. In the event that Jazz desires to make such a publication or public presentation of a technical nature describing the manufacturing process of a Product, it shall provide Pfenex with at least ten (10) days to review and comment on such proposed publication or presentation prior to its submission for publication or presentation. Pfenex shall have the right to delay publication or presentation for up to an additional thirty (30) days in order to enable patent applications protecting each Party's rights in such Information to be filed, and Pfenex shall also have the right to prohibit the disclosure of any of its Confidential Information contained in any such proposed publication or presentation. In any permitted publication or presentation by a Party, the other Party's contribution shall be duly recognized, and co-authorship shall be determined, in accordance with customary standards.

10.4 Publicity; Term of Agreement.

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 10.4 or Section 10.2.

(b) The Parties agree to issue a joint press release announcing the execution of this Agreement promptly after the Effective Date in the form attached hereto as **Exhibit 10.4(b)**.

(c) After release of such press release, if either Party desires to make a public announcement concerning the material terms of this Agreement or any activities hereunder, including announcement of the achievement of milestones under Section 6.3 and the magnitude of payments associated therewith, such Party shall give reasonable prior advance notice (which in any case shall be at least three (3) Business Days) of the proposed text of such announcement to the other Party for its prior review and approval (which approval shall not be unreasonably withheld, conditioned or delayed) and shall use good faith efforts to incorporate the other Party's reasonable comments thereon, except that in the case of a public announcement required by Laws, the disclosing Party shall provide the other Party with such advance notice as it reasonably can and shall not be required to obtain approval therefor. Notwithstanding the foregoing, (i) Pfenex may not, in any public announcement with respect to this Agreement, [***] without Jazz's prior written consent and (ii) Jazz may not, in any public announcement with respect to this Agreement, [***] without providing prior written notice to Pfenex and reasonably coordinating with Pfenex regarding such public announcement. A Party commenting on such a proposed public announcement shall provide its comments, if any, within three (3) Business Days after receiving the text of the public announcement for review. Neither Party shall be required to seek the permission of the other Party to repeat any information that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 10.4(c), provided such information remains accurate as of such time.

(d) The Parties acknowledge that either or both Parties may be obligated to file under applicable Laws or rules or regulations promulgated by Governmental Authorities or applicable securities exchanges a copy of this Agreement with the U.S. Securities and Exchange Commission or other Governmental Authorities. In the event that a Party determines in good faith that such a filing is required, such Party shall request confidential treatment of all confidential information herein, including the sensitive commercial, financial and technical terms hereof, to the extent such confidential treatment may be reasonably available to such Party. In the event of any such filing, the filing Party shall provide the other Party with a copy of this Agreement marked to show provisions for which such filing Party intends to seek confidential treatment within a reasonable amount of time prior to filing and shall use good faith efforts to incorporate the other Party's reasonable comments thereon to the extent consistent with applicable Laws or rules or regulations promulgated by Governmental Authorities or applicable securities exchanges. Each Party shall be responsible for its own legal and other external costs in connection with any such filing.

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ARTICLE 11
TERM AND TERMINATION

11.1 Term. The term of this Agreement (the "**Term**") shall commence on the Effective Date and, unless earlier terminated pursuant to this Agreement, shall continue on a Product-by-Product basis for so long as such Product is being Developed or Commercialized under and in accordance with this Agreement.

11.2 Unilateral Termination by Jazz. Jazz may terminate this Agreement, on a Product-by-Product basis or in its entirety, for any or no reason upon ninety (90) days' written notice to Pfenex.

11.3 Termination by Either Party for Breach.

(a) Breach. Subject to Section 11.3(b) and 11.3(c), each Party shall have the right to terminate this Agreement upon written notice to the other Party in the event such other Party materially breaches this Agreement and, after receiving written notice from the non-breaching Party identifying such material breach in reasonable detail, fails to cure such material breach within ninety (90) days from the date of such notice; provided that if such breach is not reasonably capable of cure within such time period, the breaching Party may submit a reasonable cure plan prior to the end of such time period, in which case the other Party shall not have the right to terminate this Agreement for up to an additional ninety (90) days so long as the breaching Party is using Commercially Reasonable Efforts to implement such cure plan.

(b) Disputed Breach. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 11.3(a), and such alleged breaching Party provides the other Party notice of such dispute within the ninety (90)-day cure period, then the non-breaching Party shall not have the right to terminate this Agreement under Section 11.3(a) unless and until an arbitrator, in accordance with Article 12, has determined that the alleged breaching Party has materially breached this Agreement and that such Party fails to cure such breach within ninety (90) days following such arbitrator's decision. It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

(c) Product-by-Product Termination. If the uncured material breach pertains to less than all of the Product(s), then termination under this Section 11.3 shall apply only with respect to such Product(s), and the non-breaching Party shall not have the right to terminate this Agreement in its entirety or with respect to the other Product(s) not affected by such breach. Without limiting the generality of the foregoing, the Parties' rights and obligations hereunder with respect to the Pegaspargase Product shall not be affected by termination of this Agreement with respect to one or both HemOnc Products, and the Parties' rights and obligations hereunder to the HemOnc Products shall not be affected by termination of this Agreement with respect to the Pegaspargase Product.

11.4 Effects of Unilateral Termination by Jazz. If this Agreement is terminated by Jazz under Section 11.2 in its entirety or with respect to one or both of the HemOnc Products or the Pegaspargase Product then the following terms shall apply:

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(a) HemOnc-Pf.

(i) Prior to Assessment Period Expiry. Upon any notice of termination of HemOnc-Pf delivered prior to the expiration of the Assessment Period for HemOnc-Pf, Jazz shall have the obligations under this Section 11.4(a)(i). Prior to the effective date of termination, Jazz shall provide Pfenex with access to all HemOnc-Pf data Controlled by Jazz that was generated by Jazz pursuant to this Agreement (the "**Jazz HemOnc-Pf Data**"). Pfenex shall have the option, exercisable within thirty (30) days following the delivery of the Jazz HemOnc-Pf Data to Pfenex by Jazz, to notify Jazz whether Pfenex desires to license (including the right to use and disclose to Third Parties) the Jazz HemOnc-Pf Data on an exclusive basis (subject to the Jazz Retained Data Rights, as defined below) solely for the development, manufacture and commercialization in the Territory of HemOnc-Pf. Jazz retains exclusive ownership of the Jazz HemOnc-Pf Data and the right to use the Jazz HemOnc-Pf Data for any and all purposes not expressly granted to Pfenex, provided that Jazz shall not disclose the Jazz HemOnc-Pf Data to any Third Party other than (A) to Third Party collaborators for any product other than HemOnc-Pf (provided that all such Third Party collaborators are subject to (x) confidentiality obligations consistent with those contained in this Agreement and (y) use restrictions that limit such Third Party collaborators' use of the Jazz HemOnc-Pf Data solely to the purposes of the collaboration and exclude any use with respect to HemOnc-Pf), (B) to any Regulatory Authority to the extent required to comply with applicable Laws or where requested by Regulatory Authorities, in which case Jazz shall promptly notify Pfenex of such requirement under applicable Laws and, to the extent practicable and permitted under applicable Laws, shall submit any proposed communication to Pfenex for prior approval (such approval not to be unreasonably withheld, conditioned, or delayed) or, if not practicable or permitted, shall provide Pfenex with a copy or summary thereof as soon as reasonably practicable thereafter, and (C) to any Governmental Authority as reasonably necessary in connection with the prosecution or maintenance of any Jazz Sole Patent or Joint Patent (the "**Jazz Retained Data Rights**"). If Pfenex elects to license the Jazz HemOnc-Pf Data, Pfenex shall pay Jazz for Pfenex's license to the Jazz HemOnc-Pf Data in an amount equal to [***], to be paid by Pfenex to Jazz in semi-annual installments over the immediate three (3)-year period following the effective date of termination, and Pfenex shall be bound by the indemnification and insurance provisions set forth on **Exhibit 11.4(a)(i)**. If Pfenex fails to timely pay Jazz any of the foregoing payments within thirty (30) days following written notice from Jazz to Pfenex of such payment default, Pfenex's license to the Jazz HemOnc-Pf Data will immediately terminate. In the event of a termination of this Agreement with respect to all HemOnc Products, Pfenex shall have the right to license the applicable data generated on a HemOnc Product-by-HemOnc Product basis, provided that Pfenex pays the amount set forth in Section 11.4 with respect to each such HemOnc Product for which such data is licensed.

(ii) Following Assessment Period Expiry. Upon any notice of termination of HemOnc-Pf delivered following the expiration of the Assessment Period for HemOnc-Pf, Jazz shall have the obligations under this Section 11.4(a)(ii).

(A) Prior to the effective date of termination, Jazz shall provide Pfenex with access to the Jazz HemOnc-Pf Data. Pfenex shall have the option, exercisable within thirty (30) days following the delivery of the Jazz HemOnc-Pf Data to Pfenex by Jazz, to notify Jazz whether Pfenex desires to license (including the right to use and disclose to Third Parties) the Jazz HemOnc-Pf Data on an exclusive basis (subject to the Jazz Retained Data Rights) solely for the development, manufacture and commercialization in the Territory of HemOnc-Pf. If Pfenex elects to license the Jazz HemOnc-Pf Data, Pfenex shall pay Jazz for Pfenex's license to the Jazz HemOnc-Pf Data in an amount equal to [***], to be paid by Pfenex to Jazz in semi-annual installments over the immediate three (3)- year period following the effective date of termination, and Pfenex shall be bound by the indemnification and insurance provisions set forth on **Exhibit 11.4(a)(i)**. If Pfenex fails to timely pay Jazz any of the foregoing payments within thirty (30) days following written notice from Jazz to Pfenex of such payment default, Pfenex's license to the Jazz HemOnc-Pf Data will immediately terminate.

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(B) If, at the time of such termination, Jazz is then clinically developing a product containing [***] (such product, the "**Alternative Product**") and Pfenex elected to license the Jazz HemOnc-Pf Data under subsection (A) above, then Jazz will pay to Pfenex a royalty of [***] of net sales of such Alternative Product for the shorter of (x) a period equal to the sum of six (6) months plus the number of months that, as of the termination, the Alternative Product is ahead of the development of HemOnc-Pf under this Agreement or (y) five (5) years from first commercial sale of such Alternative Product anywhere in the world. For purposes of Section 11.4(a)(ii)(B)(x), "ahead" means a reasonable estimate of the number of months that it would have taken HemOnc-Pf, following the effective date of termination, to attain a comparable stage of development as such Alternative Product (taking into account the relevant regulatory and technical differences, if any) as of the effective date of termination, as agreed by the Parties in writing after good faith negotiation, subject to resolution by baseball arbitration pursuant to Section 12.2(b) if the Parties are unable to agree upon such estimated number of months within sixty (60) days after the effective date of termination. For purposes of such royalty, the terms "net sales" and "first commercial sale" with respect to such Alternative Product shall have the same meanings as "Net Sales" and "First Commercial Sale," respectively, under this Agreement, and such royalty shall be paid in accordance with Sections 6.5(d), 6.7, 6.8, 6.9 and 6.10, in each case *mutatis mutandis*. The obligation to make such royalty payments to Pfenex is conditioned upon Pfenex meeting its payment obligation under subsection (A) above and shall continue for the stated period only for so long as Pfenex is using Commercially Reasonable Efforts to continue the development and commercialization of the terminated HemOnc-Pf product. Pfenex shall provide Jazz with semi-annual reports with respect to such continued development and commercialization and notify Jazz if such development or commercialization is discontinued for more than a three (3)-month period. Jazz shall have the right to set off from any such royalty an amount equal to the development costs owed and not yet paid by Pfenex under subsection (A) above.

(iii) Election Not to License Jazz HemOnc-Pf Data. If Pfenex elects not to license the Jazz HemOnc-Pf Data, then it shall immediately return or destroy the Jazz HemOnc-Pf Data, at Jazz's option, and Pfenex may not use the Jazz HemOnc-Pf Data for any purpose. Further, if Pfenex elects not to license the Jazz HemOnc-Pf Data and the termination of HemOnc-Pf occurs after commencement of the Assessment Period for HemOnc-Pf but before the earlier of (A) twelve (12) months after the expiration of such Assessment Period or (B) payment of milestone 3 in **Exhibit 6.3** for HemOnc-Pf, then Jazz shall pay to Pfenex the amount of [***] within thirty (30) days following notice of such election by Pfenex.

(b) HemOnc-NextGen.

(i) Access to Data. Upon any notice of termination of HemOnc-NextGen, Jazz shall have the obligations under this Section 11.4(b). Prior to the effective date of termination, Jazz shall provide Pfenex with access to all HemOnc-NextGen data Controlled by Jazz that was generated by Jazz pursuant to this Agreement (the "**Jazz HemOnc-NextGen Data**"). For clarity, the Jazz HemOnc-NextGen Data excludes the Jazz Extension IP. Pfenex shall have the option, exercisable within thirty (30) days following the delivery of the Jazz HemOnc-NextGen Data to Pfenex by Jazz (which period may be extended by Pfenex as reasonably necessary (not to exceed an additional ninety (90) days) for Pfenex to negotiate a direct license from any Third Party that Controls the intellectual property claiming the Half-Life Extension Component included in HemOnc-NextGen, as described below), to license (including the right to use and disclose to Third Parties) the Jazz HemOnc-NextGen Data on an exclusive basis (subject to the Jazz Retained Data Rights, as applied *mutatis mutandis* with respect to the Jazz HemOnc-NextGen Data) solely for the development, manufacture and commercialization in the Territory of HemOnc-NextGen. Upon Pfenex's exercise of such option with respect to the Jazz HemOnc- NextGen Data, Jazz shall negotiate in good faith with Pfenex, for a period of no more than sixty (60) days or such longer period as mutually agreed by the Parties, the payment terms and conditions for such license, subject to Section 11.4(b)(ii) below. Any license granted under this Section 11.4(b)(i) shall also be subject to the indemnification and insurance provisions set forth on **Exhibit 11.4(a)(i)**. In connection with Pfenex's exercise of such option with respect to the Jazz HemOnc-NextGen Data, Pfenex may notify Jazz that it desires to obtain rights to the Jazz Extension IP. Upon such notification and concurrently with the negotiation of a definitive agreement for the Jazz HemOnc-NextGen Data, Jazz shall negotiate in good faith with Pfenex to include in such definitive agreement an exclusive license to that portion of the Jazz Extension IP that is owned by Jazz solely as to the development, manufacture, and commercialization in the Territory of HemOnc-NextGen, subject to Section 11.4(b)(ii) below. In addition, Pfenex shall use good faith and reasonable efforts to obtain a direct license from

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any Third Party that Controls the intellectual property claiming the Half-Life Extension Component included in HemOnc-NextGen, and upon Pfenex's request, Jazz shall facilitate an introduction of Pfenex to such Third Party. To the extent that Pfenex is unable to obtain such a license from such Third Party after using such good faith and reasonable efforts, Jazz shall, to the extent permitted under its license agreement with such Third Party, either assign or license (in Jazz's sole discretion) to Pfenex its right, title, and interest in and to such Third Party license agreement, to the extent necessary for Pfenex to Develop, manufacture and Commercialize HemOnc-NextGen in the Territory. Pfenex shall reimburse Jazz for any amounts payable by Jazz to any Third Party in connection with such assignment of or license to such Third Party license agreement, and Pfenex shall not owe Jazz any additional consideration in connection with Pfenex's practice of such license.

(ii) Payment Terms.

(A) Prior to Expiry of Assessment Period. If such termination with respect to HemOnc-NextGen occurs prior to the expiration of the Assessment Period for HemOnc-NextGen, the payment terms of such license to the Jazz HemOnc-NextGen Data shall be limited to Pfenex paying Jazz for Pfenex's license to such data in an amount equal to [***], which amounts shall be paid by Pfenex to Jazz in semi-annual installments over the immediate three (3)-year period following the effective date of termination. If Pfenex fails to timely pay Jazz any of the foregoing payments within thirty (30) days following written notice from Jazz to Pfenex of such payment default, Pfenex's license to such data will immediately terminate.

(B) Following Expiry of Assessment Period. If such termination with respect to HemOnc-NextGen occurs after the expiration of the Assessment Period for HemOnc-NextGen, the payment terms of such license to the Jazz HemOnc-NextGen Data shall be negotiated in good faith as set forth in Section 11.4(b)(i). If the Parties are unable to agree on such payment terms and execute an agreement with respect to the Jazz HemOnc-NextGen Data during such sixty (60) day negotiation period, Pfenex shall have the right to have such payment terms determined by baseball arbitration pursuant to Section 12.2(b).

(C) Election Not to License Jazz HemOnc-NextGen Data. If Pfenex elects not to license the Jazz HemOnc- NextGen Data, then it shall immediately return or destroy such data, at Jazz's option, and Pfenex may not use the Jazz HemOnc- NextGen Data for any purpose. Further, if Pfenex elects not to license the Jazz HemOnc-NextGen Data and the termination of HemOnc-NextGen occurs after commencement of the Assessment Period for HemOnc-NextGen but before the earlier of (A) twelve (12) months after the expiration of such Assessment Period or (B) payment of milestone 3 in **Exhibit 6.3** for HemOnc-NextGen, then Jazz shall pay to Pfenex the amount of [***] within thirty (30) days following Pfenex's election notice or within thirty (30) days of the expiration or early termination of the negotiation period, as applicable.

(c) Pegaspargase Product. If Jazz terminates its rights hereunder with respect to the Pegaspargase Product prior to Option Exercise, then the Option shall terminate and the Parties' obligations under this Agreement with respect to the Pegaspargase Product shall terminate.

11.5 Effects of Other Termination.

(a) General. Upon any termination of this Agreement in its entirety (i.e., with respect to all Products) or in part (i.e., with respect to one or more, but not all, Products), the licenses and other rights and obligations under of this Agreement applicable to the terminated Product(s) shall terminate, except for the licenses granted in Section 7.1(f), which shall survive any termination.

(b) Termination by Jazz for Pfenex's Breach. If Jazz terminates this Agreement in its entirety or for a Product on account of Pfenex's uncured material breach with respect to a particular Product, then Pfenex will not have any rights with respect to any data generated by Jazz with respect to any terminated Product(s) (or all of the Products if this Agreement is terminated in its entirety), and Jazz will have no further obligation to Pfenex with respect to any such terminated Product(s) under this Section 11.5.

(c) Termination by Pfenex for Jazz's Breach. With respect to termination by Pfenex of this Agreement for one or more Products on account of Jazz's uncured material breach with respect to such Product(s):

(i) if Pfenex terminates with respect to HemOnc-Pf prior to the expiry of the Assessment Period for HemOnc-Pf, then Section 11.4(a)(i) applies;

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(ii) if Pfenex terminates with respect to HemOnc-Pf following the expiry of the Assessment Period for HemOnc-Pf, then Section 11.4(a)(ii) applies;

(iii) if Pfenex terminates with respect to HemOnc-NextGen prior to the expiry of the Assessment Period for HemOnc-NextGen, then Sections 11.4(b)(i) and 11.4(b)(ii)(A) apply;

(iv) if Pfenex terminates with respect to HemOnc-NextGen following the expiry of the Assessment Period for HemOnc-NextGen, then Sections 11.4(b)(i) and 11.4(b)(ii)(B) apply;

(v) if Pfenex terminates with respect to the Pegaspargase Product, then Section 11.4(c) applies;

in each instance of the above, with the same effect as if Jazz had terminated this Agreement with respect to such Product pursuant to Section 11.2.

(d) Termination of All Products. For clarity, if this Agreement has been terminated on a Product-by-Product basis such that all Products have been terminated, then this Agreement thereupon shall be deemed to have been terminated in its entirety and the ROFN thereupon shall be deemed to have terminated with respect to all ROFN Products, except with respect to any ROFN Exercise (and subject to the terms and conditions of the corresponding ROFN Exercise Agreement) that may have occurred prior to the effective date of such termination of this Agreement.

11.6 Survival. Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: Article 1 (to the extent defined terms are contained in the following surviving Articles and Sections), Section 2.3, Section 4.5, Section 6.9, Article 6 (solely with respect to those payments that accrued prior to the effective date of termination or expiration), Section 7.1, Section 8.4, Article 9 (with respect to any matter, fact or circumstance arising or existing prior to the termination or expiration of this Agreement), Article 10, this Section 11.6, Article 12 and Sections 13.3, 13.4, 13.5, and 13.12.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

ARTICLE 12
DISPUTE RESOLUTION

12.1 Disputes. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement (other than disputes arising from the JDC, which shall be resolved in accordance with Section 3.3), including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement (each, a "**Dispute**"), then upon the request of either Party by written notice, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting (or telephone call if an in-person meeting is impractical) between the Parties' respective Executive Officers. If the matter is not resolved within thirty (30) days following the written request for discussions, either Party may then invoke the provisions of Section 12.2.

12.2 Arbitration.

(a) JAMS. Any Dispute that is not resolved pursuant to Section 12.1, except for a dispute, claim or controversy under Section 12.9, shall be settled by binding arbitration administered by JAMS before one arbitrator pursuant to the Streamlined Arbitration Rules and Procedures of JAMS then in effect (the "**JAMS Rules**"), except as otherwise provided herein. The arbitration shall be governed by the U.S. Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the "**Federal Arbitration Act**"), to the exclusion of any inconsistent state laws. The arbitration will be conducted in Los Angeles, California, and the Parties consent to the personal jurisdiction of the U.S. federal courts, for any case arising out of or otherwise related to this arbitration, its conduct and its enforcement. The language to be used in the arbitral proceedings will be English.

(b) Baseball Arbitration. This Section 12.2(b) shall apply to Disputes identified under Sections 2.4(e), 2.5(c)(i), 11.4(a)(ii)(B) and 11.4(b)(ii)(B) as to be resolved by baseball arbitration. Baseball arbitration will be conducted by one (1) arbitrator who shall be reasonably acceptable to the Parties and who shall be appointed in accordance with JAMS Rules. If the Parties are unable to select an arbitrator within ten (10) days, then the arbitrator shall be appointed in accordance with JAMS Rules. Any arbitrator chosen hereunder shall have educational training and industry experience sufficient to demonstrate a reasonable level of scientific, financial, medical and industry knowledge relevant to the Dispute. Within twenty (20) days after the selection of the arbitrator, each Party shall submit to the arbitrator and the other Party a proposed resolution of the Dispute that is the subject of the arbitration, together with any relevant evidence in support thereof (the "**Proposals**"). Within fifteen (15) days after the delivery of the last Proposal to the arbitrator, each Party may submit a written rebuttal of the other Party's Proposal and may also amend and re-submit its original Proposal. The Parties and the arbitrator shall meet within fifteen (15) days after the Parties have submitted their final Proposals (and rebuttals, if any), at which time each Party shall have one (1) hour to argue in support of its Proposal. The Parties shall not have the right to call any witnesses in support of their arguments, nor compel any production of documents or take any discovery from the other Party in preparation for the meeting. Within thirty (30) days after such meeting, the arbitrator shall select one of the final Proposals so submitted by one of the Parties as the resolution of the Dispute, but may not alter the terms of either final Proposal and may not resolve the Dispute in a manner other than by selection of one of the submitted final Proposals. If a Party fails to submit a Proposal within the initial twenty (20)-day time frame set forth above, the arbitrator shall select the Proposal of the other Party as the resolution of the Dispute.

12.3 Governing Law. Resolution of all Disputes and any remedies relating thereto, shall be governed by and construed under the substantive laws of the State of California, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

12.4 Award. Any award shall be promptly paid in Dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the Party resisting enforcement. If as to any issue the arbitrator should determine under the applicable law that the position taken by a Party is frivolous or otherwise irresponsible or that any wrongdoing it finds is in callous disregard of law and equity or the rights of the other Party, the arbitrator shall also be entitled to award an appropriate allocation of the adversary's reasonable attorney fees, costs and expenses to be paid by the offending Party, the precise sums to be determined after a bill of attorney fees, expenses and costs consistent with such award has been presented following the award on the merits. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 12, and agrees that, subject to the Federal Arbitration Act, judgment may be entered upon the final award in the Federal District Court in the Central District of California and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of any damages incurred for breach of this Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrator.

12.5 Costs. Except as set forth in Section 12.4, each Party shall bear its own legal fees. The arbitrator shall assess his or her costs, fees and expenses against the Party losing the arbitration unless he or she believes that neither Party is the clear winner, in which case the arbitrator shall divide his or her fees, costs and expenses according to his or her sole discretion.

12.6 Injunctive Relief. Provided a Party has made a sufficient showing under the rules and standards set forth in the U.S. Federal Rules of Civil Procedure and applicable case law, the arbitrator shall have the freedom to invoke, and the Parties agree to abide by, injunctive measures after either Party submits in writing for arbitration claims requiring immediate relief. Additionally, nothing in this Article 12 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a Dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

12.7 Confidentiality. The arbitration proceeding shall be confidential and the arbitrator shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by law, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the arbitrator without prior written consent of the other Party. The existence of any Dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrator, except as required in connection with the enforcement of such award or as otherwise required by applicable Laws.

12.8 Survivability. Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

12.9 Patent and Trademark Disputes. Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patents or trademarks covering the manufacture, use, importation, offer for sale or sale of a Product shall be submitted to a court of competent jurisdiction in the country in which such patent or trademark rights were granted or arose.

12.10 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) STRICT LIABILITY OR OTHERWISE), REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 12.10 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 9.1 OR 9.2 OR DAMAGES AVAILABLE FOR BREACH OF ARTICLE 10.

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ARTICLE 13
MISCELLANEOUS

13.1 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidentiality Agreements. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations under the Confidentiality Agreements. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

13.2 Rights in Bankruptcy.

(a) The Parties agree that all rights and licenses granted under or pursuant to this Agreement by one Party to the other are, for all purposes of Title 11 of the United States Code ("**Title 11**"), licenses of rights to "intellectual property" as defined in Title 11, and, in the event that a case under Title 11 is commenced by or against either Party (the "**Bankrupt Party**"), the other Party shall have all of the rights set forth in Section 365(n) of Title 11 to the maximum extent permitted thereby. During the Term, each Party shall create and maintain current copies to the extent practicable of all such intellectual property. Without limiting the Parties' rights under Section 365(n) of Title 11, if a case under Title 11 is commenced by or against the Bankrupt Party, the other Party shall be entitled to a copy of any and all such intellectual property and all embodiments of such intellectual property, and the same, if not in the possession of such other Party, shall be promptly delivered to it (i) before this Agreement is rejected by or on behalf of the Bankrupt Party, within thirty (30) days after the other Party's written request, unless the Bankrupt Party, or its trustee or receiver, elects within thirty (30) days to continue to perform all of its obligations under this Agreement, or (ii) after any rejection of this Agreement by or on behalf of the Bankrupt Party, if not previously delivered as provided under clause (i) above. All rights of the Parties under this Section 13.2 and under Section 365(n) of Title 11 are in addition to and not in substitution of any and all other rights, powers, and remedies that each party may have under this Agreement, Title 11, and any other applicable Laws. The non-Bankrupt Party shall have the right to perform the obligations of the Bankrupt Party hereunder with respect to the maintenance of such intellectual property, but neither such provision nor such performance by the non-Bankrupt Party shall release the Bankrupt Party from any such obligation or liability for failing to perform it.

(b) The Parties agree that they intend the foregoing non-Bankrupt Party rights to extend to the maximum extent permitted by law and any provisions of applicable contracts with Third Parties, including for purposes of Title 11, (i) the right of access to any intellectual property (including all embodiments thereof) of the Bankrupt Party or any Third Party with whom the Bankrupt Party contracts to perform an obligation of the Bankrupt Party under this Agreement, and, in the case of the Third Party, which is necessary for the Development, Regulatory Approval and manufacture of Products and (ii) the right to contract directly with any Third Party described in (i) in this sentence to complete the contracted work.

(c) Any intellectual property provided pursuant to the provisions of this Section 13.2 shall be subject to the licenses set forth elsewhere in this Agreement and the payment obligations of this Agreement, which shall be deemed to be royalties for purposes of Title 11.

(d) Notwithstanding anything to the contrary in Article 7, in the event that Pfenex is the Bankrupt Party, Jazz may take appropriate actions in connection with the filing, prosecution, maintenance and enforcement of any Pfenex Patent licensed to Jazz under this Agreement without being required to consult with Pfenex before taking any such actions, provided that such actions are consistent with this Agreement.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

13.3 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than ninety (90) days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

13.4 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 13.4, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by confirmed facsimile or a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Pfenex:

Pfenex Inc.
10790 Roselle Street
San Diego, CA 92121
Attention: Patrick Lucy, Chief Business Officer

With a copy to (which shall not constitute notice):

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
Attention: Ian B. Edvalson

If to Jazz:

Jazz Pharmaceuticals, Inc.
3180 Porter Drive
Palo Alto, California 94304
USA
Attn: General Counsel

With a copy to (which shall not constitute notice):

Cooley LLP
3175 Hanover Street
Palo Alto, California 94304
USA
Attn: Marya A. Postner
Fax: 650-849-7400

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

13.5 No Strict Construction; Headings. This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The term "including" as used herein means including, without limiting the generality of any description preceding such term.

13.6 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party's consent to (a) its Affiliates (provided that, if Pfenex is the assigning Party, Pfenex (or its successor) guarantees such Affiliate's performance of its obligations under this Agreement or obtains Jazz's consent for such assignment notwithstanding the foregoing); or (b) a Third Party successor to all or substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other Change of Control transaction. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 13.6 shall be null, void and of no legal effect.

13.7 Change of Control. Each Party (the "**Acquired Party**") shall, to the extent such Party is not required to publicly disclose a Change of Control, notify the other Party in writing within one (1) Business Day after entering into any agreement providing for or intended to result in any Change of Control of the Acquired Party, identifying the parties to such agreement, and shall provide such notice where possible at least thirty (30) days prior to the effectiveness of such Change of Control. Following the effectiveness of such Change of Control, such other Party shall have the right to disband the JDC and to require the Acquired Party, including the acquiring party in such Change of Control, to adopt reasonable procedures to be agreed upon in writing with such other Party to limit the dissemination of such other Party's Confidential Information to only those personnel having a need to know such Confidential Information in order for the Acquired Party to perform its obligations or to exercise its rights under this Agreement and to prohibit and limit the use and disclosure of Confidential Information for competitive reasons against such other Party and its Affiliates; provided, however, that in the case of a Change of Control of Jazz, Pfenex may not disband the JDC prior to the Manufacturing Process Transfer under Section 4.7.

13.8 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

13.9 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

13.10 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

13.11 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

13.12 Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

13.13 Counterparts. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Executed counterpart signature pages delivered via facsimile or similar electronic transmission in .PDF or similar format shall be deemed binding as originals.

13.14 Remedies Non-Exclusive and Cumulative. Unless expressly stated otherwise in this Agreement, all remedies provided for in this Agreement shall be cumulative and in addition to, and not in lieu of, any other remedies available to either Party at law, in equity, or otherwise in accordance with the terms of this Agreement, including any claim for breach of this Agreement. Nothing in this Agreement shall be interpreted as limiting either Party's rights to pursue any remedies for breach of contract of this Agreement, except as expressly stated otherwise in this Agreement.

{Signature page follows}

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

In Witness Whereof, the Parties have executed this License and Option Agreement by their duly authorized officers as of the Effective Date.

Jazz Pharmaceuticals Ireland Limited		**Pfenex Inc.**	
By:	/s/ Paul Treacy	By:	/s/ Bertrand Liang
Name:	Paul Treacy	Name:	Bertrand Liang
Title:	Director	Title:	CEO

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential..

LIST OF EXHIBITS:

Exhibit A	–	Patents: Pfenex Patents, Pfenex Pegaspargase Product Patents, Pfenex ROFN Product Patents
Exhibit B	–	Exceptions from Exclusivity
Exhibit C	–	Initial Development Plans
Exhibit D	–	COGS Variance Calculations
Exhibit E	–	Certain Product Information
Exhibit 1.19	–	COGS Improvement
Exhibit 1.44	–	Expression Feasibility Data Package
Exhibit 1.92	–	Components of Option Data Package 1
Exhibit 1.100	–	Description of Pegaspargase Product
Exhibit 1.143	–	Successful Expression Criteria
Exhibit 1.147	–	Third Party Agreements
Exhibit 6.3	–	Development Milestones for HemOnc Products
Exhibit 6.4	–	Sales Milestones for HemOnc-NextGen
Exhibit 6.5(a)	–	Royalties on HemOnc Products
Exhibit 10.4(b)	–	Joint Press Release
Exhibit 11.4(a)(i)	–	Indemnification and Insurance Provisions Applicable to Pfenex

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Exhibit A

Patents: Pfenex Patents, Pfenex Pegaspargase Product Patents, Pfenex ROFN Product Patents

The published patents and patent application listed in Schedule A below have been assigned to Pfenex and may be relevant to a [***] process.

Schedule A

IMPROVED PROTEIN EXPRESSION SYSTEMS

Country	Appl. Number	Pat. Number	Issue Date
United States of America	12/512,930	8288127	10/16/2012
Australia	2004293810	2004293810	14-Oct-10
Canada	2545610	2545610	3/25/2014
China (People's Republic)	200480040702.7	ZL200480040702.7	9/11/2013
European Patent Convention	04811581.0	1692282	8/8/2012
Great Britain	04811581.0	1692282	
France	04811581.0	1692282	
Italy	04811581.0	1692282	
Germany	04811581.0	602004038866.1	
Ireland	04811581.0	1692282	
Switzerland	04811581.0	1692282	
India	2645/DELNP/06	258236	12/19/2013
Japan	2006-541422	5087741	9/21/2012
South Korea	10-2006-7009838	10-1237651	2/20/2013
Singapore	200603355-9	122480	28-Nov-2008
United States of America	12/512,930	8288127	10/16/2012

IMPROVED EXPRESSION SYSTEMS WITH SEC-SYSTEM SECRETION

Country	Appl. Number	Pat. Number	Issue Date
Australia	2004317306	2004317306	12/16/2010
Canada	2546157	2546157	7/22/2014
China (People's Republic)	200480034455.X	1882605	7/11/2012
European Patent Convention	04817876.8	1687324	8/22/2012
Great Britain	04817876.8	1687324	8/22/2012
France	04817876.8	1687324	8/22/2012
Italy	04817876.8	1687324	8/22/2012
Germany	04817876.8	602004039069.0	8/22/2012
Ireland	04817876.8	1687324	8/22/2012
Switzerland	04817876.8	1687324	8/22/2012
European Patent Convention	10179615.9	2327718	3/23/2016
Great Britain	10179615.9	2327718	03/23/2016
France	10179615.9	2327718	03/23/2016
Italy	10179615.9	2327718	03/23/2016
Germany	10179615.9	2327718	03/23/2016
Ireland	10179615.9	2327718	03/23/2016
Switzerland	10179615.9	2327718	03/23/2016
Poland	10179615.9	2327718	03/23/2016
Austria	10179615.9	2327718	03/23/2016

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European Patent Convention	10179651.4	2336153	3/30/2016
Great Britain	10179651.4	2336153	3/30/2016
France	10179651.4	2336153	3/30/2016
Italy	10179651.4	2336153	3/30/2016
Germany	10179651.4	2336153	3/30/2016
Ireland	10179651.4	2336153	3/30/2016
Switzerland	10179651.4	2336153	3/30/2016
Belgium	10179651.4	2336153	3/30/2016
Poland	10179651.4	2336153	3/30/2016
Austria	10179651.4	2336153	3/30/2016
India	2711/DELNP/06	252621	5/24/2012
Japan	2006-541651	5028551	9/19/2012
South Korea	10-2006-7009779	10-1265343	5/10/2013
Singapore	200603356-7	122481	31-Aug-10
United States of America	10/996,007	7985564	7/26/2011

MANNITOL INDUCED PROMOTER SYSTEMS IN BACTERIAL HOST CELLS

Country	Appl. Number	Pat. Number	Issue Date
Australia	2006255060	2006255060	12/13/2012
Canada	2610405	2610405	1/27/2015
China (People's Republic)	200680020110.8	101193906	9/05/2012
European Patent Convention	6772320.5	1888763	8/12/2015
Great Britain	6772320.5	1888763	8/12/2015
France	6772320.5	1888763	8/12/2015
Italy	6772320.5	1888763	8/12/2015
Germany	6772320.5	60 2006 046 269.7	8/12/2015
Ireland	6772320.5	1888763	8/12/2015
Switzerland	6772320.5	1888763	8/12/2015
India	9206/DELNP/07	271544	2/25/2016
Japan	2008-515835	5176114	4/3/2013
South Korea	10-2008-7000198	10-1304921	9/13/2013
Singapore	200718053-2	137574	12/31/2008
United States of America	11/447,553	7476532	1/13/2009
United States of America	12/330,723	8017355	9/13/2011
Poland	6772320.5	1888763	8/12/2015
Turkey	6772320.5	1888763	8/12/2015
Austria	6772320.5	1888763	8/12/2015
Belgium	6772320.5	1888763	8/12/2015

BACTERIAL LEADER SEQUENCES FOR INCREASED EXPRESSION

Country	Appl. Number	Pat. Number	Issue Date
Australia	20082105388	2008210538	9/19/2013
Canada	2677179	2677179	2/16/2016
European Patent Convention	8714119.8	2108047	10/24/2012
Great Britain	8714119.8	2108047	10/24/2012
France	8714119.8	2108047	10/24/2012
Italy	8714119.8	2108047	10/24/2012
Germany	8714119.8	60 2008 019 589.9	10/24/2012
Ireland	8714119.8	2108047	10/24/2012
Switzerland	8714119.8	2108047	10/24/2012
European Patent Convention	11194072.2	2468869	3/18/2015
Great Britain	11194072.2	2468869	3/18/2015

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Schedule A

France	11194072.2	2468869	3/18/2015
Italy	11194072.2	2468869	3/18/2015
Germany	11194072.2	602008037267.7	3/18/2015
Ireland	11194072.2	2468869	3/18/2015
Switzerland	11194072.2	2468869	3/18/2015
Poland	11194072.2	2468869	3/18/2015
Turkey	11194072.2	TR 2015 06439 T4	3/18/2015
India	4964/DELNP/09		
Japan	2009-548414	5714230	3/20/2015
Japan	2015-047870		
South Korea	10-2009-7017960	10-1491867	2/3/2015
Singapore	200905039-4	154246	3/15/2012
United States of America	12/022,789	7618799	17-Nov-2009
United States of America	12/604,061	7833752	11/16/2010

The patents and published applications listed in Schedule B may be relevant to a [***] process and have been licensed to Pfenex on a non-exclusive basis.

Schedule B

APPARATUS AND METHODS FOR OSMOTICALLY SHOCKING CELLS

Country	Appl. Number	Pat. Number	Issue Date
Australia	2008205632	2008205632B2	2/06/2014
Canada	CA2675183A		
European Patent Convention	EP2008724501A		
China	CN200880002148A		
India	4414/DELNP/2009		
Japan	JP2009545610A	5226697	7/3/2013
United States of America	12/013042	US8211668B2	7/3/2012

The Korean patent listed in Schedule C is assigned to Pfenex and is not licensed to Dow and may be relevant to a [***] process.

Schedule C

APPARATUS AND METHODS FOR OSMOTICALLY SHOCKING CELLS

Country	Appl. Number	Pat. Number	Issue Date
South Korea	10-2009-7016786	10-1484337	1/13/2015

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit B Exceptions from Exclusivity

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit C
Initial Development Plans

Attached.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

DEVELOPMENT PLAN NARRATIVE FOR [***]

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential..

GANTT CHART FOR [***]

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

DEVELOPMENT PLAN NARRATIVE FOR [***]

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

GANTT CHART FOR [***]

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

DEVELOPMENT PLAN NARRATIVE FOR [***]

[***]

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GANTT CHART FOR [***]

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit D
COGS Variance Calculation

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit E
Certain Product Information

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 1.19
COGS Improvement

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 1.44
Expression Feasibility Data Package

[***]

[[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential..

Exhibit 1.92
Components of Option Data Package 1

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 1.100
Description of Pegaspargase Product

Pegaspargase Product is L-asparaginase (*E. coli* derived L-asparagine amidohydrolase) that is covalently conjugated to monomethoxypolyethylene glycol (mPEG). Pfenex's proprietary L- asparaginase is a tetrameric enzyme that is produced recombinantly in *Pseudomonas fluorescens* and consists of identical 34.5 kDa subunits. Approximately 69 to 82 molecules of mPEG are linked to the L-asparaginase; the molecular weight of each mPEG molecule is about 5 kDa.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 1.143
Successful Expression Criteria

[***]

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	
[***]	[***]	[***]

[***]

[***]	[***]	[***]
[***]	[***]	
[***]	[***]	
[***]	[***]	[***]

[***]

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Exhibit 1.147
Third Party Agreements

Technology Assignment Agreement by and among Dow Global Technologies Inc., The Dow Chemical Company and Pfenex Inc. effective as of November 30, 2009

Technology Licensing Agreement by and among Dow Global Technologies Inc., The Dow Chemical Company and Pfenex Inc. effective as of November 30, 2009

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Exhibit 6.3
Development Milestones for HemOnc Products

	Development Milestone Event	Milestone Payment	
		[***]	[***]
1)	[***]	[***]	[***]
2)	[***]	[***]	[***]
	[***]	[***]	[***]
3)	[***]	[***]	[***]
	[***]	[***]	[***]
4)	[***]	[***]	[***]
5)	[***]	[***]	[***]
6)	[***]	[***]	[***]
7)	[***]	[***]	[***]
8)	[***]	[***]	[***]
9)	[***]	[***]	[***]
10)	[***]	[***]	[***]
	Total:	**$ 9,750,000**	**$ 36,250,000**

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Exhibit 6.4
Sales Milestones for HemOnc-NextGen

Sales Milestone Event	Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
Total	**$ 120,000,000**

Under no circumstances shall Jazz be obligated to pay Pfenex more than one hundred twenty million Dollars ($120,000,000) pursuant to Section 6.4.

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Exhibit 6.5(a)
Royalties on HemOnc Products

[***]	[***]	[***]	
		[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 10.4(b)
Joint Press Release

Attached.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Jazz Pharmaceuticals and Pfenex Enter into a Worldwide License and Option Agreement Related to Product Candidates in Early Development for Hematological Malignancies

DUBLIN and SAN DIEGO July 28, 2016 — Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and Pfenex Inc. (NYSE MKT: PFNX) today announced an agreement under which Pfenex granted Jazz Pharmaceuticals worldwide rights to develop and commercialize multiple early stage hematology product candidates. The agreement also includes an option for Jazz Pharmaceuticals to negotiate a license for a recombinant pegaspargase product candidate with Pfenex. This early development stage collaboration demonstrates Jazz Pharmaceuticals' focus on identifying innovative technologies that may lead to the development of important therapeutic options for patients with hematological malignancies.

Under the agreement, Pfenex will receive upfront and option payments totaling $15 million and may be eligible to receive additional payments of up to $166 million based on the achievement of certain development-, regulatory-, and sales-related milestones, including up to $41 million for certain non-sales-related milestones. Pfenex may also be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration. Both parties will be contributing to development efforts.

"The collaboration with Pfenex, including access to its unique **protein expression technology**, demonstrates our emphasis on diversifying and strengthening our portfolio to provide improved therapeutic options for patients." said Karen Smith M.D., Ph.D, global head of research and development and chief medical officer at Jazz Pharmaceuticals plc. "We look forward to working with Pfenex on the development of multiple product candidates that have the potential to broaden our hematology/oncology portfolio."

"Our collaboration with Jazz further validates Pfenex's product development capability enabled by our protein expression platform technology. We look forward to working with Jazz on these assets in support of further advancement in clinical development," said Bertrand C. Liang, chief executive officer of Pfenex.

About Pfenex Inc.

Pfenex Inc. (NYSE MKT: PFNX) is a clinical-stage biotechnology company engaged in the development of biosimilar therapeutics and high-value and difficult to manufacture proteins. The company's lead product candidate is PF582, a biosimilar candidate to Lucentis (ranibizumab), for the potential treatment of patients with retinal diseases. Pfenex has leveraged its *Pf*ēnex Expression Technology® platform to build a pipeline of product candidates and preclinical products under development including other biosimilars, as well as vaccines, therapeutic equivalents to reference listed drug products, and next generation biologics. For more information, please visit www.pfenex.com.

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. The company has a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology. In these areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*) and Defitelio® (defibrotide sodium) in the U.S. and markets Erwinase® and Defitelio® (defibrotide) in countries outside the U.S. For more information, please visit www.jazzpharmaceuticals.com.

Jazz Pharmaceuticals' "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements, including, but not limited to, statements related to the potential benefits of certain preclinical product candidates and related development activities, potential future payments to Pfenex by Jazz Pharmaceuticals, the potential broadening of Jazz Pharmaceuticals' product portfolio and other statements that are not historical facts. These forward- looking statements are based on Jazz Pharmaceuticals' current plans, objectives, estimates, expectations and intentions, and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with the difficulty and uncertainty of pharmaceutical product development and the uncertainty of preclinical and clinical success, and the risks and uncertainties described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and future filings and reports by the company. Other risks and uncertainties of which Jazz Pharmaceuticals is not currently aware may also affect its forward-looking statements and may cause actual results and timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by Jazz Pharmaceuticals on its website or otherwise. Jazz Pharmaceuticals does not undertake any obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

Pfenex Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or Pfenex's future financial or operating performance. In some cases, forward-looking statements can be identified because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern Pfenex's expectations, strategy, plans or intentions.

Forward-looking statements in this press release include, but are not limited to, statements regarding the future potential of the hematology product candidates, including future plans to develop, manufacture and commercialize these product candidates; the potential to receive future milestone and royalty payments under Pfenex's agreements with Jazz Pharmaceuticals; and the belief that these product candidates may lead to therapeutic options for patients with hematological malignancies. Actual results may differ materially from those indicated by these forward-looking statements as a result of the uncertainties inherent in the clinical drug development process, including, without limitation, challenges in successfully demonstrating the efficacy and safety of product candidates; the pre-clinical and clinical results for product candidates, which may not support further development of product candidates or may require additional clinical trials or modifications of ongoing clinical trials or regulatory pathways; challenges related to commencement, patient enrollment, completion, and analysis of clinical trials; Pfenex's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and new business initiatives; Pfenex's dependence on third parties for development, manufacture, marketing, sales and distribution of products; unexpected expenditures; and difficulties in obtaining and maintaining intellectual property protection for product candidates.

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Information on these and additional risks, uncertainties, and other information affecting Pfenex's business and operating results is contained in Pfenex's Annual Report on Form 10-K for the year ended December 31, 2015, Pfenex's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, and in Pfenex's subsequent reports filed with the Securities and Exchange Commission. The forward-looking statements in this press release are based on information available to Pfenex as of the date hereof, and Pfenex disclaims any obligation to update any forward-looking statements, except as required by law.

Pfenex investors and others should note that Pfenex announces material information to the public about Pfenex through a variety of means, including its website (http://www.pfenex.com/), investor relations website (http://pfenex.investorroom.com/), press releases, SEC filings, public conference calls, corporate Twitter account (https://twitter.com/pfenex), Facebook page (https://www.facebook.com/Pfenex-Inc-105908276167776/timeline/), and LinkedIn page (https://www.linkedin.com/company/pfenex-inc) in order to achieve broad, non-exclusionary distribution of information to the public and to comply with its disclosure obligations under Regulation FD. Pfenex encourages its investors and others to monitor and review the information Pfenex makes public in these locations as such information could be deemed to be material information. Please note that this list may be updated from time to time.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential..

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[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 11.4(a)(i)
Indemnification and Insurance Provisions Applicable to Pfenex

[***]

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Exhibit 10.1B

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Execution Version
CONFIDENTIAL

AMENDED AND RESTATED LICENSE AND OPTION AGREEMENT

This **AMENDED AND RESTATED LICENSE AND OPTION AGREEMENT** (the "**Agreement**") is entered into as of December 18, 2017 (the "**Amendment Effective Date**") by and between **PFENEX INC.**, a Delaware corporation, with its principal place of business at 10790 Roselle Street, San Diego, CA 92121 ("**Pfenex**"), and **JAZZ PHARMACEUTICALS IRELAND LIMITED**, a limited liability company incorporated under the laws of Ireland, with a registered office at Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin 4, Ireland ("**Jazz**"). Pfenex and Jazz are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, Pfenex and Jazz are parties to that certain License and Option Agreement dated as of July 27, 2016 wherein the Parties established a collaboration regarding certain [***] products and for Jazz to receive an option to certain [***] products using Pfenex's *P. fluorescens* manufacturing platform (the "**Original Agreement**"); and

WHEREAS, Pfenex and Jazz desire to amend and restate the Original Agreement as of the Amendment Effective Date to include mutually agreed amendments to the terms of the Original Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.1 "[***] **ROFN Product**" has the meaning set forth in Section 2.5(c)(i).

1.2 "**Acquired Party**" has the meaning set forth in Section 13.7.

1.3 "**Acquiring Entity**" has the meaning set forth in Section 1.15.

1.4 "**Additional Amounts**" has the meaning set forth in Section 6.10(c).

1.5 "**Affiliate**" means, with respect to a particular Party or other entity, a person, corporation, partnership, or other entity (any, a "**Person**") that controls, is controlled by or is under common control with such Party or other entity. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Person, whether by the ownership of fifty percent (50%) or more of the voting stock of such Person, or by contract or otherwise. For clarity, a Person shall be deemed an Affiliate only for so long as this definition is satisfied with respect to such Person.

1.6 "**Agreement**" has the meaning set forth in the Preamble.

1.7 "**Amendment Effective Date**" has the meaning set forth in the Preamble.

1.8 "**Assessment Materials**" has the meaning set forth in Section 2.1(a).

1.9 "**Assessment Period**" means, with respect to each HemOnc Product, a period of [***] after [***] for such HemOnc Product.

1.10 "**Bankrupt Party**" has the meaning set forth in Section 13.2(a).

1.11 "[***] **ROFN Product**" has the meaning set forth in Section 2.5(c)(ii).

1.12 "**Biosimilar Product**" has the meaning set forth in Section 7.4(a).

1.13 "**BLA**" means a Biologics License Application, as defined in Section 351(a) or (k) of the Public Health Service Act, 42 U.S.C. Section 262, as amended, and applicable regulations and guidance promulgated thereunder by the FDA or an equivalent application for Regulatory Approval outside of the United States.

1.14 "**Business Day**" means a day other than Saturday, Sunday or any day that banks in Dublin, Ireland or New York City, U.S. are required or permitted to be closed.

1.15 "**Change of Control**" of a Party means (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's business to which the subject matter of this Agreement relates, except in connection with the issuance of equity securities for financing purposes or to change the domicile of a Party (in each case (a)–(c), inclusive, such Third Party, the "**Acquiring Entity**").

1.16 "**Claims**" has the meaning set forth in Section 9.1.

1.17 "**CMC**" means the chemistry, manufacturing and controls of the Product, as specified by the FDA, or other applicable Regulatory Authorities.

1.18 "**COGS**" means, with respect to a particular Product, the fully burdened manufacturing cost in Dollars, as defined by JPP's consistent application of GAAP, of producing or obtaining supply of finished, packaged and labeled product, which cost shall include labor and material costs, quality assurance and control expenses, allocable facilities costs (e.g., insurance, water, waste, other utilities and depreciation) [***].

1.19 "**Combination Product**" has the meaning set forth in Section 1.89.

1.20 "**Commercialization**" means, with respect to a Product, the marketing, promotion, sale and/or distribution of such Product in the Territory. Commercialization shall include commercial activities conducted in preparation for Product launch. "**Commercialize**" has a correlative meaning.

1.21 "**Commercially Reasonable Efforts**" means, with respect to each Party's obligations under this Agreement to Develop, manufacture, or Commercialize a Product, the carrying out of such obligations or tasks with a level of efforts and resources that are consistent with the efforts and resources normally used by such Party in the performance of such activity for other pharmaceutical products, in each case owned by it or to which it has exclusive rights, at a similar stage of development or commercialization and with similar commercial and market potential as the Product, taking into account all relevant factors, including patent coverage, safety and efficacy, product profile, competitiveness of the marketplace and other products, proprietary position and profitability (including pricing and reimbursement). Without limiting the foregoing, such efforts shall include: (a) assigning responsibilities for activities for which such Party is responsible to specific employee(s) who are held accountable for the progress, monitoring and completion of such activities, (b) setting and seeking to reasonably achieve meaningful objectives for carrying out such activities, and (c) making and implementing reasonable decisions and allocating resources reasonably necessary or appropriate to advance progress with respect to and complete such objectives in an expeditious manner, in each case, consistent with the efforts and resources normally used by such Party in the performance of such activity for other pharmaceutical products, in each case owned by it or to which it has exclusive rights, at a similar stage of development or commercialization and with similar commercial and market potential as the Product, taking into account all relevant factors, including patent coverage, safety and efficacy, product profile, competitiveness of the marketplace and other products, proprietary position and profitability (including pricing and reimbursement).

1.22 "**Competing Program**" has the meaning set forth in Section 2.6(e).

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

1.23 "**Confidential Information**" of a Party means any and all Information of such Party that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, or electronic form. In addition, all Information disclosed by Pfenex pursuant to the Mutual Confidentiality Agreement between Pfenex and Jazz Pharmaceuticals plc ("**JPP**"), an Affiliate of Jazz, dated October 30, 2015 or the Mutual Confidentiality Agreement between Pfenex and JPP dated June 23, 2016 (collectively, the "**Confidentiality Agreements**") shall be deemed to be Pfenex's Confidential Information disclosed hereunder, and all Information disclosed by JPP pursuant to the Confidentiality Agreements shall be deemed to be Jazz's Confidential Information disclosed hereunder.

1.24 "**Confidentiality Agreements**" has the meaning set forth in Section 1.23.

1.25 "**Conjugated Protein**" has the meaning set forth in **Exhibit D**.

1.26 "**Conjugation Election**" has the meaning set forth in Section 2.1(a).

1.27 "**Control**" means, with respect to any material, Information, or intellectual property right, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement) to such material, Information, or intellectual property right and, in each case (a) and (b), has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other legally enforceable arrangement with any Third Party. Notwithstanding anything to the contrary in this Agreement, in the event of a Change of Control of a Party, (i) any subject matter owned or controlled by any Acquiring Entity (and not Controlled by such Party or its Affiliates) immediately prior to the effective date of such Change of Control and (ii) any subject matter independently developed or acquired by or on behalf of any Acquiring Entity without access to or use of any subject matter used or made available under this Agreement, in each case (i) and (ii) shall not be deemed to be Controlled by such Party or its Affiliates after the effective date of such Change of Control for purposes of this Agreement.

1.28 "**Cover**" means, with respect to a claim of a Patent and a Product, that such claim would be infringed, absent a license, by the manufacture, use, offer for sale, sale or importation of such Product (considering claims of patent applications to be issued as pending).

1.29 "**Declination Notice**" has the meaning set forth in Section 2.1(a).

1.30 "**Develop**" or "**Development**" means, with respect to a Product, all activities that relate to the development of such Product, including (a) obtaining, maintaining or expanding Regulatory Approvals for such Product, or (b) developing the ability to manufacture clinical and commercial quantities of such Product. Development includes: (i) the conduct of preclinical testing, toxicology, and clinical trials; (ii) preparation, submission, review, and development of Information for the purpose of submission to a Governmental Authority to obtain, maintain or expand Regulatory Approvals for such Product; and (iii) manufacturing process development and scale-up, bulk production, and fill/finish work associated with the supply of such Product for preclinical testing, toxicology and clinical trials, and related quality assurance and technical support activities.

1.31 "**Development Plan**" has the meaning set forth in Section 4.2(a).

1.32 "**Development Program**" has the meaning set forth in Section 4.2(a).

1.33 "**Development Step-In Triggering Event**" means a material breach by Pfenex of its obligation to conduct the manufacturing process development of HemOnc-NextGen in accordance with Section 4.7.

1.34 **"Disclosed Platform**" has the meaning set forth in Section 7.1(c).

1.35 "**Dispute**" has the meaning set forth in Section 12.1.

1.36 "**Divestiture**" has the meaning set forth in Section 2.6(e)(ii).

1.37 "**Dollar**" means a U.S. dollar, and "**$**" shall be interpreted accordingly.

1.38 "**Effective Date**" means July 27, 2016.

1.39 "**EMA**" means the European Medicines Agency or any successor entity.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

1.40 "**Escrow Triggering Event**" means (a) Pfenex (i) admits in writing that it has become insolvent or makes an assignment for the benefit of creditors; (ii) disposes of all or a substantial portion of its property, (iii) ceases to conduct its business in the ordinary course; or (iv) files a petition for bankruptcy, insolvency or reorganization, or for the appointment of a receiver, trustee, or custodian for a material portion of its property, or any similar petition or commencement of any similar action under applicable law, or has such a petition filed or proceeding commenced against it and such petition has not been dismissed within sixty (60) days or (b) a Development Step-In Triggering Event has occurred.

1.41 "**EU**" or "**European Union**" means the European Union member states as of the Effective Date or as may be added or subtracted from time to time during the Term. As of the Effective Date, the European Union member states are Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. Notwithstanding the foregoing, the EU shall include the United Kingdom for purposes of this definition regardless of whether such country officially exits the EU during the Term.

1.42 "**EU Approval**" has the meaning set forth in Section 6.3(b).

1.43 "**Executive Officer**" means, with respect to Pfenex, its Chief Executive Officer, and with respect to Jazz, its Chief Executive Officer, or, in each case, a designee with senior decision-making authority.

1.44 "**Expression Feasibility Data Package**" means, with respect to each HemOnc Product, the data with respect to such HemOnc Product generated by Pfenex in the performance of the Pfenex Expression Feasibility Activities as described in **Exhibit 1.44**.

1.45 "**FD&C Act**" means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

1.46 "**FDA**" means the U.S. Food and Drug Administration or any successor entity.

1.47 "**Federal Arbitration Act**" has the meaning set forth in Section 12.2(a).

1.48 "**Field**" means the diagnosis, prevention and treatment of any and all diseases and conditions.

1.49 "**First Commercial Sale**" means, with respect to a Product, the first sale to a Third Party of such Product in a given regulatory jurisdiction after Regulatory Approval has been obtained in such jurisdiction for such Product.

1.50 "**Fused Protein**" has the meaning set forth in **Exhibit D**.

1.51 "**Fusion Election**" has the meaning set forth in Section 2.1(a).

1.52 "**GAAP**" means United States generally accepted accounting principles consistently applied.

1.53 "**GCP**" or "**Good Clinical Practices**" means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

1.54 "**GLP**" or "**Good Laboratory Practices**" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

1.55 "**GMP**" or "**Good Manufacturing Practices**" means the then-current good manufacturing practices required by the FDA, as set forth in the FD&C Act and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable laws and regulations applicable to the manufacture and testing of pharmaceutical materials promulgated by other Regulatory Authorities, as they may be updated from time to time.

1.56 "**Governmental Authority**" means any multi-national, national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

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1.57 "**Half-Life Extension Component**" means a component that may be included as part of a pharmaceutical product that has been incorporated by chemical conjugation, or by fusion with another protein or other genetic means, with the intended purpose of extending the time it takes for such pharmaceutical product to lose half of its pharmacologic activity when administered to humans.

1.58 "**HemOnc-NextGen**" has the meaning set forth in **Exhibit D**.

1.59 "**HemOnc-Pf**" has the meaning set forth in **Exhibit D**.

1.60 "**HemOnc Products**" means HemOnc-Pf and HemOnc-NextGen.

1.61 "**ICH**" means International Conference on Harmonisation.

1.62 "**IND**" means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, or (b) the equivalent application to a Governmental Authority in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

1.63 "**Indemnified Party**" has the meaning set forth in Section 9.3.

1.64 "**Indemnifying Party**" has the meaning set forth in Section 9.3.

1.65 "**Indication**" means a separately defined, well-categorized class of human disease or condition for which a separate MAA (including any extensions or supplements) may be filed with a Regulatory Authority. For clarity, if an MAA is approved for a Product in a particular Indication and patient population, a label expansion for such Product to include such Indication in a different patient population shall not be considered a separate Indication. For further clarity, all subtypes of a particular tumor type and all treatments thereof, including all lines of treatment shall be deemed the same Indication.

1.66 "**Information**" means any data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical and clinical test data and data resulting from non-clinical studies), CMC information, stability data and other study data and procedures.

1.67 "**Invention**" means any Information, process, method, composition of matter, article of manufacture, discovery or finding, patentable or otherwise, that is invented, made or generated as a result of a Party (acting solely or jointly with the other Party) exercising its rights or carrying out its obligations under this Agreement, whether directly or via its Affiliates, agents or independent contractors, including all rights, title and interest in and to the intellectual property rights therein.

1.68 "**JAMS Rules**" has the meaning set forth in Section 12.2(a).

1.69 "**Jazz**" has the meaning set forth in the Preamble.

1.70 "**Jazz Assessment Activities**" means, with respect to each HemOnc Product, such testing of the Assessment Materials as performed by Jazz for purposes of evaluating whether to terminate its license hereunder with respect to such HemOnc Product.

1.71 "**Jazz Extension IP**" means the data, technical information, and Patents (a) Controlled by Jazz or its Affiliates as of the Effective Date or any time during the Term, and (b) relating to or Covering the Half-Life Extension Component for HemOnc-NextGen selected by Jazz, in its sole discretion. For clarity, Jazz Extension IP includes Jazz Improvements.

1.72 "**Jazz HemOnc-NextGen Data**" has the meaning set forth in Section 11.4(b).

1.73 "**Jazz HemOnc-Pf Data**" has the meaning set forth in Section 11.4(a).

1.74 "**Jazz Improvements**" has the meaning set forth in Section 7.1(d).

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1.75 "**Jazz Indemnitees**" has the meaning set forth in Section 9.1.

1.76 "**Jazz Sole Patents**" has the meaning set forth in Section 7.3(a).

1.77 "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 3.1(a).

1.78 "**Joint Inventions**" has the meaning set forth in Section 7.1(b).

1.79 "**Joint Management Team**" or "**JMT**" has the meaning set forth in Section 3.2(a).

1.80 "**Joint Patents**" has the meaning set forth in Section 7.1(b).

1.81 "**JPP**" has the meaning set forth in Section 1.23.

1.82 "**Laws**" means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

1.83 "**Lead Indication**" has the meaning set forth in **Exhibit D**.

1.84 "**Major European Country**" means any one of the United Kingdom, Germany, France, Italy and Spain.

1.85 "**Manufacturing Process Transfer**" has the meaning set forth in Section 4.7(b).

1.86 "**Manufacturing Process Transfer Criteria**" has the meaning set forth in Section 4.7(a).

1.87 "**Marketing Authorization Application**" or "**MAA**" means an application to the appropriate Regulatory Authority for approval to market a Product (but excluding Pricing Approval) in any particular jurisdiction, including a BLA.

1.88 "**Marketing Partner**" means a Third Party that has received from Jazz or its Affiliate a sublicense, under Section 2.1(d), of the rights granted to Jazz either: (a) to develop and sell a Product, provided that Jazz or its Affiliates receives payment based upon sales of such Product by or on behalf of such Third Party (e.g., such Third Party pays Jazz or its Affiliates a royalty, milestone, profit share or other payment with respect to the sale of such Product by or on behalf of such Third Party); or (b) to make (to the extent Jazz is so permitted to make or sublicense such right to a Third Party to make as described in Section 2.1(d)) Product and sell Product.

1.89 "**Net Sales**" means, with respect to any Product, the gross amounts invoiced by Jazz and its Affiliates, sublicensees and Marketing Partners (each, a "**Selling Party**") for sales of such Product in the Field to unaffiliated Third Parties, less the following deductions provided to unaffiliated entities to the extent actually taken, paid, accrued, allowed, included or allocated:

(a) cash, trade, quantity or other discounts, coupons, or co-pay expenditures, charge-back payments, and rebates to trade customers, retail pharmacy chains, wholesalers, managed health care organizations, pharmaceutical benefit managers, insurers, group purchasing organizations and national, state, or local government, including any Medicaid or other rebate payments or other price reductions provided based on sales to any Governmental Authority or Regulatory Authority in respect of any state or federal Medicare, Medicaid or similar programs;

(b) credits, rebates or allowances related to prompt payment or on account of damaged goods, rejections or returns of Products, including in connection with recalls, and the actual amount of any write-offs for bad debt (provided that any amount subsequently recovered will be added back as Net Sales);

(c) reasonable distributors', wholesalers' and dispensing fees in connection with Products;

(d) freight, postage, shipping, transportation and insurance charges; and

(e) taxes (other than income taxes), duties, tariffs, mandated contributions or other governmental charges levied on the manufacture or sale of Products, including VAT, excise taxes and sales taxes.

Notwithstanding the foregoing, sales among Selling Parties shall not be included in the computation of Net Sales hereunder (except where such Selling Party is an end user). Net Sales shall be accounted for in accordance with the Selling Party's standard practices in the relevant country in the Territory, applied consistently with respect to all of such Selling Party's products in such country. For clarity, the gross invoiced price for sale of a Product to any wholesaler or distributor (i.e., a Third Party to whom a Selling Party sells units of such Product for resale in a particular market or country) shall be included in Net Sales as sales of such Selling Party, but amounts received by such a wholesaler or distributor for subsequent sale of the Product shall not be included in Net Sales.

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Notwithstanding the foregoing, "Net Sales" shall not include any amounts invoiced for sales of Products supplied for use in clinical trials of Products, or under early access, compassionate use, named patient, indigent access, patient assistance or other reduced pricing programs, in each case provided that the gross amount invoiced is at or below the Selling Party's COGS for the applicable Product.

If the Product (a) contains any active pharmaceutical ingredient in addition to any active pharmaceutical ingredient specified in the applicable Product definition, or (b) is sold in combination with another pharmaceutical product that contains any active pharmaceutical ingredient other than [***], in each case (a) and (b) for a single price, such Product shall be referred to as a "**Combination Product**", and the other active pharmaceutical ingredient(s) in clause (a) and the other pharmaceutical product(s) in clause (b) are each referred to as the "**Other Product(s)**".

Net Sales for a Combination Product in a particular country shall be calculated as follows:

(i) If the Product and Other Product(s) each are sold separately in such country, Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction A/(A+B), where A is the price in such country of the Product sold separately, and B is the (sum of the) price(s) in such country of the Other Product(s) sold separately.

(ii) If the Product, but not the Other Product(s), is sold separately in such country, Net Sales will be calculated by multiplying the total Net Sales (as described above) of such Combination Product by the fraction A/C, where A is the price in such country of the Product sold separately, and C is the price in such country of the Combination Product.

(iii) If the Other Product(s), but not the Product, is sold separately in such country, Net Sales will be calculated by multiplying the total Net Sales (as described above) of such Combination Product by the fraction 1-B/C, where B is the (sum of the) price(s) in such country of the Other Product(s) and C is the price in such country of the Combination Product.

(iv) If the Product and the Other Product(s) are not sold separately in such country, Net Sales shall be determined by mutual written agreement of the Parties based on the relative value of such Product and such Other Product(s).

1.90 "**Option**" has the meaning set forth in Section 2.4(a).

1.91 "**Option Data Package 1**" means the data and materials generated in the performance of Pfenex's Development of the Pegaspargase Product as described in **Exhibit 1.91**.

1.92 "**Option Data Package 2**" means [***].

1.93 "**Option Exercise**" means the entry by the Parties into an Option Exercise Agreement pursuant to Section 2.4(d).

1.94 "**Option Exercise Agreement**" has the meaning set forth in Section 2.4(d).

1.95 "**Option Exercise Notice**" has the meaning set forth in Section 2.4(c).

1.96 "**Other Product(s)**" has the meaning set forth in Section 1.89.

1.97 "**Party**" or "**Parties**" has the meaning set forth in the Preamble.

1.98 "**Patents**" means (a) pending patent applications, issued patents, utility models and designs anywhere in the world; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; (c) patents that issue with respect to any of the foregoing applications; and (d) extensions, renewals or restorations of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

1.99 "**Pegaspargase Product**" means the product described on **Exhibit 1.99** as may be agreed to be amended by the Parties.

1.100 "**Person**" has the meaning set forth in Section 1.5.

1.101 "**Pfenex**" has the meaning set forth in the Preamble.

1.102 "**Pfenex Expression Feasibility Activities**" means, with respect to each HemOnc Product, the protein expression activities performed by Pfenex as set forth in the Development Plan for such HemOnc Product.

1.103 "**Pfenex General Product Patent**" means a Pfenex Sole Patent that (a) claims an Invention and (b) is not a Pfenex Product- Specific Patent.

1.104 "**Pfenex Improvements**" has the meaning set forth in Section 7.1(c).

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

1.105 "**Pfenex Indemnitees**" has the meaning set forth in Section 9.2.

1.106 "**Pfenex IP**" means the Pfenex Know-How and Pfenex Patents.

1.107 "**Pfenex Know-How**" means all data and technical information (a) Controlled by Pfenex or its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize any HemOnc Product. Pfenex Know-How includes Pfenex Improvements, Sole Inventions owned by Pfenex, and Pfenex's interest in Joint Inventions, in each case to the extent that the foregoing are necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize any HemOnc Product.

1.108 "**Pfenex Patent**" means any Patent (a) Controlled by Pfenex or its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize any HemOnc Product, including any and all Patents claiming any Pfenex Know-How, Patents listed on **Exhibit A**, Patents claiming Pfenex Improvements and Sole Inventions owned by Pfenex, and Pfenex's interest in any Joint Patents, in each case to the extent that the foregoing are necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize any HemOnc Product.

1.109 "**Pfenex Pegaspargase Product IP**" means the Pfenex Pegaspargase Product Know-How and Pfenex Pegaspargase Product Patents.

1.110 "**Pfenex Pegaspargase Product Know-How**" means all data and technical information (a) Controlled by Pfenex or its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize the Pegaspargase Product. Pfenex Know-How includes Pfenex Improvements, Sole Inventions owned by Pfenex, and Pfenex's interest in Joint Inventions, in each case to the extent that the foregoing are necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize the Pegaspargase Product.

1.111 "**Pfenex Pegaspargase Product Patent**" means any Patent (a) Controlled by Pfenex or its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize the Pegaspargase Product, including any and all Patents claiming any Pfenex Pegaspargase Product Know-How, Patents listed on **Exhibit A**, Patents claiming Pfenex Improvements and Sole Inventions owned by Pfenex, and Pfenex's interest in any Joint Patents, in each case to the extent that the foregoing are necessary or useful to Develop, manufacture, use, offer for sale, sell, import or otherwise Commercialize the Pegaspargase Product.

1.112 "**Pfenex Product-Specific Patent**" means a Pfenex Sole Patent that claims only a Product (including the composition of matter, manufacture or use thereof) and no other subject matter.

1.113 "**Pfenex ROFN Product IP**" means, with respect to a particular ROFN Product, the Pfenex ROFN Product Know-How and Pfenex ROFN Product Patents.

1.114 "**Pfenex ROFN Product Know-How**" means, with respect to a particular ROFN Product, all data and technical information (a) Controlled by Pfenex or its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or useful to develop, manufacture, use, offer for sale, sell, import or otherwise commercialize such ROFN Product. Pfenex Know-How includes Pfenex Improvements, Sole Inventions owned by Pfenex, and Pfenex's interest in Joint Inventions, in each case to the extent that the foregoing are necessary or useful to develop, manufacture, use, offer for sale, sell, import or otherwise commercialize such ROFN Product.

1.115 "**Pfenex ROFN Product Patent**" means, with respect to a particular ROFN Product, any Patent (a) Controlled by Pfenex or its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or useful to develop, manufacture, use, offer for sale, sell, import or otherwise commercialize such ROFN Product, including any and all Patents claiming any Pfenex ROFN Product Know-How, Patents listed on **Exhibit A**, Patents claiming Pfenex Improvements and Sole Inventions owned by Pfenex, and Pfenex's interest in any Joint Patents, in each case to the extent that the foregoing are necessary or useful to develop, manufacture, use, offer for sale, sell, import or otherwise commercialize such ROFN Product.

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1.116 "**Pfenex Sole Patent**" means a Pfenex Patent that is not a Joint Patent.

1.117 "**Post-Primary Recovery Inventions**" has the meaning set forth in Section 7.1(g).

1.118 "**Pricing Approval**" means such governmental approval, agreement, determination or decision establishing prices for a Product that can be charged and/or reimbursed in regulatory jurisdictions where it is required by applicable Laws or customary for the applicable Governmental Authorities to approve or determine the price and/or reimbursement of pharmaceutical products prior to the commencement of commercial sales of such Product in the applicable regulatory jurisdiction.

1.119 "**Product**" means HemOnc-Pf, HemOnc-NextGen, and/or the Pegaspargase Product, excluding (a) any such Product in the event that this Agreement is terminated with respect to such Product and (b) the Pegaspargase Product in the event that the Option expires without Option Exercise.

1.120 "**Product A**" has the meaning set forth in **Exhibit D**.

1.121 "**Product B**" has the meaning set forth in **Exhibit D**.

1.122 "**Product Infringement**" has the meaning set forth in Section 7.4(a).

1.123 "**Product Marks**" has the meaning set forth in Section 7.8.

1.124 "**Production Techniques Patents**" has the meaning set forth in the Technology Licensing Agreement among Dow Global Technologies Inc., The Dow Chemical Company and Pfenex dated November 30, 2009.

1.125 "**Proposals**" has the meaning set forth in Section 12.2(b).

1.126 "[***]" has the meaning set forth in **Exhibit D**.

1.127 "[***]" has the meaning set forth in **Exhibit D**.

1.128 "[***]" has the meaning set forth in **Exhibit D**.

1.129 "**Regulatory Approval**" means all approvals, including, if applicable, Pricing Approvals, that are necessary for the commercial sale of a Product in the Field in a given country or regulatory jurisdiction.

1.130 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

1.131 "**Regulatory Materials**" means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, manufacture, market, sell or otherwise Commercialize a Product in a particular country or jurisdiction, including INDs.

1.132 "**ROFN**" has the meaning set forth in Section 2.5(a).

1.133 "**ROFN Data Package**" means, with respect to a particular ROFN Product, (a) the data that [***] for such ROFN Product and (b) any additional data that [***], prior to filing an IND for such ROFN Product, to further develop and commercialize such ROFN Product.

1.134 "**ROFN Exercise**" means, with respect to a particular ROFN Product, the entry by the Parties into a ROFN Exercise Agreement pursuant to Section 2.5(c).

1.135 "**ROFN Exercise Agreement**" has the meaning set forth in Section 2.5(c).

1.136 "**ROFN Exercise Notice**" has the meaning set forth in Section 2.5(a).

1.137 "**ROFN Product**" means a product (other than a Product) that contains [***] and for which Pfenex conducts any research or development activities, excluding any such product comprising a Competing Program.

1.138 "**ROFN Third Party Notice**" has the meaning set forth in Section 2.5(c)(ii).

1.139 "**Royalty Term**" has the meaning set forth in Section 6.5(b).

1.140 "**Royalty Valuation**" has the meaning set forth in Section 6.6.

1.141 "**Selling Party**" has the meaning set forth in Section 1.89.

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1.142 "**Sole Inventions**" has the meaning set forth in Section 7.1(a).

1.143 "**Successful Expression**" has the meaning set forth on **Exhibit 1.143**.

1.144 "**Term**" has the meaning set forth in Section 11.1.

1.145 "**Territory**" means all countries of the world.

1.146 "**Third Party**" means any entity other than Pfenex or Jazz or an Affiliate thereof.

1.147 "**Third Party Agreements**" means the agreements listed on **Exhibit 1.147**.

1.148 "**Title 11**" has the meaning set forth in Section 13.2(a).

1.149 "**United States**" or "**U.S.**" means the United States of America, including all possessions and territories thereof.

1.150 "**Valuation Firm**" has the meaning set forth in Section 6.6.

1.151 "**VAT**" means value-added tax, consumption taxes and other similar taxes required by Law to be disclosed on an invoice.

1.152 "**Withholding Tax Action**" has the meaning set forth in Section 6.10(c).

1.153 "**Working Group**" has the meaning set forth in Section 3.4.

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ARTICLE 2
LICENSES AND EXCLUSIVITY

2.1 License to Jazz for HemOnc Products.

(a) Election for HemOnc Products. Pfenex shall use Commercially Reasonable Efforts to perform the Pfenex Expression Feasibility Activities for each of HemOnc-Pf and the Fused Protein. Pfenex shall promptly notify Jazz in writing if Pfenex reasonably believes, after using Commercially Reasonable Efforts, that it will not be able to achieve Successful Expression for either HemOnc-Pf or the Fused Protein. Promptly following completion of the Pfenex Expression Feasibility Activities for each HemOnc Product, Pfenex shall promptly provide Jazz with the Expression Feasibility Data Package for such HemOnc Product. Pfenex shall, within ten (10) Business Days following Jazz's written request, provide Jazz with any additional information reasonably requested by Jazz with respect to the Expression Feasibility Data Package (provided that such additional information is in Pfenex's possession and does not require the expenditure of additional funds or the performance of additional studies to generate), or Pfenex shall notify Jazz in writing during such period that Pfenex does not have such additional information in its possession, as the case may be. Following the mutual agreement of the Parties with respect to the achievement of Successful Expression for each HemOnc Product, Pfenex shall provide Jazz with the amount of such HemOnc Product set forth in **Exhibit 1.143** meeting the specifications as described in **Exhibit 1.143** (with respect to each HemOnc Product, the "**Assessment Materials**"). The data contained in the Expression Feasibility Data Package shall be the Confidential Information of Jazz, and Jazz shall have all right, title, and interest in and to the data contained in the Expression Feasibility Data Package and the Assessment Materials. Notwithstanding anything to the contrary in this Agreement, as between the Parties, Pfenex shall retain all right, title and interest in and to any Pfenex IP (including any Information disclosed by Pfenex to Jazz in connection with such Assessment Materials or otherwise under this Agreement) and all Pfenex Improvements assigned to Pfenex pursuant to Section 7.1(c). Commencing upon receipt of the Assessment Materials for each HemOnc Product, Jazz shall use Commercially Reasonable Efforts to conduct the Jazz Assessment Activities with respect to such HemOnc Product (subject to the final sentence of Section 4.7(a)). Prior to expiration of the Assessment Period for the applicable HemOnc Product, Jazz may provide Pfenex with written notice that Jazz elects to terminate its license hereunder with respect to such HemOnc Product (with respect to such HemOnc Product, the "**Declination Notice**"). If Jazz provides Pfenex with a Declination Notice for a HemOnc Product, then Jazz shall be deemed to have terminated this Agreement with respect to such HemOnc Product pursuant to Section 11.2, and such termination shall be deemed to be effective as of the date of receipt of notice. If Jazz does not provide Pfenex with a Declination Notice during the Assessment Period with respect to either HemOnc Product, Jazz will retain its license hereunder and be obligated to commence its obligations with respect to such HemOnc Product, and such HemOnc Product will remain a Product for the purposes of this Agreement. [***].

(b) License to Jazz. Pfenex hereby grants Jazz an exclusive (even as to Pfenex except as provided in Section 2.1(c) below), royalty-bearing and sublicenseable (subject to Section 2.1(d)) license, under the Pfenex IP to research, Develop, make, have made, use, sell, have sold, offer for sale, import, and otherwise Commercialize the HemOnc Products in the Field in the Territory. Notwithstanding anything to the contrary in this Agreement, all licenses granted to Jazz pursuant to this Agreement under the Production Techniques Patents shall be non-exclusive. Pfenex shall not grant a license under the Production Techniques Patents to any Third Parties to research, Develop, make, have made, use, sell, have sold, offer for sale, import, or otherwise Commercialize any HemOnc Product in the Field in the Territory.

(c) Pfenex Retained Rights. Notwithstanding the rights granted to Jazz in Section 2.1(b), Pfenex retains the non-exclusive right to practice the Pfenex IP in the Territory solely as necessary to (i) conduct the activities assigned to Pfenex under the Development Plans in accordance with the terms of this Agreement; and (ii) manufacture the HemOnc Products solely for supply to Jazz, its Affiliates or its/their sublicensees and Marketing Partners.

(d) Sublicenses. Jazz shall have the right to grant sublicenses through multiple tiers, under any or all of the rights granted in Section 2.1(b) or 13.2(c)(ii), to its Affiliates and/or to Third Parties. Each agreement in which Jazz grants a sublicense under the Pfenex IP shall be consistent with the terms and conditions of this Agreement relevant to such sublicense. Jazz shall be liable to Pfenex for the performance of its direct and indirect sublicensees, including their compliance with the applicable provisions of this Agreement. Jazz shall ensure that the efforts of each Third Party sublicensee to Develop and Commercialize a Product shall be at least equivalent to Jazz's Commercially Reasonable Efforts in accordance with Sections 4.4 and 5.2.

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2.2 License to Pfenex. Effective on commencement of the Pfenex Expression Feasibility Activities for HemOnc-NextGen, Jazz shall, and hereby does, grant to Pfenex a non-exclusive, royalty-free, non-sublicenseable and non-transferable license or sublicense, under the Jazz Extension IP, solely as necessary (i) to conduct the Pfenex activities for HemOnc-NextGen as specified in the Development Plan for such Product, and (ii) subject to the Parties' agreement in accordance with Section 4.7, to manufacture HemOnc- NextGen for supply to Jazz or its designees. Jazz shall disclose to Pfenex the potential Half-Life Extension Component(s) within the Jazz Extension IP (and any changes thereto) to be evaluated and/or used in the Development of HemOnc-NextGen under this Agreement to the extent necessary for Pfenex to perform such activities.

2.3 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party. All rights not otherwise expressly granted hereunder by a Party shall be retained.

2.4 Option for Pegaspargase Product.

(a) Option Grant. Pfenex hereby grants Jazz an exclusive option (the "**Option**") to obtain an exclusive, sublicenseable (through multiple tiers) license from Pfenex under the Pfenex Pegaspargase Product IP to Develop, make, have made, use, sell, have sold, offer for sale and import and otherwise Commercialize the Pegaspargase Product in the Field in the Territory, subject to payment of such amounts as may be agreed in any Option Exercise Agreement. The foregoing license shall permit Pfenex to retain the right to perform any Development or manufacturing activities that the Parties agree to allocate to Pfenex in the Option Exercise Agreement.

(b) Development of Pegaspargase Product. Pfenex shall Develop the Pegaspargase Product only in accordance with the mutually agreed Development Plan for such Product and with a primary objective for the Pegaspargase Product to have enzyme activity comparable to that of Oncaspar®. Pfenex shall keep Jazz informed of its Development of the Pegaspargase Product through the JDC or more frequently upon Jazz's reasonable request, including the timeline, data and results of such Development activities. Pfenex shall notify Jazz through the JDC if Pfenex proposes to amend the then-current Development Plan for the Pegaspargase Product. Promptly following completion of the corresponding activities under the Development Plan for the Pegaspargase Product, Pfenex shall provide Jazz with Option Data Package 1 and, if Jazz has not previously delivered to Pfenex an Option Exercise Notice or if Jazz delivered an Option Exercise Notice but the Parties were unable to negotiate and enter into an Option Exercise Agreement pursuant to Section 2.4(d), Option Data Package 2. Pfenex shall, within ten (10) Business Days following Jazz's written request, provide Jazz with any additional information reasonably requested by Jazz with respect to Option Data Package 1 or Option Data Package 2, as applicable (provided that such additional information is in Pfenex's possession and does not require the expenditure of additional funds or the performance of additional studies to generate), or Pfenex shall notify Jazz in writing during such period that Pfenex does not have such additional information in its possession, as the case may be.

(c) Option Exercise. Jazz may exercise the Option by providing written notice (an "**Option Exercise Notice**") to Pfenex either:

(i) during the twenty-five (25) Business Day period commencing upon Jazz's receipt of Option Data Package 1; or

(ii) to the extent that an Option Exercise Notice has not previously been delivered by Jazz to Pfenex in connection with Option Data Package 1 or if Jazz delivered an Option Exercise Notice but the Parties were unable to negotiate and enter into an Option Exercise Agreement pursuant to Section 2.4(d), during the twenty-five (25) Business Day period commencing upon Jazz's receipt of Option Data Package 2.

If Jazz does not provide an Option Exercise Notice before the expiration of the period referenced in subsection (ii) above, then the Option shall lapse for the Pegaspargase Product and this Agreement shall be deemed terminated with respect to the Pegaspargase Product, and Pfenex may decide, in its sole discretion, whether to terminate or continue the Development and Commercialization of the Pegaspargase Product, itself or in collaboration with one or more Third Parties, and the terms of Section 2.6(c)(iii) shall apply with respect to such Product.

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(d) Negotiation. Following Jazz's delivery of an Option Exercise Notice, the Parties shall use good faith efforts to negotiate the terms and conditions of a definitive agreement regarding the Pegaspargase Product (an "**Option Exercise Agreement**") on an exclusive basis, meaning that Pfenex and its representatives shall not engage in discussions with any Third Party regarding a potential grant of rights to such Third Party with respect to the Pegaspargase Product during the negotiation period. The terms of such Option Exercise Agreement shall be commercially reasonable and all applicable non-financial terms and conditions shall be substantially the same as those in this Agreement, including decision-making, diligence, exclusivity (as applicable to the Pegaspargase Product), development, commercialization, manufacture, rights and obligations of the Parties, risk-allocation, intellectual property-related matters, dispute resolution, and general agreement structure, but excluding any rights of first negotiation or other rights except solely with respect to the Pegaspargase Product. Notwithstanding the foregoing, under the Option Exercise Agreement, Pfenex may opt-in to contribute to the Development costs of the Pegaspargase Product, and upon such opt-in, shall be responsible for between [***] and [***] of the Development costs in Pfenex's discretion. The Option Exercise Agreement will also set forth usual and customary economic terms similar to those of this Agreement, including an upfront payment, clinical developmental and commercial milestone payments, and royalty payments, which payments shall take into account Pfenex's level of contribution to the Development costs of the Pegaspargase Product. Without limiting the foregoing, the economic terms of the Option Exercise Agreement will reflect the level of development or commercial funding and risk assumed by each Party (taking into account Pfenex's investment and risk prior to the Option Exercise Notice) and include the period over which royalties would be paid, as well as applicable deductions from royalty payments based upon royalty stacking for third party intellectual property (substantially the same as Section 6.5(c) herein) and generic competition.

(e) If the Parties are unable to reach agreement upon and do not enter into a mutually acceptable Option Exercise Agreement within three (3) months from Jazz's delivery of the Option Exercise Notice, then either Party shall have the right to refer the matter for at least one in-person meeting (or telephone call if an in-person meeting is impractical) between the Parties' respective Executive Officers. If the Parties are unable to reach mutual agreement on the terms of the Option Exercise Agreement within such three (3)- month period, Jazz may have the terms and conditions of the Option Exercise Agreement determined by baseball arbitration in accordance with Section 12.2(b), and the Parties shall promptly enter into the Option Exercise Agreement on such terms decided by such arbitration; provided that Jazz initiates such arbitration within sixty (60) days after such three (3)-month negotiation period. With respect to the arbitration process, the Parties shall work with the arbitrator, who will determine a reasonable framework for resolving the issues in dispute between the Parties. This framework shall address a means to evaluate the overall economic value proposed by each party, the relative investments and risks assumed by each Party, the underlying assumptions in valuation models and the time- weighted allocation of overall economic value through the combination of milestone and royalty payments.

2.5 ROFN Products.

(a) ROFN. With respect to each ROFN Product, Pfenex hereby grants Jazz an exclusive right of first negotiation (the "**ROFN**") to obtain an exclusive, sublicenseable (through multiple tiers) license from Pfenex under the Pfenex ROFN Product IP for such ROFN Product to Develop, make, have made, use, sell, have sold, offer for sale and import and otherwise Commercialize such ROFN Product in the Field in the Territory under a definitive agreement as negotiated by the Parties pursuant to Section 2.5(c) for such ROFN Product. Jazz shall have the right to exercise the ROFN for each ROFN Product by delivery of written notice to Pfenex (a "**ROFN Exercise Notice**") within sixty (60) days of Jazz's receipt of the ROFN Data Package for such ROFN Product in accordance with the terms of this Section 2.5. If Jazz does not provide a ROFN Exercise Notice to Pfenex within sixty (60) days after Jazz's receipt of the applicable ROFN Data Package, then Jazz's ROFN shall lapse only with respect to such ROFN Product.

(b) ROFN Data Package. Pfenex shall keep Jazz reasonably informed of material research and development activities with respect to each ROFN Product through the regular meetings of the JDC, including by providing summaries in reasonable detail of any material data generated in connection with such activities. Following the completion of IND-enabling toxicology studies for a ROFN Product and in all events prior to the filing of an IND for such ROFN Product, Pfenex shall provide to Jazz the ROFN Data Package for such ROFN Product. Pfenex shall, within ten (10) Business Days following Jazz's written request, provide Jazz with any additional information reasonably requested by Jazz with respect to such ROFN Data Package (provided that such additional information is in Pfenex's possession and does not require the expenditure of additional funds or the performance of additional studies to generate), or Pfenex shall notify Jazz in writing during such period that Pfenex does not have such additional information in its possession, as the case may be.

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(c) **Negotiation.** Following Jazz's delivery of a ROFN Exercise Notice for a particular ROFN Product, the Parties shall use good faith efforts to negotiate the terms and conditions of a definitive agreement regarding the ROFN Product (a "**ROFN Exercise Agreement**") on an exclusive basis, meaning that Pfenex and its representatives shall not engage in discussions with any Third Party regarding a potential grant of rights to such Third Party with respect to such ROFN Product during the negotiation period. The terms of such ROFN Exercise Agreement shall be commercially reasonable and provide usual and customary terms for such arrangements. If the Parties are unable to reach agreement upon and do not enter into a mutually acceptable ROFN Exercise Agreement within three (3) months from Jazz's delivery of the applicable ROFN Exercise Notice, then the Parties shall refer the matter for at least one in-person meeting (or telephone call if an in-person meeting is impractical) between the Parties' respective Executive Officers.

(i) With respect to any ROFN Product [***] (in each case, prior to the effect of any Half-Life Extension Component) (a "[***] **ROFN Product**"), if the Parties are unable to reach mutual agreement on the terms of the ROFN Exercise Agreement within the three (3)-month period, Jazz may have the terms of the ROFN Exercise Agreement determined by baseball arbitration in accordance with Section 12.2(b), and the Parties shall promptly execute the ROFN Exercise Agreement on terms and conditions decided by such arbitration; provided that Jazz initiates such arbitration within sixty (60) days after such three (3)-month negotiation period. The arbitrator shall determine the terms and conditions of such ROFN Exercise Agreement generally taking into consideration the factors described in Section 2.4(d) for the Option Exercise Agreement.

(ii) With respect to any ROFN Product [***] (in each case, prior to the effect of any Half-Life Extension Component) (a "[***] **ROFN Product**"), if the Parties are unable to reach mutual agreement on the terms of the ROFN Exercise Agreement within the three (3)-month period, then the ROFN shall lapse for such [***] ROFN Product, and Pfenex may decide, in its sole discretion, whether to terminate or continue the development and commercialization of such [***] ROFN Product, itself or in collaboration with one or more Third Parties; *provided* that Pfenex shall notify Jazz within thirty (30) days after a Third Party first communicates in writing to Pfenex the general terms applicable to the development and commercialization of (or granting an option to develop and commercialize) such [***] ROFN Product as contained in a term sheet or proposed definitive agreement, [***]. Jazz further acknowledges and agrees that Pfenex has no obligation to conduct or continue any research or development of any ROFN Product.

2.6 Exclusivity.

(a) Pfenex. Subject to the terms of this Section 2.6, during the Term, Pfenex shall not research, develop, manufacture or commercialize, itself or with or through any Affiliate or Third Party (including by performing any services on a contract basis or activities on a Third Party product), any product containing [***] except for (i) the manufacture of HemOnc Products for supply to Jazz and its Affiliates under this Agreement; (ii) the Development of the Pegaspargase Product under the corresponding Development Plan and any activities agreed to be conducted by Pfenex for such Pegaspargase Product under any Option Exercise Agreement; (iii) the development of the applicable ROFN Product for purposes of developing the ROFN Data Package for such ROFN Product; (iv) if the Parties enter into a ROFN Exercise Agreement for a particular ROFN Product, the manufacture of such ROFN Product for supply to Jazz and its Affiliates to the extent set forth in the applicable ROFN Exercise Agreement; and (v) as provided in Sections 2.6(d)(i) and 2.6(e) below.

(b) Jazz. Subject to the terms of this Section 2.6, from and after the expiration of the last Assessment Period and thereafter during the Term, Jazz shall not research, develop, manufacture or commercialize, itself or with or through any Affiliate or Third Party (including by performing any services on a contract basis or activities on a Third Party product), any product containing [***] for such product; (iii) Development, manufacture and Commercialization of HemOnc-Pf under this Agreement, HemOnc-NextGen under this Agreement, if Jazz exercises the Option, the Pegaspargase Product in accordance with the Option Exercise Agreement, or if Jazz exercises its ROFN for a particular ROFN Product, such ROFN Product in accordance with the applicable ROFN Exercise Agreement and (iv) as provided in subsection(e) below.

(c) Termination of Exclusivity. The exclusivity obligations set forth in Section 2.6(a) and (b) shall terminate as follows:

(i) If this Agreement is terminated with respect to HemOnc-Pf, the exclusivity obligations set forth in Section 2.6(a) and (b) shall thereafter no longer apply with respect to products containing [***].

(ii) If this Agreement is terminated with respect to HemOnc-NextGen, the exclusivity obligations set forth in Section 2.6(a) and (b) shall thereafter no longer apply with respect to products containing [***].

(iii) If either this Agreement is terminated with respect to the Pegaspargase Product or the Option expires without Option Exercise, the exclusivity obligations set forth in Section 2.6(a) and (b) shall no longer apply with respect to products containing or comprising [***]; provided that the ROFN in Section 2.5 shall continue to apply.

For clarity, clauses (i), (ii) and (iii) above are cumulative (i.e., more than one clause may apply).

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(d) ROFN Products.

(i) In the event that, with respect to a particular [***] ROFN Product, Jazz declines its ROFN, Jazz's ROFN expires without delivery by Jazz to Pfenex of a ROFN Exercise Notice or the Parties do not enter into a ROFN Exercise Agreement for such ROFN Product in accordance with the terms of Section 2.5, then Sections 2.6(a) shall no longer apply to such ROFN Product. Pfenex may not file an IND for a [***] ROFN Product until Jazz declines its ROFN, Jazz's ROFN expires without delivery by Jazz to Pfenex of a ROFN Exercise Notice, or the Parties fail to enter into a ROFN Exercise Agreement for such ROFN Product in accordance with the terms of Section 2.5.

(ii) Pfenex's obligations under Section 2.6(a) shall continue to apply to any [***] ROFN Product, regardless of whether Jazz declines its ROFN, Jazz's ROFN expires without delivery by Jazz to Pfenex of a ROFN Exercise Notice, or the Parties fail to enter into a definitive ROFN Exercise Agreement.

(e) Acquisition of Competing Product. In the event that a Third Party becomes an Affiliate of a Party after the Effective Date through merger, acquisition, consolidation or other similar transaction, and as of the closing date of such transaction, such Third Party is engaged in the research, development, manufacture or commercialization of a product that, if conducted by such Party, would cause such Party to be in breach of its exclusivity obligations set forth above (a "**Competing Program**"), then:

(i) if such transaction results in a Change of Control of such Party, then such new Affiliate shall have the right to continue such Competing Program and such continuation shall not constitute a breach of such Party's exclusivity obligations set forth in Section 2.6(a) or 2.6(b), respectively; provided that such new Affiliate conducts such Competing Program independently of the activities of this Agreement and does not use any of the other Party's intellectual property rights or Confidential Information (except as may be separately licensed by such other Party to such new Affiliate) in the conduct of such Competing Program; and

(ii) if such transaction does not result in a Change of Control of such Party, then such Party and its new Affiliate shall have twelve (12) months from the closing date of such transaction to wind down or complete the divestiture of such Competing Program, and its new Affiliate's conduct of such Competing Program during such twelve (12)-month period shall not be deemed a breach of such Party's exclusivity obligations set forth above; provided that such new Affiliate conducts such Competing Program during such twelve (12)-month period independently of the activities of this Agreement and does not use any of the other Party's intellectual property or Confidential Information (except as may be separately licensed by such other Party to such new Affiliate) in the conduct of such Competing Program. "**Divestiture**", as used in this Section 2.6(e)(ii), means the sale or transfer of rights to the Competing Program to a Third Party without receiving a continuing share of profit, royalty payment or other economic interest in the success of such Competing Program.

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ARTICLE 3
GOVERNANCE

3.1 Joint Development Committee and Joint Management Team and.

(a) Formation and Role. Promptly, and in any event within thirty (30) days after the Effective Date, the Parties shall establish a joint development committee (the "**Joint Development Committee**" or "**JDC**") and such JDC will:

(i) coordinate the activities of the Parties under the Development Plans, including facilitating information exchange and discussions between the Parties with respect to the Development of Products, the progress and results (whether preliminary or final) under the Development Plans and ROFN Products;

(ii) review and discuss any proposed amendments or revisions to the Development Plans;

(iii) review and discuss any cost to be shared by the Parties;

(iv) oversee all activities relating to the manufacturing-related activities, including Product supply, process development/optimization and any related procedures;

(v) oversee technology transfer from Pfenex to Jazz's Third Party manufacturer, if applicable;

(vi) establish such Working Groups as it deems necessary to achieve the objectives and intent of this Agreement;

(vii) discuss the mitigation of potential delays related to the Development Plan and review any actual delays related to the Development Plan;

(viii) perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as agreed by the Parties in writing.

It is the expectation of the Parties that the JDC will set forth the general principles and strategies upon which the Parties will perform their activities under the Development Plans. The JDC shall have only the powers expressly assigned to it in this Section 3.1 and all other matters are expressly excluded. In no event shall the JDC have the right to amend, modify, or waive compliance with this Agreement.

(b) Members. Each Party shall initially appoint up to three (3) representatives to the JDC. Each Party may change the number of its representatives and may replace its representatives at any time upon written notice to the other Party; provided that neither Party shall have more than three (3) representatives in the JDC and each representative shall be an officer or employee of the applicable Party or its Affiliate having sufficient experience and responsibility within such Party to make decisions arising within the scope of the JDC's responsibilities. The JDC shall have a chairperson selected by Jazz. The role of the chairperson shall be to convene and preside at the meetings of the JDC and to ensure the preparation of meeting minutes, but the chairperson shall have no additional powers or rights beyond those held by other JDC representatives.

(c) Meetings. The JDC shall meet at least two (2) times per calendar year, unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the JDC (by videoconference or teleconference) by at least ten (10) Business Days' prior written notice to the other Party, and such Party shall provide the JDC, no later than ten (10) Business Days prior to the special meeting, with materials reasonably adequate to enable informed discussion or decision-making, as applicable. No later than ten (10) Business Days prior to any meeting of the JDC, the chairperson of the JDC shall prepare and circulate an agenda for such meeting; provided, however, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. The JDC may meet in person, by videoconference or by teleconference, as the Parties agree. Each Party shall bear the expense of its respective JDC members' participation in JDC meetings. Meetings of the JDC shall be effective only if at least one (1) representative of each Party is present or participating in such meeting. The chairperson of the JDC shall be responsible for preparing written minutes of all JDC meetings that reflect, without limitation, all material actions taken at such meeting and further issues to be considered. The JDC chairperson shall send draft meeting minutes to each member of the JDC for review and approval within ten (10) Business Days after each JDC meeting. Such minutes shall be deemed approved unless one or more members of the JDC object to the accuracy of such minutes within ten (10) Business Days of receipt. The JDC may be disbanded at any time by the mutual agreement of the Parties, it being understood that matters previously to be considered by the JDC shall be considered directly by the Parties in good faith with the decision making allocation as described below in the event of any dispute on such matters.

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3.2 Joint Management Team

(a) Formation. Promptly, and in any event within thirty (30) days after the Effective Date, the Parties shall establish a joint management team (the "**Joint Management Team**" or "**JMT**") and such JMT will:

(i) Manage and coordinate the strategic relationship of the Parties in the performance of the obligations under this Agreement; and

(ii) Address and resolve any disputes of the JDC.

(b) Members. Each Party shall appoint one senior executive to the JMT. Each Party may replace its representative at any time upon written notice to the other Party; provided that each representative shall be an executive of the applicable Party or its Affiliate having sufficient experience and responsibility within such Party to make decisions arising within the scope of the JMT's responsibilities.

(c) Meetings. The JMT shall meet at least one (1) time per calendar year. Either Party may also call a special meeting of the JMT (by videoconference or teleconference) by at least ten (10) Business Days' prior written notice to the other Party, and such Party shall provide the other member, no later than ten (10) Business Days prior to the special meeting, with materials reasonably adequate to enable informed discussion or decision-making, as applicable. The JMT may meet in person, by videoconference or by teleconference, as the Parties agree. Each Party shall bear the expense of its respective JMT members' participation in JMT meetings. Meetings of the JMT shall be effective only if both representatives are present or participating in such meeting.

3.3 Decision Making. The JDC and JMT each shall strive to act by consensus. The representatives from each Party on the JDC will have, collectively, one (1) vote on behalf of that Party; each Party will have one vote on the JMT. If the JDC is unable to reach consensus on any matter within the JDC's authority within thirty (30) days after first considering such matter, then such matter shall be referred to the JMT for resolution. If the JMT, after good faith efforts and consideration of the other party's position, cannot resolve such matter within thirty (30) days after such matter has been referred to the JMT, then:

(a) Jazz shall have the final decision making authority with respect to all matters relating to the HemOnc Products; provided that such final decision making authority shall not apply with respect to (i) the prosecution and enforcement of Pfenex Patents (for which decisions shall be made as set forth in Sections 7.3 and 7.4), and (ii) material changes to the Pfenex Expression Feasibility Activities;

(b) prior to Option Exercise, Pfenex shall have the final decision making authority with respect to all matters relating to the development of the Pegaspargase Product; provided that Pfenex may not materially change any of its development obligations outlined in the applicable Development Plan with respect to the Pegaspargase Product without Jazz's prior written consent; and

(c) prior to ROFN Exercise with respect to the applicable ROFN Product, Pfenex shall have the final decision making authority with respect to all matters relating to the development of such ROFN Product.

Notwithstanding the foregoing, a Party may not exercise such final decision making authority in a manner that would increase the financial obligations of the other Party. For clarity, the JDC and JMT have no authority to determine, and neither Party may exercise final-decision making authority to resolve, the achievement of a milestone set forth on **Exhibit 6.3** or the allocation of responsibility for any delay in achievement thereof.

3.4 Working Groups. From time to time, the JDC may establish and delegate duties to other committees, sub-committees or directed teams (each, a "**Working Group**") on an "as-needed" basis to oversee particular projects or activities, which delegation shall be reflected in the minutes of the meetings of the JDC. For illustrative purposes only, the JDC may establish a Working Group focused on CMC matters and a Working Group focused on intellectual property matters. Each Working Group shall be constituted and shall operate as the JDC determines and shall report to the JDC. Each Working Group and its activities shall be subject to the oversight, review and approval of the JDC. In no event shall the authority of the Working Group exceed that specified for the JDC in Section 3.1(a). Any disagreement between the designees of Pfenex and of Jazz on a Working Group shall be referred to the JDC for resolution.

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ARTICLE 4
DEVELOPMENT; MANUFACTURE; REGULATORY

4.1 Overview. The Parties agree to conduct Development of Products as provided in this Article 4.

4.2 Development Programs.

(a) General. The Parties shall undertake, using Commercially Reasonable Efforts, a development program to Develop each Product (with respect to each Product, the "**Development Program**") in accordance with the terms of this Article 4. Development of each Product under this Agreement by the Parties will be conducted pursuant to a development plan (with respect to each Product, the "**Development Plan**") that describes all Development activities to be conducted by the Parties in an initial twelve (12)-month period and, after expiry of the applicable Assessment Period, in a twenty-four (24)-month period, including to the extent applicable for the period included under such plan: (i) the proposed overall program of Development for such Product in the Territory, including preclinical studies, toxicology, formulation, process development, supply, manufacturing technology transfer, clinical studies, regulatory plans and other elements of obtaining Regulatory Approval(s) of such Product, and (ii) the tasks allocated to each Party under the Development Program and estimated timelines for such tasks and responsibilities. The Development Plan for each HemOnc Product shall also set forth the scope and timeline for completion of the Pfenex Expression Feasibility Activities and the Jazz Assessment Activities. In the event of any inconsistency between a Development Plan and this Agreement, the terms of this Agreement shall prevail.

(b) Initial Development Plans and Amendments. The Parties have set forth an initial Development Plan, together with applicable amendments as of the Amendment Effective Date, for each of the Development Programs as **Exhibit C**. From time to time (at least on an annual basis), Jazz shall prepare proposed amendments, as appropriate, to the then-current Development Plans for the HemOnc Products and, prior to Option Exercise, Pfenex shall prepare proposed amendments, as appropriate, to the then-current Development Plan for the Pegaspargase Product for review and discussion at the JDC. Following Option Exercise, the Development Plan for the Pegaspargase Product shall be prepared and amended by the Parties as set forth in the Option Exercise Agreement. Once discussed by the JDC (and as amended based on such discussion), each amended Development Plan shall become effective and supersede the previous Development Plan as of the date of approval by the applicable Party.

4.3 Allocation of Development Responsibilities.

(a) HemOnc Products. Subject to Pfenex's performance of the Pfenex Expression Feasibility Activities and manufacturing process development activities pursuant to Section 4.7, Jazz shall be responsible for conducting the Jazz Assessment Activities (subject to the final sentence of Section 4.7(a)) and all Development (other than manufacturing process development) of the HemOnc Products, including all activities during the applicable Assessment Period and all pre-clinical and clinical studies in accordance with the terms of this Agreement. Notwithstanding the foregoing and subject to Section 6.2(b)(ii), after the successful achievement of [***] as set forth on **Exhibit 6.3**, the JDC may request through an update to the applicable Development Plan that Pfenex perform, and Pfenex shall so perform upon such request, (i) [***] pursuant to the Development Plan and (ii) [***] pursuant to Section 4.7(a) for a HemOnc Product.

(b) Pegaspargase Product. Prior to Option Exercise, Pfenex shall be solely responsible, at its expense, for all Development of the Pegaspargase Product, including the manufacturing and supply of the Pegaspargase Product for Development use. Following Option Exercise, the responsibilities for the Development of the Pegaspargase Product shall be allocated between the Parties as agreed by the Parties under the Option Exercise Agreement.

4.4 Development Standards of Conduct. After the expiration of the applicable Assessment Period, Jazz shall use Commercially Reasonable Efforts to Develop the HemOnc Products for the Lead Indication in the United States and to achieve the Development milestones numbered 5 and 6 referenced in **Exhibit 6.3** that specifically relate to the Lead Indication in the United States. For clarity, Jazz's Development obligations under this Section 4.4 do not require Jazz to Develop the HemOnc Products in more than one subtype, subgroup, or line of treatment for the Lead Indication. Pfenex shall use Commercially Reasonable Efforts to Develop the manufacturing process for the HemOnc Products as set forth in the Development Plans for such Products and to Develop the Pegaspargase Product for the United States. Without limiting the foregoing, each Party shall use Commercially Reasonable Efforts to carry out the tasks assigned to it under the respective Development Plans, and each Party shall conduct its activities under the Development Plans in a good scientific manner.

4.5 Development Records and Reports. Each Party shall maintain complete, current and accurate records of all Development activities conducted by it hereunder, and all Information resulting from such activities. Such records shall accurately and completely reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes.

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4.6 Development Reports. Each Party shall keep the JDC reasonably informed on the Development activities performed by such Party under this Agreement. Without limiting the foregoing, at each regularly scheduled JDC meeting, each Party shall provide the JDC with a summary report of the Development or manufacturing activity performed by it since the last JDC meeting and the results thereof. The JDC shall discuss the progress and results of the Parties' Development or manufacturing activity and each Party shall promptly respond to the other Party's reasonable questions or requests for additional information relating to such Development. Notwithstanding the foregoing, during the applicable Assessment Period, Jazz shall only be obligated to share with Pfenex a high level plan for its activities with respect to such HemOnc Product during such time period.

4.7 Process Development; Manufacture of Products

(a) Process Development. Each Party shall be responsible, at its expense, for manufacturing process development in accordance with the applicable Development Plan. The Development Plan for each HemOnc Product shall set forth the timeline and the Parties' respective activities for the development of the manufacturing process for each such HemOnc Product, to be generally assigned to each Party consistent with the table below for each such HemOnc Product. In addition, manufacturing process development activities shall include technology transfer to Third Party manufacturers or Third Party research organizations for scale up and production of materials for clinical trials, and all other such activities related to development and validation of a commercial manufacturing process. Further, the Development Plan for each HemOnc Product shall set forth the criteria with respect to the manufacturing process for such HemOnc Product that must be satisfied prior to the transfer of such manufacturing process pursuant to Section 4.7(b) (with respect to such HemOnc Product, the "**Manufacturing Process Transfer Criteria**"). Each Party shall provide periodic written reports on its Development of the applicable manufacturing process.

Pfenex Activity	**Jazz Activity**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Pfenex Activity	**Jazz Activity**
[***]	[***]
[***]	[***]
[***]	[***]

Subject to Section 6.2(b)(ii), with respect to HemOnc-NextGen, at any time after achievement of [***] as set forth on **Exhibit 6.3** and irrespective of whether Jazz has conducted any Jazz Assessment Activities, Jazz may request in writing that Pfenex begin, and Pfenex shall so begin, [***] in accordance with the applicable Development Plan.

(b) Manufacturing Process Transfer.

(i) At Jazz's request after achievement of the Manufacturing Process Transfer Criteria with respect to the applicable HemOnc Product, Pfenex shall transfer, at its expense, Pfenex's manufacturing process for such HemOnc Product to Jazz, its Affiliate, or a Third Party manufacturer, in Jazz's sole discretion (with respect to such HemOnc Product, the "**Manufacturing Process Transfer**"). For clarity, Pfenex shall not be required to perform more than a maximum of two (2) Manufacturing Process Transfers (i.e., one for each HemOnc Product). If the Manufacturing Process Transfer is to a Third Party manufacturer for commercial supply of the applicable Product, then the Parties shall negotiate in good faith to agree on the Third Party manufacturer, but if the Parties are unable to agree, Jazz may select the Third Party manufacturer; *provided* that Pfenex may reasonably object to any proposed Third Party manufacturer on the basis of reasonable concerns regarding the protection of Pfenex's Confidential Information or intellectual property rights based on the Third Party manufacturer's history of patent infringement or misappropriation or specific geographic concerns. Notwithstanding anything to the contrary in this Agreement, if Jazz requests that Pfenex perform the Manufacturing Process Transfer with respect to the applicable HemOnc Product prior to achievement of the Manufacturing Process Transfer Criteria for such HemOnc Product, then, provided that the Parties agree in writing (such agreement not to be unreasonably withheld) with respect to alternative criteria for such Manufacturing Process Transfer following discussion of any risk factors reasonably identified by Pfenex in response to such request, Pfenex shall perform such Manufacturing Process Transfer, at its expense, pursuant to such alternative criteria.

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Notwithstanding the foregoing, Pfenex shall perform a Manufacturing Process Transfer for an applicable Product at Jazz's request (A) not later than the applicable time set forth in the Development Plan and/or (B) if after good faith discussions with Pfenex with an opportunity for Pfenex to take corrective action, Jazz reasonably determines that Pfenex will be unable achieve the Manufacturing Process Transfer Criteria by the applicable time set forth in the Development Plan.

(ii) The Parties shall conduct the applicable Manufacturing Process Transfer in accordance with this Section 4.7 and in accordance with a written Manufacturing Process Transfer plan to be mutually and reasonably agreed by the Parties prior to such Manufacturing Process Transfer. The Manufacturing Process Transfer shall include the transfer of all data, technical information, documents, and materials necessary or useful to enable Jazz or such Affiliate or Third Party manufacturer, as applicable, to manufacture and supply the applicable HemOnc Product in compliance with the applicable specifications for Development and Commercialization use and the generally accepted practices and principles for such technology transfer. The Manufacturing Process Transfer also includes reasonable and customary on-site support by Pfenex at the Third Party manufacturer's facilities during the Manufacturing Process Transfer, including participation by Pfenex in technical exchange meetings, review by Pfenex of draft batch records, and provision by Pfenex of technical supervision during any batches necessary to demonstrate that the Manufacturing Process Transfer is complete. Following the Manufacturing Process Transfer for each HemOnc Product and upon Jazz's reasonable request, Pfenex [***], as applicable, to implement the manufacturing process and analytical methods for such HemOnc Product developed by Pfenex without additional compensation and (B) such additional technical assistance (including access to its technical personnel) as may be requested by Jazz for compensation at Pfenex's then applicable hourly rates, in each case (A) and (B) subject to reimbursement of Pfenex's documented travel and other out-of-pocket expenses incurred in performing providing such assistance within thirty (30) days of invoice therefor. Jazz may use any unused portion of Pfenex's [***] with respect to the [***] following Manufacturing Process Transfer.

(c) Product Supply. Prior to Manufacturing Process Transfer under Section 4.7(b) (if applicable), Pfenex shall use reasonable efforts to manufacture and supply to Jazz all non-GMP HemOnc Products reasonably required for pre-clinical and process development studies in accordance with the specifications, quantities and timeline set forth in the applicable Development Plan. After the completion of a Manufacturing Process Transfer for a HemOnc Product, Jazz shall be responsible, at its expense and through Jazz, its Affiliates or a designated Third Party manufacturer, for the manufacture and supply of all HemOnc Product required for use in the remaining clinical Development and the Commercialization of such HemOnc Product. Upon Jazz's request, at a reasonable time during the manufacturing development process, the Parties shall negotiate in good faith for a reasonable period of time, not to exceed ninety (90) days or such longer period as mutually agreed by the Parties, the terms and conditions of a supply agreement pursuant to which Pfenex will be Jazz's supplier of one or both GMP HemOnc Products for use in clinical Development and Commercialization, on a non-exclusive or exclusive basis as agreed by the Parties. For clarity, neither Party shall be required to enter into such an agreement except on such terms as are acceptable to such Party in its sole and absolute discretion.

4.8 Regulatory Matters for HemOnc Products.

(a) Jazz Responsibilities. Except as expressly set forth herein, Jazz shall be responsible, at its expense, for all regulatory activities required to obtain and maintain Regulatory Approval for the HemOnc Products, including the preparation of all Regulatory Materials and all communications and interactions with Regulatory Authorities with respect to the HemOnc Products and pharmacovigilance reporting. Jazz shall own all Regulatory Materials (including all INDs, BLAs, MAAs and Regulatory Approvals) for the HemOnc Products. Pfenex shall not submit any Regulatory Materials for the HemOnc Products without the prior written consent of Jazz. Except as expressly requested by Jazz in writing, Pfenex shall not communicate with any Regulatory Authority with respect to the HemOnc Products, unless so required to comply with applicable Laws, in which case Pfenex shall promptly notify Jazz of such requirement under applicable Laws and, to the extent practicable and permitted under applicable Laws, shall submit any proposed communication to Jazz for prior approval or, if not practicable or permitted, shall provide Jazz with a copy or summary thereof as soon as reasonably practicable thereafter.

(b) Regulatory Collaboration. Upon Jazz's request, Pfenex shall provide reasonable support with respect to CMC (including writing applicable M3 modules of the International Conference on Harmonisation Common Technical Document specifically related to the production strains with respect to the applicable Product), pharmacovigilance, and other matters for the HemOnc Products in connection with Jazz's regulatory activities. Without limiting the foregoing, at the direction of Jazz, the Parties shall collaborate and work together to prepare CMC related Regulatory Materials for the HemOnc Products and the JDC may establish a Working Group to coordinate and oversee such regulatory work.

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(c) Regulatory Information Sharing. Jazz shall conduct all interactions with Regulatory Authorities with respect to the HemOnc Products and shall keep Pfenex reasonably informed on the regulatory development for the HemOnc Products through the JDC. At its option, Jazz may provide Pfenex with drafts of Regulatory Materials prepared by Jazz for the HemOnc Products reasonably in advance of filing where practicable for Pfenex's review and comment. If Jazz so provides Pfenex with drafts of Regulatory Materials, Jazz will consider in good faith any such comments where practicable.

(d) Regulatory Meetings. To the extent permitted by applicable Laws, (i) upon Jazz's request, Pfenex shall have a representative present in any meetings and teleconferences with Regulatory Authorities, or (ii) with Jazz's prior written consent, Pfenex may have a representative present in any meetings and teleconferences with Regularly Authorities; provided, that in each case Pfenex may only actively participate in such meeting with respect to topics that pertain to activities performed by Pfenex under the applicable Development Plan and the content of such participation is subject to the prior agreement of the Parties. Jazz shall reimburse Pfenex for out-of-pocket expenses reasonably incurred by Pfenex in attending a meeting with a Regulatory Authority in person following Jazz's request pursuant to clause (i) above.

(e) Regulatory Inspection.

(i) Pfenex shall promptly (and in any event within one (1) Business Day of becoming aware thereof) notify Jazz of any Regulatory Authority inspections relating to any HemOnc Product or related activities under the applicable Development Plan. Jazz shall have the right to be present at any such inspections and shall have the opportunity to provide, review and comment on any responses that may be required. Pfenex shall provide Jazz with copies of all materials, correspondence, statements, forms and records received or generated pursuant to any such inspection. In addition to such obligations with respect to Regulatory Authority inspections, Pfenex shall promptly (and in any event within one (1) Business Day following receipt thereof) notify Jazz of any information it receives regarding any threatened or pending action or communication by or from any Third Party, including a Regulatory Authority, that may materially affect the Development, manufacturing, Commercialization or regulatory status of HemOnc Products.

(ii) Jazz shall promptly notify Pfenex of any Regulatory Authority inspections relating specifically to the manufacturing process developed by Pfenex for any HemOnc Product (or any modified version of such manufacturing process for such HemOnc Product) and conducted by Jazz, its Affiliate or any Third Party manufacturer. Jazz shall provide Pfenex with a written summary of such inspection. In addition to such obligations with respect to Regulatory Authority inspections, Jazz shall promptly notify Pfenex of any information it receives regarding any threatened or pending action or communication by or from any Third Party, including a Regulatory Authority, that may materially affect the manufacturing or regulatory status of HemOnc Products; provided that Jazz shall only provide Pfenex with any such information received by a Third Party to the extent permitted under Jazz's agreement with such Third Party.

4.9 Regulatory Matters for Pegaspargase Product. Prior to Option Exercise, Pfenex shall be solely responsible for all regulatory activities for the Pegaspargase Product, shall be solely responsible for all interactions with Regulatory Authorities with respect to the Pegaspargase Product and shall keep Jazz reasonably informed on regulatory developments for the Pegaspargase Product through the JDC. After Option Exercise, the responsibilities for the regulatory activities required to obtain and maintain Regulatory Approval of the Pegaspargase Product shall be allocated between the Parties as agreed by the Parties under the Option Exercise Agreement.

4.10 Subcontracts. Each Party may perform its Development Program obligations under this Agreement through one or more subcontractors, provided that (a) Pfenex's subcontractors shall be subject to Jazz's prior written approval (except that, in the case of the Development Program for the Pegaspargase Product prior to Option Exercise, Pfenex may engage subcontractors without such approval), (b) the subcontracting Party shall remain responsible for the work delegated to, and payment to (subject to Section 6.2(b)), its subcontractors to the same extent it would if it had done such work itself and (c) the subcontracting Party shall enter into a written agreement with the subcontractor that is consistent with this Agreement, including provisions relating to confidentiality and intellectual property rights that are at least as restrictive as those in this Agreement. The subcontracting Party shall enforce any breach by a subcontractor under such subcontracting agreement for the non-subcontracting Party's benefit and on its behalf.

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ARTICLE 5
COMMERCIALIZATION

5.1 Commercialization Responsibilities. Subject to the terms hereof, Jazz will have the exclusive right to conduct, and will be solely responsible for all aspects of, the Commercialization of HemOnc Products and, subject to Option Exercise, the Pegaspargase Product in the Field in the Territory, including: (a) developing and executing a commercial launch and pre-launch plan; (b) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of Products; (c) marketing and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; (g) conforming its practices and procedures to applicable Laws relating to the marketing, detailing and promotion of Products in the Territory; and (h) manufacturing of Products for commercial use (subject to the terms of any definitive manufacturing agreement between the Parties). As between the Parties, Jazz shall bear all of its costs and expenses incurred in connection with the Commercialization activities for the HemOnc Products.

5.2 Commercial Diligence; Report. After Jazz has obtained Regulatory Approval for a HemOnc Product, Jazz shall use Commercially Reasonable Efforts to Commercialize such HemOnc Product for the Lead Indication in the United States. For clarity, Jazz's Commercialization obligations under this Section 5.2 do not require Jazz to Commercialize the applicable HemOnc Product in more than one subtype, subgroup, or line of treatment of the Lead Indication. In addition, subject to Option Exercise, Jazz will use Commercially Reasonable Efforts to Commercialize the Pegaspargase Product following Regulatory Approval in the United States. On an annual basis, Jazz shall provide Pfenex with a summary of Jazz's significant Commercialization activities with respect to each Product in the Territory since the last such report.

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ARTICLE 6
COMPENSATION

6.1 Upfront Payments.

(a) Within two (2) Business Days after the Effective Date, Jazz shall pay to Pfenex a one-time, non-refundable (i) upfront payment of [***] Dollars ($[***]) in consideration of the licenses and related rights granted under this Agreement for HemOnc- NextGen; and (ii) option payment of [***] Dollars ($[***]) in consideration of the Option granted under Section 2.4. The Parties acknowledge and agree that Jazz paid to Pfenex fifteen million Dollars ($15,000,000) pursuant to this Section 6.1(a) under the Original Agreement.

(b) Within ten (10) Business Days after the Amendment Effective Date, Jazz shall pay to Pfenex a one-time, non-refundable payment of five million Dollars ($5,000,000) in consideration of the amendment and restatement of this Agreement.

6.2 Development Costs.

(a) General. Except as expressly set forth herein, each Party shall be responsible for the cost and expenses it incurs to carry out the Development work under the Development Plans, including in the case of Pfenex, the cost and expense of the manufacturing technology transfer under Section 4.7(b).

(b) HemOnc Products. If Pfenex is required to perform any Development activities for the HemOnc Products under the applicable Development Plan or at Jazz's request, the Parties shall promptly agree on a budget for such activities either in the applicable Development Plan or otherwise prior to the commencement of the applicable activity.

(i) If Pfenex engages a Third Party to perform such activities because Pfenex does not have the capability to perform such Development activities, then Jazz shall reimburse Pfenex for its reasonable and documented actual expenses paid by Pfenex to Third Parties to perform such Development activities, without markup, to the extent such expenses do not exceed a mutually agreed written budget for such activities or an amount otherwise approved in advance and in writing by Jazz. Within five (5) Business Days after the end of each month during which Pfenex incurred any such expenses, Pfenex shall provide Jazz with a good faith estimate of all amounts paid to Third Parties in such month, without markup, to engage such Third Party to conduct such Development activities. Within thirty (30) days after the end of each month during which Pfenex incurred any such expenses, Pfenex shall provide Jazz with an invoice and reasonable supporting documentation for all amounts paid to Third Parties in such month, without markup, to engage such Third Party to conduct such Development activities (up to the amount budgeted for such Development activities or otherwise approved in writing by Jazz). Jazz shall pay each such invoice within forty-five (45) days after receipt thereof, except to the extent disputed by Jazz in good faith. Jazz shall notify Pfenex if it disputes any portion of any such invoice prior to the due date for payment. For clarity, Jazz shall not be required to pay any invoiced amount for a particular Development activity that exceeds the amount budgeted or approved for such activity. Jazz shall notify Pfenex if it disputes any portion of any such invoice within ten (10) Business Days from receipt of the invoice.

(ii) Pfenex shall perform Development activities for a single HemOnc-Pf candidate and a single HemOnc-NextGen candidate pursuant to the applicable Development Plan at its sole cost and expense; *provided*, that if Jazz proposes a new HemOnc- NextGen candidate that incorporates the Half-Life Extension Component by fusion using genetic means, other than the Amendment Date HemOnc-NextGen Product, Jazz shall reimburse Pfenex for documented internal personnel, at a rate of [***], for time actually spent by Pfenex for process development activities performed on the previous candidate up to the date of notification of the change and prior to Pfenex beginning Pfenex Expression Feasibility Studies and process development activities on the new proposed HemOnc- NextGen candidate, and for the avoidance of doubt, such reimbursed costs exclude costs associated with Pfenex Expression Feasibility Activities, the cost to produce material required in milestone 3 in **Exhibit 6.3**, and costs associated with Manufacturing Process Transfer. Jazz may propose no more than two (2) additional HemOnc-NextGen candidates. If any of milestones 1–3 set forth on **Exhibit 6.3** is achieved a second or third time by any HemOnc-NextGen Product other than a HemOnc-NextGen Product which has previously achieved such milestone, then the milestone payment due for such HemOnc-NextGen Product candidate achieving such milestone for such second or third time is as set forth in the column entitled "Second and third HemOnc-NextGen Products to achieve such milestone (under Section 6.2(b)(ii))" on **Exhibit 6.3**. The Parties acknowledge and agree that, notwithstanding the terms of the Original Agreement (including this Section 6.2(b)(ii)), Jazz is not required to pay Pfenex for any Pfenex Expression Feasibility Activities conducted by Pfenex under the Original Agreement.

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(c) Pegaspargase Product. Prior to Option Exercise, Pfenex shall be solely responsible for all cost and expenses it incurs for the Development of the Pegaspargase Product. After Option Exercise, the Parties will allocate the Development cost for the Pegaspargase Product as agreed by the Parties under the Option Exercise Agreement.

6.3 Development Milestone Payments for HemOnc Products. Jazz shall notify Pfenex within ten (10) days after the achievement by the applicable Party or its Affiliates or sublicensees of the development milestone events set forth on **Exhibit 6.3**. Thereafter, Pfenex shall invoice Jazz for the corresponding milestone payment set forth on **Exhibit 6.3**, and Jazz shall pay each such invoice within forty-five (45) days after receipt thereof. Notwithstanding the preceding sentence, concurrently with the delivery of materials set forth in milestone payments numbered 1 and 2 listed on **Exhibit 6.3**, Pfenex shall invoice Jazz for the corresponding milestone payment, and Jazz shall pay each invoice within five (5) Business Days after receipt thereof. Each payment set forth in this Section 6.3 shall be non-refundable and non-creditable. The Parties acknowledge and agree that Jazz has previously paid to Pfenex [***] for achievement of milestone 1 for HemoOnc-Pf, [***] for achievement of milestone 2 for HemOnc-Pf, and [***] for achievement of milestone 3 for HemOnc-Pf, in each case pursuant to this Section 6.3 under the Original Agreement.

(a) Except for milestones 1-3 set forth on **Exhibit 6.3** which may be payable up to three times with respect to HemOnc-NextGen Products, each milestone payment is payable one time only with respect to the first Product to achieve such milestone, regardless of the number of times the corresponding event is achieved by a Product and regardless of the number of Products to achieve such event. Under no circumstances shall Jazz be obligated to pay Pfenex more than eighty-four million five hundred thousand Dollars ($84,500,000) pursuant to this Section 6.3.

(b) "EU Approval" means the later of (i) first achievement of MAA approval in the European Union by the centralized procedure or in at least three of the five Major European Countries; and (b) first receipt of Pricing Approval in at least three Major European Countries, provided that Jazz uses Commercially Reasonable Efforts to obtain such Pricing Approvals after the corresponding MAA approval.

(c) For clarity, in the case of development milestone events numbered 1 through 4 listed on **Exhibit 6.3** only, if any such higher numbered development milestone event for a particular HemOnc Product is achieved and any such lower numbered development milestone event for such HemOnc Product has not yet been achieved for any reason, notwithstanding anything herein to the contrary, such lower numbered development milestone event shall be deemed to have been achieved and the corresponding development milestone payment listed on **Exhibit 6.3** shall be payable simultaneously with the development milestone payment for achievement of such higher numbered development milestone event.

6.4 Sales Milestones for HemOnc-NextGen. Jazz shall notify Pfenex, concurrently with the delivery of the royalty report under Section 6.5(d), after the end of the calendar quarter in which the aggregate annual Net Sales of HemOnc-NextGen by Jazz and its Affiliates and sublicensees first reaches each of the amounts specified on **Exhibit 6.4**. Thereafter, Pfenex shall invoice Jazz for the corresponding milestone payment set forth on **Exhibit 6.4**, and Jazz shall pay each such invoice within thirty (30) days after receipt thereof. Each such sales milestone payment shall be payable one time only. For clarity, the milestone payments in **Exhibit 6.4** shall be additive such that if more than one milestone below is met in the same calendar year, Jazz shall pay all applicable payments to Pfenex for that calendar year in accordance with this Section 6.4.

6.5 Royalties on HemOnc Products.

(a) Royalty Rates. Subject to Sections 6.5(b) and 6.5(c), Jazz shall pay to Pfenex royalties on aggregate annual Net Sales of HemOnc-Pf and HemOnc-NextGen, as calculated by multiplying the applicable royalty rate by the corresponding amount of Net Sales of HemOnc-Pf and HemOnc-NextGen in each calendar year as set forth on **Exhibit 6.5(a)**. For clarity, Net Sales and the applicable royalty rate shall be determined separately for each of HemOnc-Pf and HemOnc-NextGen.

(b) Royalty Term. Royalties shall be paid under this Section 6.5, on a Product-by-Product basis, for so long as Jazz or any other Selling Party is Commercializing or having Commercialized the HemOnc Products (with respect to each Product, the "**Royalty Term**").

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(c) Third Party Royalty Stacking. If Jazz obtains a license from a Third Party to any intellectual property right in order to manufacture, import, sell or Commercialize a HemOnc Product, Jazz shall have the right to deduct, from the royalty payment that would otherwise have been due pursuant to this Section 6.5 with respect to Net Sales of such HemOnc Product in the applicable country in a particular calendar quarter, an amount equal to [***] of the royalties paid by Jazz to such Third Party pursuant to such license on account of the sale of such HemOnc Product in such country during such calendar quarter; [***]. Jazz shall not be entitled to any reduction for any Third Party payments made under any intellectual property licensed by Jazz from any Third Party as of the Effective Date or for any Jazz Extension IP.

(d) Royalty Reports and Payments. Within forty-five (45) days after the end of each calendar quarter (or sixty (60) days for the last calendar quarter of the calendar year) after the First Commercial Sale of any HemOnc Product, Jazz shall deliver to Pfenex a statement, on a country-by-country and Product-by-Product basis, of the amount of gross sales and Net Sales of the HemOnc Products during the applicable calendar quarter and a calculation of the amount of royalty payment due on such sales for such calendar quarter, including royalty reduction under Section 6.5(c), if applicable. Following receipt of each royalty report, Pfenex shall invoice Jazz for the royalty payment, and Jazz shall pay each such invoice within fifteen (15) days after receipt thereof.

(e) Third Party Payments. Pfenex will be solely responsible for all amounts owed to Third Parties pursuant to agreements between Pfenex and Third Parties with respect to HemOnc Products.

6.6 Royalty Purchase Right.

(a) With respect to each HemOnc Product, at any time following the first Regulatory Approval of such HemOnc Product, Jazz may elect to replace all future royalties that would otherwise be due under Section 6.5 for such HemOnc Product with a one-time cash payment equal to the risk-adjusted net present value of such future royalties for such HemOnc Product, determined in accordance with normal and customary valuation methodologies and taking into account relevant commercial and other factors (the "**Royalty Valuation**"), pursuant to this Section 6.6.

(b) If Jazz so elects, the Parties shall use good faith efforts to negotiate the Royalty Valuation for such HemOnc Product for a period of thirty (30) days.

(c) If the Parties are unable to agree on the Royalty Valuation for such HemOnc Product after such good faith negotiations within such thirty (30)-day period, such Royalty Valuation will be determined by a nationally recognized investment bank, professional valuation firm, or consulting firm that is independent from the Parties (a "**Valuation Firm**") in accordance with Section 6.6(d)–(e).

(d) Jazz shall initially designate the Valuation Firm and notify Pfenex of such designation within fifteen (15) days of the expiration of the thirty (30)-day period set forth in Section 6.6(b) above. If Pfenex agrees to the Valuation Firm initially designated by Jazz, then the Parties shall jointly engage such Valuation Firm pursuant to Section 6.6(d). If, after good faith discussions, the Parties are unable to agree on a Valuation Firm, then Pfenex shall also select a Valuation Firm, and the Jazz-designated and the Pfenex-designated Valuation Firms will together appoint a third Valuation Firm, which the Parties will engage pursuant to Section 6.6(e).

(e) The Parties shall engage the Valuation Firm determined pursuant to Section 6.6(d) to promptly determine the Royalty Valuation for such HemOnc Product and to deliver to each of Jazz and Pfenex the Royalty Valuation together with a report summarizing the methodology and basis for its determination following the procedures set forth in this Section 6.6(e). Within twenty (20) days after the selection of such Valuation Firm, each Party shall provide such Valuation Firm and the other Party a proposed Royalty Valuation for such HemOnc Product, together with any relevant background information, assumptions and calculations in support thereof (the "**Royalty Valuation Proposals**"). Within fifteen (15) days after the delivery of the last Royalty Valuation Proposal to such Valuation Firm, each Party may submit a written rebuttal of the other Party's Royalty Valuation Proposal and may also amend and re-submit its original Royalty Valuation Proposal. Each Party shall also provide the Valuation Firm (with a copy to the other Party) with all information reasonably requested by the Valuation Firm regarding such Royalty Valuation Proposal and any other information such Party reasonably deems relevant to the Valuation Firm's determination of the Royalty Valuation. Within thirty (30) days after the expiration of the fifteen (15)-day period set forth in this Section 6.6(e) above, the Valuation Firm shall select one of the final Royalty Valuation Proposals for such HemOnc Product so submitted by one of the Parties as the Royalty Valuation for such HemOnc Product, but may not alter the terms of any final Royalty Valuation Proposal and may not determine the Royalty Valuation for such HemOnc Product in a manner other than by selection of one of the submitted final Royalty Valuation Proposals for such HemOnc Product.

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(f) Within thirty (30) days of its receipt of the Royalty Valuation and the accompanying report, Jazz shall notify Pfenex in writing whether Jazz elects to pay the Royalty Valuation and terminate all remaining royalties that would otherwise be due under Section 6.5 for the applicable HemOnc Product. If Jazz so elects to pay the Royalty Valuation, then (i) Jazz shall pay Pfenex the amount of the Royalty Valuation for such HemOnc Product within fifteen (15) days after the date of Jazz's notice of election pursuant to the preceding sentence, (ii) no further royalties will accrue or become due under this Agreement for such HemOnc Product beyond any royalties already due or accrued at the time of Jazz's payment to Pfenex pursuant to clause (i), (iii) this Agreement shall be deemed amended to reflect the payment of the Royalty Valuation and the termination of the obligation to pay royalties, as set forth in this Section 6.6(e); and (iv) each Party shall be responsible for fifty percent (50%) of the amounts invoiced by the Valuation Firm to conduct the Royalty Valuation. If Jazz does not elect to pay the Royalty Valuation or does not provide Pfenex with notice of its election within such thirty (30)-day period, then Section 6.5 will remain unchanged for such HemOnc Product, and Jazz shall be solely responsible for the amounts invoiced by the Valuation Firm to determine the Royalty Valuation.

6.7 Foreign Exchange. The rate of exchange to be used in computing the amount of currency equivalent in Dollars of Net Sales invoiced in other currencies shall be the rate used by Jazz in its financial reporting in accordance with applicable GAAP or other standard as then-used by Jazz.

6.8 Manner and Place of Payment. All payments owed by Jazz under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Pfenex.

6.9 Records; Audits. Jazz agrees that it and all other Selling Parties will maintain complete and accurate records in reasonably sufficient detail to permit Pfenex to confirm the accuracy of the calculation of royalty payments and the achievement of sales milestone events. Upon reasonable prior notice, such records shall be available during regular business hours for a period of three (3) years from the end of the calendar year to which they pertain for examination, not more often than once each calendar year, by an independent certified public accountant selected by Pfenex and reasonably acceptable to Jazz, for the sole purpose of verifying the accuracy of the financial reports furnished by Jazz pursuant to this Agreement. Any such auditor shall enter into a confidentiality agreement with Jazz and shall not disclose Jazz's Confidential Information to Pfenex or to any Third Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Jazz or the amount of payments due by Jazz to Pfenex under this Agreement. Any amounts shown to be owed but unpaid shall be paid by Jazz to Pfenex, and any amounts showed to be overpaid will be refunded by Pfenex to Jazz, within forty-five (45) days from the accountant's report. Pfenex shall bear the full cost of such audit unless such audit discloses an underpayment by Jazz of more than ten percent (10%) of the amount due, in which case Jazz shall bear the full cost of such audit.

6.10 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Jazz to Pfenex under this Agreement. To the extent Jazz is required to deduct and withhold taxes on any payment to Pfenex, Jazz shall deduct the amounts of such taxes from the payment to Pfenex, pay such amounts to the proper Governmental Authority in a timely manner and promptly transmit to Pfenex an official tax certificate or other evidence of such withholding sufficient to enable Pfenex to claim such payment of taxes. Pfenex shall provide Jazz any tax forms that may be reasonably necessary in order for Jazz not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

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(c) Withholding Tax Action. If either Party (or its Affiliates or successors) is required to make a payment to the other Party subject to a deduction or withholding of tax, then (A) if such deduction or withholding of tax obligation arises as a result of any action by the first Party, such as a Change of Control, change of domicile, or assignment by such first Party and such action has the effect of increasing the amount of tax deducted or withheld (a "**Withholding Tax Action**"), then the amount payable by the Party taking such Withholding Tax Action (in respect of which such increased deduction or withholding is required to be made) shall be increased by the amount necessary (the "**Additional Amounts**") to ensure that the other Party receives the same amount that it would have received had no such Withholding Tax Action occurred, and (B) the Additional Amounts shall be deducted and withheld by the Party paying the Additional Amounts. The Additional Amounts, along with any other tax deducted and withheld from the payment made by such Party, shall be timely remitted to the proper Governmental Authority for the account of the other Party in accordance with applicable Law. Notwithstanding the foregoing, any sublicense or assignment in contravention of Sections 2.1(d) or 13.6, respectively, of this Agreement will not constitute a Withholding Tax Action.

(d) Refund of Additional Amounts. In the event a Party actually receives a credit against any tax on its income for any Additional Amounts paid to a Governmental Authority on its behalf (whether for the taxable year with respect to which such Additional Amounts are deducted and withheld, or in any prior or subsequent taxable year), the Party obtaining such credit shall refund and pay to the other Party an amount equal to the lesser of the credit obtained and such Additional Amounts. Whether a credit is obtained for Additional Amounts or for other taxes paid by a Party shall be determined in a manner consistent with applicable Laws.

ARTICLE 7
INTELLECTUAL PROPERTY MATTERS

7.1 Ownership of Inventions.

(a) Sole Inventions. Each Party shall solely own any Inventions made solely by it or its Affiliates' employees, agents, or independent contractors that are not Pfenex Improvements, Jazz Improvements or Post-Primary Recovery Inventions ("**Sole Inventions**").

(b) Joint Inventions. The Parties shall jointly own: (i) any Inventions that (A) are made jointly by employees, agents, or independent contractors of one Party or its Affiliates together with employees, agents, or independent contractors of the other Party or its Affiliates and (B) are not Pfenex Improvements or Jazz Improvements; and (ii) Post-Primary Recovery Inventions ((i) and (ii) together, "**Joint Inventions**"). All Patents claiming Joint Inventions shall be referred to herein as "**Joint Patents**." Except to the extent a Party is expressly limited by the terms of this Agreement, including 7.1(g), each Party shall be entitled to practice, license, assign and otherwise exploit the Joint Inventions and Joint Patents without the duty of accounting or seeking consent from the other Party. Inventorship shall be determined in accordance with U.S. patent laws.

(c) Pfenex Improvements. Notwithstanding Sections 7.1(a) and 7.1(b) and subject to Section 7.1(g), Pfenex shall solely own all Inventions (developed solely by or on behalf of a Party or jointly by or on behalf of the Parties) that constitute an improvement, modification or enhancement of Pfenex's proprietary *P. fluorescens* protein expression and manufacturing technology that has been disclosed by Pfenex to Jazz in writing (the "**Disclosed Platform**"), where such improvement, modification, and enhancement is applicable to the manufacture of drug substance for products in addition to the Products, including (i) improvements, modifications and enhancements to the Disclosed Platform generated under this Agreement (excluding, for clarity, any protein sequence), and (ii) growth media and conditions generally applicable to *P. fluorescens* and products that do not contain [***], but excluding (A) Post-Primary Recovery Inventions and (B) any Inventions, Information, or improvements relating to the process of formulating a Product or the formulated Product (the "**Pfenex Improvements**"). To the extent any Pfenex Improvement is made by Jazz's or its Affiliates' employees, agents, or independent contractors (whether solely or jointly with Pfenex), Jazz hereby assigns to Pfenex all of the right, title and interest in and to such Pfenex Improvement.

(d) Jazz Improvements. Notwithstanding Sections 7.1(a) and 7.1(b), Jazz shall solely own all Inventions (developed solely by or on behalf of a Party or jointly by or on behalf of the Parties) that constitute an improvement, modification or enhancement of the Half-Life Extension Component for HemOnc-NextGen selected by Jazz, in its sole discretion, including any fusion protein comprised of [***] together with a Half-Life Extension Component (the "**Jazz Improvements**"). To the extent any Jazz Improvement is made by Pfenex's or its Affiliates' employees, agents, or independent contractors (whether solely or jointly with Jazz), Pfenex hereby assigns to Jazz all of the right, title and interest in and to such Jazz Improvement.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

(e) Product Licenses. Pfenex Improvements, Sole Inventions owned by Pfenex, and Pfenex's interest in Joint Inventions shall be included in Pfenex IP and automatically licensed to Jazz under Section 2.1. Jazz Improvements shall be included in Jazz Extension IP and automatically licensed to Pfenex under Section 2.2.

(f) Improvement Licenses. In addition to the license grant contained in Section 7.1(e), Pfenex hereby grants to Jazz a non-exclusive, worldwide, transferrable, fully paid, perpetual, irrevocable, sublicenseable license (through multiple tiers) under Pfenex Improvements assigned by Jazz to Pfenex under Section 7.1(c) solely to manufacture any product that contains [***] or includes a Half-Life Extension Component. In addition to the license grant contained in Section 7.1(e), Jazz hereby grants to Pfenex a non-exclusive, worldwide, transferrable, fully paid, perpetual, irrevocable, sublicenseable (through multiple tiers) license under Jazz Improvements Controlled by Jazz assigned by Pfenex to Jazz under Section 7.1(d) solely to use with Pfenex's proprietary *P. fluorescens* manufacturing platform to manufacture biological products. For clarity, the foregoing licenses granted by each Party expressly exclude (by implication or otherwise) any license or other right to practice any other intellectual property right Controlled by a Party that may be necessary or useful to practice the subject Jazz Improvement or Pfenex Improvement, as applicable.

(g) Post-Primary Recovery Inventions. Notwithstanding Sections 7.1(a), 7.1(b), and 7.1(c), the Parties shall jointly own all Inventions (developed solely by or on behalf of a Party or jointly by or on behalf of the Parties) made prior to completion of the applicable Manufacturing Process Transfer that constitute a process, or an improvement, modification, or enhancement of a process, used in the manufacture of proteins following the primary recovery of such proteins, excluding any Inventions, Information, or improvements relating to the process of formulating a Product or the formulated Product (the "**Post-Primary Recovery Inventions**"). To the extent any Post-Primary Recovery Invention is made solely by the employees, agents, or independent contractors of a Party or its Affiliates, such Party hereby assigns to the other Party a joint ownership interest in and to such Post-Primary Recovery Invention such that the Parties shall jointly own such Post-Primary Recovery Invention. For clarity, after completion of the applicable Manufacturing Process Transfer, Sections 7.1(a) and 7.1(b) shall govern ownership of Inventions that constitute a process, or an improvement, modification, or enhancement of a process, used in the manufacture of proteins following the primary recovery of such proteins. Neither Party may file a Patent on Post-Primary Recovery Inventions without the consent of the other Party, such consent not to be unreasonably withheld, conditioned, or delayed.

7.2 Disclosure of Inventions. Each Party shall promptly disclose to the other Party, subject to any Third Party obligations, all Inventions made by such Party to which the other Party has rights hereunder, including any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing such Inventions, and shall promptly respond to reasonable requests from the other Party for additional Information relating to such Inventions.

7.3 Patent Prosecution.

(a) Jazz Sole Patents. As between the Parties, Jazz shall have the sole and exclusive right to file, prosecute and maintain all Patents contained in Jazz Extension IP (including Jazz Improvements) and Patents claiming Jazz's Sole Inventions (collectively, the "**Jazz Sole Patents**"), at its own cost and expense. Jazz shall periodically provide Pfenex with updates on the status of the Jazz Sole Patents. For the purpose of this Article 7, "prosecution" shall include conducting any *inter partes* review, post-grant review, or any other post-grant proceeding including any patent interference proceeding, opposition proceeding and reexamination.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

(b) Pfenex Sole Patents. As between the Parties, Pfenex shall have the first right to file, prosecute and maintain all Pfenex Sole Patents, at its own cost and expense. Pfenex shall consult with Jazz and keep Jazz reasonably informed of the status of the Pfenex Sole Patents and shall promptly provide Jazz with all material correspondence received from any patent authority in connection therewith. In addition, Pfenex shall promptly provide Jazz with drafts of all proposed material filings and correspondence to any patent authority with respect to the Pfenex Sole Patents for Jazz's review and comment prior to the submission of such proposed filings and correspondence. Pfenex shall confer with Jazz and shall (i) accept Jazz's comments to any Pfenex Product-Specific Patent and (ii) consider in good faith Jazz's comments to any other Pfenex Sole Patent (including Pfenex General Product Patent), in each case prior to submitting such filings and correspondence. Each Party shall have the right to refer any such matters for further discussion to the JDC or to any Working Group focused on intellectual property as may be established by the JDC. Pfenex shall file patents covering Sole Inventions owned by Pfenex in a manner to separate the claims specifically related to a Product from other subject matter to the extent possible and in consultation with Jazz, if doing so does not, in Pfenex's reasonable, good faith determination, cause a material adverse effect on Pfenex's intellectual property rights covering products other than a Product. If Pfenex decides to no longer prosecute or maintain any Pfenex Product-Specific Patent in any jurisdiction in the Territory, it shall notify Jazz in writing. Thereafter, Jazz shall have the right to prosecute and maintain such Pfenex Product-Specific Patent in such jurisdiction at its own cost and expense. If Pfenex decides to no longer prosecute or maintain any Pfenex General Product Patent, it shall notify Jazz in writing. Thereafter, Jazz shall have the right to prosecute and maintain such Pfenex General Product Patent in such jurisdiction at its own cost and expense if doing so does not, in Pfenex's reasonable, good faith determination, cause a material adverse effect on Pfenex's intellectual property rights covering products other than a Product.

(c) Joint Patents. As between the Parties, Jazz shall have the first right to file, prosecute and maintain all Joint Patents, at its own cost and expense. Jazz shall consult with Pfenex and keep Pfenex reasonably informed of the status of the Joint Patents and shall promptly provide Pfenex with all material correspondence received from any patent authority in connection therewith. In addition, Jazz shall promptly provide Pfenex with drafts of all proposed material filings and correspondence to any patent authority with respect to the Joint Patents for Pfenex's review and comment prior to the submission of such proposed filings and correspondences. Jazz shall confer with Pfenex and consider in good faith Pfenex's comments prior to submitting such filings and correspondences. If Jazz decides to no longer prosecute or maintain any Joint Patent in any jurisdiction in the Territory, it shall notify Pfenex in writing. Thereafter, Pfenex shall have the right to prosecute and maintain such Joint Patent in such jurisdiction at its own cost and expense.

(d) Cooperation. Each Party shall provide the other Party all reasonable assistance and cooperation, at the other Party's request and expense, in the patent prosecution efforts provided above in this Section 7.3, including providing any necessary powers of attorney, executing any other required documents or instruments for such prosecution, and making its personnel with appropriate scientific expertise available to assist in such efforts.

7.4 Patent Enforcement.

(a) Notification. If either Party becomes aware of (i) any existing or threatened infringement of any Pfenex Patent in the Territory, which infringing activity involves the using, making, importing, exporting, offering for sale or selling Products or products that otherwise are competitive with Products, (ii) a declaratory judgment action asserting the invalidity, unenforceability or non-infringement of any Pfenex Patent in the Territory in connection with any infringement described in clause (i), or (iii) an application for a Biosimilar Product (defined below) referencing a Product submitted to a Party or a Regulatory Authority for Regulatory Approval (each of (i), (ii), and (iii) a "**Product Infringement**"), it shall promptly notify the other Party in writing to that effect, and the Parties will consult with each other regarding any actions to be taken with respect to such Product Infringement. For purpose of this definition, "**Biosimilar Product**" means, with respect to a particular Product in a particular country in the Territory, any pharmaceutical product that is claimed to be biosimilar to or interchangeable with such Product (including a product that is the subject of an application submitted under Section 351(k) of the Public Health Service Act as set forth at 42 U.S.C. Chapter 6A, as amended, citing the Product as the reference product) or for which the BLA otherwise references or relies on such Product or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval.

(b) Enforcement Rights. For any Product Infringement, each Party shall share with the other Party all information available to it that may be shared subject to Third Party obligations regarding such alleged infringement, pursuant to a mutually agreeable "common interest agreement" executed by the Parties under which the Parties agree to their shared, mutual interest in the outcome of any suit to enforce the Pfenex Patents against such Product Infringement.

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(i) Jazz shall have the first right, but not the obligation, to bring an appropriate suit or take other action against any person or entity engaged in, or to defend against, a Product Infringement to the extent involving infringement of (A) any Pfenex Product-Specific Patent and (B) any Pfenex General Product Patent. Jazz shall consult with Pfenex and keep Pfenex reasonably informed of the status of the enforcement of such Pfenex Product-Specific Patent or Pfenex General Product Patent, as the case may be. Jazz shall consider Pfenex's comments with respect to the enforcement of such Pfenex General Product Patent in good faith. Jazz shall not settle any such suit or action without providing Pfenex an opportunity to review and comment on such proposed settlement. Jazz shall not settle any such suit or action with respect to a Pfenex General Product Patent if Pfenex promptly notifies Jazz that it reasonably and in good faith believes that doing so would cause a material adverse effect on Pfenex's intellectual property rights covering products other than a Product.

(ii) If Jazz does not, within one hundred eighty (180) days after its receipt or delivery of notice under Section 7.4(a), commence a suit to enforce an applicable Pfenex Sole Patent, take other action to terminate such Product Infringement with respect to an applicable Pfenex Sole Patent, or initiate a defense against such Product Infringement with respect to an applicable Pfenex Sole Patent, then upon Jazz's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, Pfenex shall have the right, but not the obligation, to commence such a suit or take such an action to enforce the applicable Pfenex Sole Patent. In such event, Jazz shall take appropriate actions in order to enable Pfenex to commence a suit or take the actions set forth in the preceding sentence. Pfenex shall not settle any such suit or action in any manner that would negatively impact the applicable Pfenex Sole Patent or that would limit or restrict the ability of Jazz to sell Products anywhere in the Territory without the prior written consent of Jazz.

(c) Collaboration. Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff to ensure legal standing if required by applicable Laws to pursue such action or if requested by the enforcing Party. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any such efforts. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

(d) Expenses and Recoveries. The Party bringing or defending a claim, suit or action under Section 7.4(b) shall be solely responsible for any expenses incurred by such Party as a result of such claim, suit or action. If such enforcing Party recovers monetary damages in such claim, suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel), and any remaining amounts shall be allocated as follows: (i) if Jazz is the enforcing or defending Party, the remaining amounts will be retained by Jazz, except that any imputed lost sales upon which such amounts were calculated shall be included in Net Sales subject to the royalty payment by Jazz to Pfenex pursuant to Section 6.5, and (ii) if Pfenex is the enforcing or defending Party, the remaining amounts will be shared equally by Pfenex and by Jazz.

7.5 Enforcement of Jazz Sole Patents and Joint Patents. Jazz shall have the sole right, but not the obligation, in the case of the Jazz Sole Patents and the first right, but not the obligation, in the case of the Joint Patents to bring an appropriate suit or other action against any person or entity allegedly infringing any Jazz Sole Patents or Joint Patents, as the case may be, and to defend against any declaratory judgment action against any Jazz Sole Patents or Joint Patents, as the case may be. In the case of any existing or threatened infringement of any Joint Patent in the Territory that does not involve the using, making, importing, exporting, offering for sale or selling Products or products that otherwise are competitive with Products, if Jazz does not, within one hundred eighty (180) days after written request by Pfenex, commence a suit to enforce an applicable Joint Patent or take other action to terminate such infringement with respect to an applicable Joint Patent, then Pfenex shall have the right, but not the obligation, to commence such a suit or take such other action to enforce the applicable Joint Patent. Each Party shall provide reasonable assistance to the enforcing Party in such enforcement or defense, at such enforcing Party's request and expense, including joining such action as a party plaintiff to ensure legal standing if required by applicable Laws to pursue such action or if requested by such enforcing Party. If such enforcing Party recovers monetary damages in such claim, suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel), and any remaining amounts shall be retained by such enforcing Party.

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7.6 Patent Term Extensions. Pfenex shall cooperate with Jazz, at Jazz's request, in seeking and obtaining patent term extensions (including any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country with respect to any Pfenex Product-Specific Patents and Products. If elections with respect to obtaining such patent term extensions are to be made, Jazz shall consider in good faith any comments provided by Pfenex in regard to such elections, provided that Jazz have the sole right to make such elections with respect to any Pfenex Product-Specific Patents. Pfenex shall further cooperate with Jazz, at Jazz's request, in seeking and obtaining patent term extensions (including any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country with respect to any Pfenex General Product Patents and Products, which Pfenex shall file and manage in good faith unless Pfenex has previously extended the applicable Pfenex General Product Patent in connection with any product other than the applicable Product.

7.7 Personnel Obligations. Prior to beginning work under this Agreement relating to any Development of a Product, each employee, agent or independent contractor of a Party or its Affiliates shall be bound by invention assignment obligations that are consistent with the obligations of such Party in this Article 7, including: (a) promptly reporting any invention, discovery, process or other intellectual property right; (b) assigning to such Party all of the right, title and interest in and to any invention, discovery, process or other intellectual property right; (c) cooperating in the preparation, filing, prosecution, maintenance and enforcement of any Patent; (d) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement; and (e) complying with obligations of confidentiality and non-use consistent with those contained in this Agreement.

7.8 Trademarks. Jazz and its Affiliates and sublicensees shall have the right to brand the Products in the Territory using any trademarks it determines appropriate for the Products, which may vary by country or within a country (the "**Product Marks**"), provided that Jazz shall not, and shall ensure that its Affiliates and sublicensees will not make any use of the trademarks or house marks of Pfenex (including Pfenex's corporate name) or any trademark confusingly similar thereto (except to the extent required by applicable Laws (e.g., to indicate the manufacturer of the Product)). As between the Parties, Jazz shall own all rights in the Product Marks and shall register and maintain, in its discretion and at its own cost and expense, the Product Marks in the countries and regions in the Territory that it determines to be appropriate. Jazz shall have the sole right, in its discretion and at its expense, to defend and enforce the Product Marks. Pfenex shall not, and shall ensure that its Affiliates and sublicensees will not, file or use any trademark confusingly similar to the Product Marks.

ARTICLE 8
REPRESENTATIONS AND WARRANTIES; COVENANTS

8.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows:

(a) Corporate Existence. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated or otherwise formed.

(b) Corporate Power, Authority and Binding Agreement. As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) No Conflicts. It has not entered, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted by it under this Agreement, and has not taken and shall not take any action that would in any way prevent it from granting the rights granted to, or contemplated to be granted to, the other Party under this Agreement, or that would otherwise materially conflict with or adversely affect such other Party's rights under this Agreement.

(d) No Debarment. As of the Effective Date, none of its employees, consultants or contractors is debarred by any Regulatory Authority or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

8.2 Additional Representations and Warranties of Pfenex. Pfenex represents and warrants and, as applicable, covenants to Jazz as follows, as of the Effective Date:

(a) Title; Encumbrances. Pfenex Controls the Patents listed on **Exhibit A** and other intellectual property rights within the Pfenex IP, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreements, and, to Pfenex's knowledge, other encumbrances, charges or claims of any kind, subject to the terms and conditions of the Third Party Agreements. Pfenex has the full and legal rights and authority to license to Jazz the Pfenex IP for the purposes expressly provided in this Agreement.

(b) Patent Matters. **Exhibit A** is an accurate listing by owner, inventor(s), serial number, filing date, country, and status of all patents and patent applications Controlled by Pfenex as of the Effective Date that may be necessary or useful for the development, manufacture, use, offer for sale, sale or import of the Products as contemplated herein.

(c) Control. Pfenex Controls and shall Control throughout the Term (i) all Patents listed on **Exhibit A**, and (ii) all data and technical information owned, generated or licensed by Pfenex that is related to any Product, in each case subject to the terms and conditions of the Third Party Agreements.

(d) Validity. There is no fact or circumstance known to Pfenex that would cause Pfenex to reasonably conclude that any of the issued patents in the Pfenex Patents is invalid or unenforceable.

(e) Inventorship. To Pfenex's knowledge, the inventorship of each Pfenex Patent is properly identified on the corresponding patent or patent application.

(f) Good Standing. All official fees, maintenance fees and annuities for the Pfenex Patents have been paid and all administrative procedures with Governmental Authorities are in process or have been completed for the Pfenex Patents such that the Pfenex Patents are pending, subsisting or in good standing.

(g) Duty of Disclosure. Pfenex has complied with the U.S. PTO duty of disclosure with respect to the prosecution of all of the Pfenex Patents for which Pfenex controls the prosecution. To Pfenex's knowledge, all Third Parties that control the prosecution of a Pfenex Patent have complied with the U.S. PTO duty of disclosure.

(h) Notice of Infringement. Pfenex has not received any written notice or written threat from any Third Party asserting or alleging, nor does Pfenex have any knowledge of any basis for any assertion or allegation, that any use of any Pfenex IP by Pfenex prior to the Effective Date infringed or would infringe the issued Patents of such Third Party.

(i) Notice of Misappropriation. Pfenex has not received any written notice or written threat from any Third Party asserting or alleging, nor does Pfenex have any knowledge of any basis for any assertion or allegation, that any use or creation of Pfenex IP by Pfenex prior to the Effective Date misappropriated the intellectual property rights of such Third Party.

(j) Third Party Technology. To Pfenex's knowledge, the manufacture, Development, and Commercialization of Products (excluding any Half-Life Extension Component incorporated into any Product), and the use of Pfenex's proprietary *P. fluorescens* expression technology, in each case as contemplated herein, does not infringe any valid and enforceable issued Patent of a Third Party.

(k) Third Party Infringement. To Pfenex's knowledge, no Third Party is infringing or has infringed any issued Pfenex Patent or has misappropriated any Pfenex Know-How.

(l) No Proceeding. There are no pending, and to Pfenex's knowledge, no threatened, adverse actions, suits or proceedings (including interferences, reissues, reexaminations, cancellations, oppositions, nullity actions, invalidation actions or post-grant reviews) against Pfenex involving the Pfenex IP or Products.

(m) Contracts. Pfenex has irrevocably terminated all rights granted to Agila Biotech Private Limited with respect to the Pegaspargase Product, and a copy of the documentation effecting such termination has been provided to Jazz..

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8.3 Mutual Covenants.

(a) No Debarment. In the course of the Development of the Products, neither Party shall use any employee or consultant who has been debarred by any Regulatory Authority or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority. Each Party shall notify the other Party in writing promptly upon becoming aware that any of its employees or consultants has been debarred or is the subject of debarment proceedings by any Regulatory Authority.

(b) Compliance. Each Party and its Affiliates (and, in the case of Jazz, other Selling Parties) shall comply in all material respects with all Laws applicable to the Development, manufacture and Commercialization of Products and performance of its obligations under this Agreement, including, to the extent applicable, the statutes, regulations and written directives of the FDA (including GCP, GLP, and GMP), the EMA and any Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law, 42 U.S.C. § 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other health care programs, as defined in 42 U.S.C. § 1320a-7b(f), and the Foreign Corrupt Practices Act of 1977, each as may be amended from time to time.

8.4 Disclaimer. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

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ARTICLE 9
INDEMNIFICATION

9.1 Indemnification by Pfenex. Pfenex shall defend, indemnify, and hold harmless Jazz and its Affiliates and their respective officers, directors, employees, and agents (the "**Jazz Indemnitees**") from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such Jazz Indemnitees, resulting from any claims, suits, proceedings or causes of action brought by such Third Party (collectively, "**Claims**") against such Jazz Indemnitee to the extent arising from or based on (a) the Development or manufacture of Products by or on behalf of Pfenex or its Affiliates or sublicensees prior to the Effective Date, (b) Pfenex's and its Affiliates' performance of the activities allocated to Pfenex under the applicable Development Plan, including the manufacture of Products, (c) the breach of any of Pfenex's obligations, representations or warranties under this Agreement, or (d) the willful misconduct or negligent acts of Pfenex, its Affiliates, or the officers, directors, employees, or agents of Pfenex or its Affiliates in connection with this Agreement. The foregoing indemnity obligation shall not apply to the extent that (i) the Jazz Indemnitees fail to comply with the indemnification procedures set forth in Section 9.3 and Pfenex's defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from or is based on any activity set forth in Section 9.2 for which Jazz is obligated to indemnify the Pfenex Indemnitees under Section 9.2.

9.2 Indemnification by Jazz. Jazz shall defend, indemnify, and hold harmless Pfenex and its Affiliates and their respective officers, directors, employees, and agents (the "**Pfenex Indemnitees**") from and against damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such Pfenex Indemnitees, resulting from any Claims against such Pfenex Indemnitee to the extent arising from or based on (a) the Development, manufacture or Commercialization of Products by or on behalf of Jazz or its Affiliates or sublicensees (in each case other than by Pfenex), (b) the breach of any of Jazz's obligations, representations or warranties under this Agreement, or (c) the willful misconduct or negligent acts of Jazz, its Affiliates, or the officers, directors, employees, or agents of Jazz or its Affiliates in connection with this Agreement. The foregoing indemnity obligation shall not apply to the extent that (i) the Pfenex Indemnitees fail to comply with the indemnification procedures set forth in Section 9.3 and Jazz's defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from or is based on any activity set forth in Section 9.1 for which Pfenex is obligated to indemnify the Jazz Indemnitees under Section 9.1.

9.3 Indemnification Procedures. The Party claiming indemnity under this Article 9 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. Unless the settlement involves only the payment of money, the Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, such consent not to be unreasonably withheld, conditioned or delayed. So long as the Indemnifying Party is conducting the defense of the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 9.

9.4 Insurance. Each Party shall procure and maintain product liability insurance of at least [***] at all times during which any Product is being clinically tested in human subjects and of at least [***] at all times during which any Product is being commercially distributed or sold by such Party and for the five (5)-year period thereafter. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 9. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation or non-renewal of such insurance.

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ARTICLE 10
CONFIDENTIALITY

10.1 Confidentiality. Each Party agrees that, during the Term and for a period of ten (10) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it by the other Party pursuant to this Agreement, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application or use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

As between the Parties, each Party shall own its Confidential Information.

10.2 Authorized Disclosure. Notwithstanding the obligations set forth in Section 10.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary to its employees, agents, consultants, contractors, licensees or sublicensees on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement; or

(b) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, licensee, sublicensee, or other financial or commercial partner for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; provided that in connection with such disclosure, such Party shall use all reasonable efforts to inform each disclosee of the confidential nature of such Confidential Information and, in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement; or

(c) such disclosure is reasonably necessary to comply with applicable Laws, rules or regulations promulgated by Governmental Authorities or applicable securities exchanges, court order, or administrative subpoena or order; provided that the Party subject to such Laws, rules, regulations, court order, or administrative subpoena or order shall (i) promptly notify the other Party prior to making such required disclosure; (ii) provide reasonable prior advance notice of the proposed text of such disclosure to the other Party for its prior review; (iii) use good faith efforts to incorporate the reviewing Party's reasonable comments thereon and (iv) use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

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10.3 Technical Publication. Pfenex may not publish peer reviewed manuscripts, or provide other forms of public disclosure including abstracts and presentations, of results of studies carried out under the Development Plans, or otherwise pertaining to a Product, without the prior written consent of Jazz. Commencing upon (a) the end of the Assessment Period for a HemOnc Product for which Jazz has not provided a Declination Notice in the case of each HemOnc Product and (b) Option Exercise in the case of the Pegaspargase Product, Jazz shall have the right to publish and otherwise publicly disclose peer reviewed manuscripts, or provide other forms of public disclosure including abstracts and presentations, of results of studies carried out by or on behalf of Jazz under the Development Plan for the applicable Product concerning the Development and Commercialization of such Product, including on clinicaltrials.gov, subject to compliance with this Section 10.3. In the event that Jazz desires to make such a publication or public presentation of a technical nature describing the manufacturing process of a Product, it shall provide Pfenex with at least ten (10) days to review and comment on such proposed publication or presentation prior to its submission for publication or presentation. Pfenex shall have the right to delay publication or presentation for up to an additional thirty (30) days in order to enable patent applications protecting each Party's rights in such Information to be filed, and Pfenex shall also have the right to prohibit the disclosure of any of its Confidential Information contained in any such proposed publication or presentation. In any permitted publication or presentation by a Party, the other Party's contribution shall be duly recognized, and co-authorship shall be determined, in accordance with customary standards.

10.4 Publicity; Term of Agreement.

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 10.4 or Section 10.2.

(b) The Parties agree to issue a joint press release announcing the execution of this Agreement promptly after the Effective Date in the form attached hereto as **Exhibit 10.4(b)**.

(c) After release of such press release, if either Party desires to make a public announcement concerning the material terms of this Agreement or any activities hereunder, including announcement of the achievement of milestones under Section 6.3 and the magnitude of payments associated therewith, such Party shall give reasonable prior advance notice (which in any case shall be at least three (3) Business Days) of the proposed text of such announcement to the other Party for its prior review and approval (which approval shall not be unreasonably withheld, conditioned or delayed) and shall use good faith efforts to incorporate the other Party's reasonable comments thereon, except that in the case of a public announcement required by Laws, the disclosing Party shall provide the other Party with such advance notice as it reasonably can and shall not be required to obtain approval therefor. Notwithstanding the foregoing, (i) Pfenex may not, in any public announcement with respect to this Agreement, [***] without Jazz's prior written consent and (ii) Jazz may not, in any public announcement with respect to this Agreement, [***] without providing prior written notice to Pfenex and reasonably coordinating with Pfenex regarding such public announcement. A Party commenting on such a proposed public announcement shall provide its comments, if any, within three (3) Business Days after receiving the text of the public announcement for review. Neither Party shall be required to seek the permission of the other Party to repeat any information that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 10.4(c), provided such information remains accurate as of such time.

(d) The Parties acknowledge that either or both Parties may be obligated to file under applicable Laws or rules or regulations promulgated by Governmental Authorities or applicable securities exchanges a copy of this Agreement with the U.S. Securities and Exchange Commission or other Governmental Authorities. In the event that a Party determines in good faith that such a filing is required, such Party shall request confidential treatment of all confidential information herein, including the sensitive commercial, financial and technical terms hereof, to the extent such confidential treatment may be reasonably available to such Party. In the event of any such filing, the filing Party shall provide the other Party with a copy of this Agreement marked to show provisions for which such filing Party intends to seek confidential treatment within a reasonable amount of time prior to filing and shall use good faith efforts to incorporate the other Party's reasonable comments thereon to the extent consistent with applicable Laws or rules or regulations promulgated by Governmental Authorities or applicable securities exchanges. Each Party shall be responsible for its own legal and other external costs in connection with any such filing.

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ARTICLE 11
TERM AND TERMINATION

11.1 Term. The term of this Agreement (the "**Term**") shall commence on the Effective Date and, unless earlier terminated pursuant to this Agreement, shall continue on a Product-by-Product basis for so long as such Product is being Developed or Commercialized under and in accordance with this Agreement.

11.2 Unilateral Termination by Jazz. Jazz may terminate this Agreement, on a Product-by-Product basis or in its entirety, for any or no reason upon ninety (90) days' written notice to Pfenex.

11.3 Termination by Either Party for Breach.

(a) Breach. Subject to Section 11.3(b) and 11.3(c), each Party shall have the right to terminate this Agreement upon written notice to the other Party in the event such other Party materially breaches this Agreement and, after receiving written notice from the non-breaching Party identifying such material breach in reasonable detail, fails to cure such material breach within ninety (90) days from the date of such notice; provided that if such breach is not reasonably capable of cure within such time period, the breaching Party may submit a reasonable cure plan prior to the end of such time period, in which case the other Party shall not have the right to terminate this Agreement for up to an additional ninety (90) days so long as the breaching Party is using Commercially Reasonable Efforts to implement such cure plan.

(b) Disputed Breach. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 11.3(a), and such alleged breaching Party provides the other Party notice of such dispute within the ninety (90)-day cure period, then the non-breaching Party shall not have the right to terminate this Agreement under Section 11.3(a) unless and until an arbitrator, in accordance with Article 12, has determined that the alleged breaching Party has materially breached this Agreement and that such Party fails to cure such breach within ninety (90) days following such arbitrator's decision. It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

(c) Product-by-Product Termination. If the uncured material breach pertains to less than all of the Product(s), then termination under this Section 11.3 shall apply only with respect to such Product(s), and the non-breaching Party shall not have the right to terminate this Agreement in its entirety or with respect to the other Product(s) not affected by such breach. Without limiting the generality of the foregoing, the Parties' rights and obligations hereunder with respect to the Pegaspargase Product shall not be affected by termination of this Agreement with respect to one or both HemOnc Products, and the Parties' rights and obligations hereunder to the HemOnc Products shall not be affected by termination of this Agreement with respect to the Pegaspargase Product.

11.4 Effects of Unilateral Termination by Jazz. If this Agreement is terminated by Jazz under Section 11.2 in its entirety or with respect to one or both of the HemOnc Products or the Pegaspargase Product then the following terms shall apply:

(a) HemOnc-Pf. Upon any notice of termination of HemOnc-Pf, Pfenex may notify Jazz in writing that Pfenex desires to negotiate for a license to any or all HemOnc-Pf data Controlled by Jazz that was generated by Jazz pursuant to this Agreement (the "**Jazz HemOnc-Pf Data**"). Upon such request, if Jazz also desires to negotiate for such license, Jazz may provide Pfenex with access to the applicable Jazz HemOnc-Pf Data. Pfenex may, within thirty (30) days following the delivery of the Jazz HemOnc-Pf Data to Pfenex by Jazz, notify Jazz that Pfenex desires to continue to negotiate for a license to any or all of the Jazz HemOnc-Pf Data. If Pfenex elects to negotiate for a license to any or all of the Jazz HemOnc-Pf Data, the Parties shall negotiate the terms of such license for a ninety (90)-day period from the date of Pfenex's election; *provided*, that if the Parties are unable to agree on the terms of such license, Jazz will have no obligation to grant Pfenex any right, title, interest, or license in or to the Jazz HemOnc-Pf Data and Pfenex will not obtain any right, title, interest, or license in or to the Jazz HemOnc-Pf Data. Regardless of whether the Parties agree on the terms of a license for the Jazz HemOnc-Pf Data, Jazz retains exclusive ownership of the Jazz HemOnc-Pf Data.

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(b) HemOnc-NextGen. Upon any notice of termination of HemOnc-NextGen, Pfenex may notify Jazz in writing that Pfenex desires to negotiate for a license to any or all HemOnc-NextGen data Controlled by Jazz that was generated by Jazz pursuant to this Agreement (the "**Jazz HemOnc-NextGen Data**"). Upon such request, if Jazz also desires to negotiate for such license, Jazz may provide Pfenex with access to the applicable Jazz HemOnc-NextGen Data. Pfenex may, within thirty (30) days following the delivery of the Jazz HemOnc-NextGen Data to Pfenex by Jazz, notify Jazz that Pfenex desires to continue to negotiate for a license to any or all of the Jazz HemOnc-NextGen Data. If Pfenex elects to negotiate for a license to any or all of the Jazz HemOnc-NextGen Data, the Parties shall negotiate the terms of such license for a ninety (90)-day period from the date of Pfenex's election; *provided*, that if the Parties are unable to agree on the terms of such license, Jazz will have no obligation to grant Pfenex any right, title, interest, or license in or to the Jazz HemOnc-NextGen Data and Pfenex will not obtain any right, title, interest, or license in or to the Jazz HemOnc-NextGen Data. Regardless of whether the Parties agree on the terms of a license for the Jazz HemOnc-NextGen Data, Jazz retains exclusive ownership of the Jazz HemOnc-NextGen Data.

(c) Pegaspargase Product. If Jazz terminates its rights hereunder with respect to the Pegaspargase Product prior to Option Exercise, then the Option shall terminate and the Parties' obligations under this Agreement with respect to the Pegaspargase Product shall terminate.

11.5 Effects of Other Termination.

(a) General. Upon any termination of this Agreement in its entirety (i.e., with respect to all Products) or in part (i.e., with respect to one or more, but not all, Products), the licenses and other rights and obligations under of this Agreement applicable to the terminated Product(s) shall terminate, except for the licenses granted in Section 7.1(f), which shall survive any termination.

(b) Termination by Jazz for Pfenex's Breach. If Jazz terminates this Agreement in its entirety or for a Product on account of Pfenex's uncured material breach with respect to a particular Product, then Pfenex will not have any rights with respect to any data generated by Jazz with respect to any terminated Product(s) (or all of the Products if this Agreement is terminated in its entirety), and Jazz will have no further obligation to Pfenex with respect to any such terminated Product(s) under this Section 11.5.

(c) Termination by Pfenex for Jazz's Breach. With respect to termination by Pfenex of this Agreement for one or more Products on account of Jazz's uncured material breach with respect to such Product(s):

(i) if Pfenex terminates with respect to HemOnc-Pf, then Section 11.4(a) applies;

(ii) if Pfenex terminates with respect to HemOnc-NextGen, then Section 11.4(b) applies;

(iii) if Pfenex terminates with respect to the Pegaspargase Product, then Section 11.4(c) applies;

in each instance of the above, with the same effect as if Jazz had terminated this Agreement with respect to such Product pursuant to Section 11.2.

(d) Termination of All Products. For clarity, if this Agreement has been terminated on a Product-by-Product basis such that all Products have been terminated, then this Agreement thereupon shall be deemed to have been terminated in its entirety and the ROFN thereupon shall be deemed to have terminated with respect to all ROFN Products, except with respect to any ROFN Exercise (and subject to the terms and conditions of the corresponding ROFN Exercise Agreement) that may have occurred prior to the effective date of such termination of this Agreement.

11.6 Survival. Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: Article 1 (to the extent defined terms are contained in the following surviving Articles and Sections), Section 2.3, Section 4.5, Section 6.9, Article 6 (solely with respect to those payments that accrued prior to the effective date of termination or expiration), Section 7.1, Section 8.4, Article 9 (with respect to any matter, fact or circumstance arising or existing prior to the termination or expiration of this Agreement), Article 10, Section 11.4, Section 11.5, this Section 11.6, Article 12 and Sections 13.3, 13.4, 13.5, and 13.12.

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ARTICLE 12
DISPUTE RESOLUTION

12.1 Disputes. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement (other than disputes arising from the JDC, which shall be resolved in accordance with Section 3.3), including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement (each, a "**Dispute**"), then upon the request of either Party by written notice, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting (or telephone call if an in-person meeting is impractical) between the Parties' respective Executive Officers. If the matter is not resolved within thirty (30) days following the written request for discussions, either Party may then invoke the provisions of Section 12.2.

12.2 Arbitration.

(a) JAMS. Any Dispute that is not resolved pursuant to Section 12.1, except for a dispute, claim or controversy under Section 12.9, shall be settled by binding arbitration administered by JAMS before one arbitrator pursuant to the Streamlined Arbitration Rules and Procedures of JAMS then in effect (the "**JAMS Rules**"), except as otherwise provided herein. The arbitration shall be governed by the U.S. Federal Arbitration Act, 9 U.S.C. §§ 1-16 (the "**Federal Arbitration Act**"), to the exclusion of any inconsistent state laws. The arbitration will be conducted in Los Angeles, California, and the Parties consent to the personal jurisdiction of the U.S. federal courts, for any case arising out of or otherwise related to this arbitration, its conduct and its enforcement. The language to be used in the arbitral proceedings will be English.

(b) Baseball Arbitration. This Section 12.2(b) shall apply to Disputes identified under Sections 2.4(e) and 2.5(c)(i) as to be resolved by baseball arbitration. Baseball arbitration will be conducted by one (1) arbitrator who shall be reasonably acceptable to the Parties and who shall be appointed in accordance with JAMS Rules. If the Parties are unable to select an arbitrator within ten (10) days, then the arbitrator shall be appointed in accordance with JAMS Rules. Any arbitrator chosen hereunder shall have educational training and industry experience sufficient to demonstrate a reasonable level of scientific, financial, medical and industry knowledge relevant to the Dispute. Within twenty (20) days after the selection of the arbitrator, each Party shall submit to the arbitrator and the other Party a proposed resolution of the Dispute that is the subject of the arbitration, together with any relevant evidence in support thereof (the "**Proposals**"). Within fifteen (15) days after the delivery of the last Proposal to the arbitrator, each Party may submit a written rebuttal of the other Party's Proposal and may also amend and re-submit its original Proposal. The Parties and the arbitrator shall meet within fifteen (15) days after the Parties have submitted their final Proposals (and rebuttals, if any), at which time each Party shall have one (1) hour to argue in support of its Proposal. The Parties shall not have the right to call any witnesses in support of their arguments, nor compel any production of documents or take any discovery from the other Party in preparation for the meeting. Within thirty (30) days after such meeting, the arbitrator shall select one of the final Proposals so submitted by one of the Parties as the resolution of the Dispute, but may not alter the terms of either final Proposal and may not resolve the Dispute in a manner other than by selection of one of the submitted final Proposals. If a Party fails to submit a Proposal within the initial twenty (20)-day time frame set forth above, the arbitrator shall select the Proposal of the other Party as the resolution of the Dispute.

12.3 Governing Law. Resolution of all Disputes and any remedies relating thereto, shall be governed by and construed under the substantive laws of the State of California, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

12.4 Award. Any award shall be promptly paid in Dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the Party resisting enforcement. If as to any issue the arbitrator should determine under the applicable law that the position taken by a Party is frivolous or otherwise irresponsible or that any wrongdoing it finds is in callous disregard of law and equity or the rights of the other Party, the arbitrator shall also be entitled to award an appropriate allocation of the adversary's reasonable attorney fees, costs and expenses to be paid by the offending Party, the precise sums to be determined after a bill of attorney fees, expenses and costs consistent with such award has been presented following the award on the merits. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 12, and agrees that, subject to the Federal Arbitration Act, judgment may be entered upon the final award in the Federal District Court in the Central District of California and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of any damages incurred for breach of this Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrator.

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12.5 Costs. Except as set forth in Section 12.4, each Party shall bear its own legal fees. The arbitrator shall assess his or her costs, fees and expenses against the Party losing the arbitration unless he or she believes that neither Party is the clear winner, in which case the arbitrator shall divide his or her fees, costs and expenses according to his or her sole discretion.

12.6 Injunctive Relief. Provided a Party has made a sufficient showing under the rules and standards set forth in the U.S. Federal Rules of Civil Procedure and applicable case law, the arbitrator shall have the freedom to invoke, and the Parties agree to abide by, injunctive measures after either Party submits in writing for arbitration claims requiring immediate relief. Additionally, nothing in this Article 12 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a Dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

12.7 Confidentiality. The arbitration proceeding shall be confidential and the arbitrator shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by law, no Party shall make (or instruct the arbitrator to make) any public announcement with respect to the proceedings or decision of the arbitrator without prior written consent of the other Party. The existence of any Dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrator, except as required in connection with the enforcement of such award or as otherwise required by applicable Laws.

12.8 Survivability. Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

12.9 Patent and Trademark Disputes. Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patents or trademarks covering the manufacture, use, importation, offer for sale or sale of a Product shall be submitted to a court of competent jurisdiction in the country in which such patent or trademark rights were granted or arose.

12.10 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) STRICT LIABILITY OR OTHERWISE), REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 12.10 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 9.1 OR 9.2 OR DAMAGES AVAILABLE FOR BREACH OF ARTICLE 10.

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ARTICLE 13
MISCELLANEOUS

13.1 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Amendment Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidentiality Agreements and the Original Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Amendment Effective Date, by the other Party of its obligations under the Confidentiality Agreements or the Original Agreement. For clarity, the Parties agree and acknowledge that the Original Agreement shall govern the Parties' rights and obligations regarding the subject thereof from the Effective Date to the Amendment Effective Date (except that the Parties acknowledge and agree that, notwithstanding the terms of the Original Agreement (including, in particular, Section 6.2(b)(ii)), Jazz is not required to pay Pfenex for any Pfenex Expression Feasibility Activities conducted by Pfenex under the Original Agreement). There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

13.2 Rights in Bankruptcy.

(a) 365(n) Rights.

(i) The Parties agree that all rights and licenses granted under or pursuant to this Agreement by one Party to the other are, for all purposes of Title 11 of the United States Code ("**Title 11**"), licenses of rights to "intellectual property" as defined in Title 11, and, in the event that a case under Title 11 is commenced by or against either Party (the "**Bankrupt Party**"), the other Party shall have all of the rights set forth in Section 365(n) of Title 11 to the maximum extent permitted thereby. During the Term, each Party shall create and maintain current copies to the extent practicable of all such intellectual property. Without limiting the Parties' rights under Section 365(n) of Title 11, if a case under Title 11 is commenced by or against the Bankrupt Party, the other Party shall be entitled to a copy of any and all such intellectual property and all embodiments of such intellectual property, and the same, if not in the possession of such other Party, shall be promptly delivered to it (i) before this Agreement is rejected by or on behalf of the Bankrupt Party, within thirty (30) days after the other Party's written request, unless the Bankrupt Party, or its trustee or receiver, elects within thirty (30) days to continue to perform all of its obligations under this Agreement, or (ii) after any rejection of this Agreement by or on behalf of the Bankrupt Party, if not previously delivered as provided under clause(i) above. All rights of the Parties under this Section 13.2 and under Section 365(n) of Title 11 are in addition to and not in substitution of any and all other rights, powers, and remedies that each party may have under this Agreement, Title 11, and any other applicable Laws. The non-Bankrupt Party shall have the right to perform the obligations of the Bankrupt Party hereunder with respect to the maintenance of such intellectual property, but neither such provision nor such performance by the non-Bankrupt Party shall release the Bankrupt Party from any such obligation or liability for failing to perform it.

(ii) The Parties agree that they intend the foregoing non-Bankrupt Party rights to extend to the maximum extent permitted by law and any provisions of applicable contracts with Third Parties, including for purposes of Title 11, (i) the right of access to any intellectual property (including all embodiments thereof) of the Bankrupt Party or any Third Party with whom the Bankrupt Party contracts to perform an obligation of the Bankrupt Party under this Agreement, and, in the case of the Third Party, which is necessary for the Development, Regulatory Approval and manufacture of Products and (ii) the right to contract directly with any Third Party described in (i) in this sentence to complete the contracted work.

(iii) Any intellectual property provided pursuant to the provisions of this Section 13.2 shall be subject to the licenses set forth elsewhere in this Agreement and the payment obligations of this Agreement, which shall be deemed to be royalties for purposes of Title 11.

(b) Prosecution of Patents. Notwithstanding anything to the contrary in Article 7, in the event that Pfenex is the Bankrupt Party, Jazz may take appropriate actions in connection with the filing, prosecution, maintenance and enforcement of any Pfenex Patent licensed to Jazz under this Agreement without being required to consult with Pfenex before taking any such actions, provided that such actions are consistent with this Agreement.

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(c) Escrow.

(i) Establishment and Update. Within [***] days after Jazz's written request, the Parties shall enter into an escrow agreement (the "**Escrow Agreement**") with a mutually agreeable Third Party escrow agent (the "**Escrow Agent**"). The Escrow Agreement will contain terms and conditions that are typically included in such a technology escrow agreement, [***]. Under the Escrow Agreement, Pfenex shall, within [***] Business Days of execution of the Escrow Agreement, deposit with the Escrow Agent [***] (the "**Escrow Materials**"). Pfenex shall keep the Escrow Materials reasonably current and complete, and shall be updated by or on behalf of Pfenex from time to time and in no event more than [***] days after Pfenex has made one or more material modifications to any of the Escrow Materials. Jazz shall reimburse Pfenex for the reasonable out-of-pocket costs incurred by Pfenex in connection with the Escrow Agreement and preparation and deposit of Escrow Materials with the Escrow Agent.

(ii) Right to Use Escrow Materials. Following an Escrow Triggering Event, Jazz may access and use [***] the Escrow Materials [***], and, effective as of an Escrow Triggering Event, [***].

(d) Development Step-In. In addition to its other rights under this Agreement, and notwithstanding anything herein to the contrary, upon the occurrence of the Development Step-In Triggering Event, Jazz may notify Pfenex in writing that a Development Step-In Trigger Event has occurred. Pfenex shall have [***] Business Days to dispute the occurrence of the Development Step-In Triggering Event. If Pfenex disputes such occurrence, the Parties shall discuss in good faith. If Pfenex agrees that a Development Step-In Triggering Event has occurred, or does not respond within such [***]-Business Day period, [***].

(e) Technology Transfer and Assistance. In connection with Jazz's rights to access and use the Escrow Materials pursuant to Section 13.2(c)(ii), Pfenex shall provide to Jazz [***].

13.3 Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than ninety (90) days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

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13.4 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 13.4, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by confirmed facsimile or a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to Pfenex:

Pfenex Inc.
10790 Roselle Street
San Diego, CA 92121
Attention: Patrick Lucy, Chief Business Officer

With a copy to (which shall not constitute notice):

Wilson Sonsini Goodrich & Rosati
650 Page Mill Road
Palo Alto, CA 94304
Attention: Ian B. Edvalson

If to Jazz:

Jazz Pharmaceuticals, Inc.
3180 Porter Drive
Palo Alto, California 94304
USA
Attn: General Counsel

With a copy to (which shall not constitute notice):

Cooley LLP
3175 Hanover Street
Palo Alto, California 94304
USA
Attn: Marya A. Postner
Fax: 650-849-7400

13.5 No Strict Construction; Headings. This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). The term "including" as used herein means including, without limiting the generality of any description preceding such term.

13.6 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party's consent to (a) its Affiliates (provided that, if Pfenex is the assigning Party, Pfenex (or its successor) guarantees such Affiliate's performance of its obligations under this Agreement or obtains Jazz's consent for such assignment notwithstanding the foregoing); or (b) a Third Party successor to all or substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other Change of Control transaction. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 13.6 shall be null, void and of no legal effect.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

13.7 Change of Control. Each Party (the "**Acquired Party**") shall, to the extent such Party is not required to publicly disclose a Change of Control, notify the other Party in writing within one (1) Business Day after entering into any agreement providing for or intended to result in any Change of Control of the Acquired Party, identifying the parties to such agreement, and shall provide such notice where possible at least thirty (30) days prior to the effectiveness of such Change of Control. Following the effectiveness of such Change of Control, such other Party shall have the right to disband the JDC and to require the Acquired Party, including the acquiring party in such Change of Control, to adopt reasonable procedures to be agreed upon in writing with such other Party to limit the dissemination of such other Party's Confidential Information to only those personnel having a need to know such Confidential Information in order for the Acquired Party to perform its obligations or to exercise its rights under this Agreement and to prohibit and limit the use and disclosure of Confidential Information for competitive reasons against such other Party and its Affiliates; provided, however, that in the case of a Change of Control of Jazz, Pfenex may not disband the JDC prior to the Manufacturing Process Transfer under Section 4.7.

13.8 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

13.9 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

13.10 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

13.11 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

13.12 Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

13.13 Counterparts. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Executed counterpart signature pages delivered via facsimile or similar electronic transmission in .PDF or similar format shall be deemed binding as originals.

13.14 Remedies Non-Exclusive and Cumulative. Unless expressly stated otherwise in this Agreement, all remedies provided for in this Agreement shall be cumulative and in addition to, and not in lieu of, any other remedies available to either Party at law, in equity, or otherwise in accordance with the terms of this Agreement, including any claim for breach of this Agreement. Nothing in this Agreement shall be interpreted as limiting either Party's rights to pursue any remedies for breach of contract of this Agreement, except as expressly stated otherwise in this Agreement.

{Signature page follows}

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

IN WITNESS WHEREOF, the Parties have executed this Amended and Restated License and Option Agreement by their duly authorized officers as of the Amendment Effective Date.

JAZZ PHARMACEUTICALS IRELAND LIMITED	**PFENEX INC.**
By: /s/ Patricia Carr	By: /s/ E.B. Schimmelpennink
Name: Patricia Carr	Name: E.B. Schimmelpennink
Title: VP Finance/Director	Title: CEO

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LIST OF EXHIBITS:

Exhibit A – Patents: Pfenex Patents, Pfenex Pegaspargase Product Patents, Pfenex ROFN Product Patents
Exhibit B –Exceptions from Exclusivity
Exhibit C – Initial Development Plans together with Amended Development Plans
Exhibit D – Certain Product Information
Exhibit 1.44 – Expression Feasibility Data Package
Exhibit 1.91 – Components of Option Data Package 1
Exhibit 1.99 – Description of Pegaspargase Product
Exhibit 1.143 – Successful Expression Criteria
Exhibit 1.147 – Third Party Agreements
Exhibit 6.3 – Development Milestones for HemOnc Products
Exhibit 6.4 – Sales Milestones for HemOnc-NextGen
Exhibit 6.5(a) – Royalties on HemOnc Products
Exhibit 10.4(b) – Joint Press Release

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

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Exhibit A
Patents: Pfenex Patents, Pfenex Pegaspargase Product Patents, Pfenex ROFN Product Patents

The published patents and patent application listed in Schedule A below have been assigned to Pfenex and may be relevant to an [***] process.

Schedule A
IMPROVED PROTEIN EXPRESSION SYSTEMS

Country	Appl. Number	Pat. Number	Issue Date
United States of America	12/512,930	8288127	10/16/2012
Australia	2004293810	2004293810	14-Oct-10
Canada	2545610	2545610	3/25/2014
China (People's Republic)	200480040702.7	ZL200480040702.7	9/11/2013
European Patent Convention	04811581.0	1692282	8/8/2012
Great Britain	04811581.0	1692282	
France	04811581.0	1692282	
Italy	04811581.0	1692282	
Germany	04811581.0	602004038866.1	
Ireland	04811581.0	1692282	
Switzerland	04811581.0	1692282	
India	2645/DELNP/06	258236	12/19/2013
Japan	2006-541422	5087741	9/21/2012
South Korea	10-2006-7009838	10-1237651	2/20/2013
Singapore	200603355-9	122480	28-Nov-2008
United States of America	12/512,930	8288127	10/16/2012

IMPROVED EXPRESSION SYSTEMS WITH SEC-SYSTEM SECRETION

Country	Appl. Number	Pat. Number	Issue Date
Australia	2004317306	2004317306	12/16/2010
Canada	2546157	2546157	7/22/2014
China (People's Republic)	200480034455.X	1882605	7/11/2012
European Patent Convention	04817876.8	1687324	8/22/2012
Great Britain	04817876.8	1687324	8/22/2012
France	04817876.8	1687324	8/22/2012
Italy	04817876.8	1687324	8/22/2012
Germany	04817876.8	602004039069.0	8/22/2012
Ireland	04817876.8	1687324	8/22/2012
Switzerland	04817876.8	1687324	8/22/2012
European Patent Convention	10179615.9	2327718	3/23/2016
Great Britain	10179615.9	2327718	03/23/2016
France	10179615.9	2327718	03/23/2016
Italy	10179615.9	2327718	03/23/2016
Germany	10179615.9	2327718	03/23/2016
Ireland	10179615.9	2327718	03/23/2016
Switzerland	10179615.9	2327718	03/23/2016
Poland	10179615.9	2327718	03/23/2016
Austria	10179615.9	2327718	03/23/2016
European Patent Convention	10179651.4	2336153	3/30/2016
Great Britain	10179651.4	2336153	3/30/2016
France	10179651.4	2336153	3/30/2016
Italy	10179651.4	2336153	3/30/2016

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Schedule A

Germany	10179651.4	2336153	3/30/2016
Ireland	10179651.4	2336153	3/30/2016
Switzerland	10179651.4	2336153	3/30/2016
Belgium	10179651.4	2336153	3/30/2016
Poland	10179651.4	2336153	3/30/2016
Austria	10179651.4	2336153	3/30/2016
India	2711/DELNP/06	252621	5/24/2012
Japan	2006-541651	5028551	9/19/2012
South Korea	10-2006-7009779	10-1265343	5/10/2013
Singapore	200603356-7	122481	31-Aug-10
United States of America	10/996,007	7985564	7/26/2011

MANNITOL INDUCED PROMOTER SYSTEMS IN BACTERIAL HOST CELLS

Country	Appl. Number	Pat. Number	Issue Date
Australia	2006255060	2006255060	12/13/2012
Canada	2610405	2610405	1/27/2015
China (People's Republic)	200680020110.8	101193906	9/05/2012
European Patent Convention	6772320.5	1888763	8/12/2015
Great Britain	6772320.5	1888763	8/12/2015
France	6772320.5	1888763	8/12/2015
Italy	6772320.5	1888763	8/12/2015
Germany	6772320.5	60 2006 046 269.7	8/12/2015
Ireland	6772320.5	1888763	8/12/2015
Switzerland	6772320.5	1888763	8/12/2015
India	9206/DELNP/07	271544	2/25/2016
Japan	2008-515835	5176114	4/3/2013
South Korea	10-2008-7000198	10-1304921	9/13/2013
Singapore	200718053-2	137574	12/31/2008
United States of America	11/447,553	7476532	1/13/2009
United States of America	12/330,723	8017355	9/13/2011
Poland	6772320.5	1888763	8/12/2015
Turkey	6772320.5	1888763	8/12/2015
Austria	6772320.5	1888763	8/12/2015
Belgium	6772320.5	1888763	8/12/2015

BACTERIAL LEADER SEQUENCES FOR INCREASED EXPRESSION

Country	Appl. Number	Pat. Number	Issue Date
Australia	20082105388	2008210538	9/19/2013
Canada	2677179	2677179	2/16/2016
European Patent Convention	8714119.8	2108047	10/24/2012
Great Britain	8714119.8	2108047	10/24/2012
France	8714119.8	2108047	10/24/2012
Italy	8714119.8	2108047	10/24/2012
Germany	8714119.8	60 2008 019 589.9	10/24/2012
Ireland	8714119.8	2108047	10/24/2012
Switzerland	8714119.8	2108047	10/24/2012
European Patent Convention	11194072.2	2468869	3/18/2015
Great Britain	11194072.2	2468869	3/18/2015
France	11194072.2	2468869	3/18/2015
Italy	11194072.2	2468869	3/18/2015
Germany	11194072.2	602008037267.7	3/18/2015
Ireland	11194072.2	2468869	3/18/2015
Switzerland	11194072.2	2468869	3/18/2015
Poland	11194072.2	2468869	3/18/2015
Turkey	11194072.2	TR 2015 06439 T4	3/18/2015
India	4964/DELNP/09		
Japan	2009-548414	5714230	3/20/2015

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Schedule A

Japan	2015-047870		
South Korea	10-2009-7017960	10-1491867	2/3/2015
Singapore	200905039-4	154246	3/15/2012
United States of America	12/022,789	7618799	17-Nov-2009
United States of America	12/604,061	7833752	11/16/2010

The patents and published applications listed in Schedule B may be relevant to an [***] process and have been licensed to Pfenex on a non-exclusive basis.

Schedule B
APPARATUS AND METHODS FOR OSMOTICALLY SHOCKING CELLS

Country	Appl. Number	Pat. Number	Issue Date
Australia	2008205632	2008205632B2	2/6/2014
Canada	CA2675183A		
European Patent Convention	EP2008724501A		
China	CN200880002148A		
India	4414/DELNP/2009		
Japan	JP2009545610A	5226697	7/3/2013
United States of America	12/013042	US8211668B2	7/3/2012

The Korean patent listed in Schedule C is assigned to Pfenex and is not licensed to Dow and may be relevant to an [***] process.

Schedule C
APPARATUS AND METHODS FOR OSMOTICALLY SHOCKING CELLS

Country	Appl. Number	Pat. Number	Issue Date
South Korea	10-2009-7016786	10-1484337	1/13/2015

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Exhibit B
Jazz Products Excepted from Exclusivity

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit C
Initial Development Plans together with Amended Development Plans

Attached.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

DEVELOPMENT PLAN NARRATIVE FOR [***]

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

AMENDED GANTT CHART FOR [***]
[Attached.]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

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DEVELOPMENT PLAN NARRATIVE FOR [***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

AMENDED DEVELOPMENT PLAN FOR [***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

AMENDED GANTT CHART FOR [***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

DEVELOPMENT PLAN NARRATIVE FOR [***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

GANTT CHART FOR [***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit D
Certain Product Information

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 1.44
Expression Feasibility Data Package

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 1.91
Components of Option Data Package 1

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 1.99
Description of Pegaspargase Product

Pegaspargase Product is L-asparaginase (*E. coli* derived L-asparagine amidohydrolase) that is covalently conjugated to monomethoxypolyethylene glycol (mPEG). Pfenex's proprietary L- asparaginase is a tetrameric enzyme that is produced recombinantly in *Pseudomonas fluorescens* and consists of identical 34.5 kDa subunits. Approximately 69 to 82 molecules of mPEG are linked to the L-asparaginase; the molecular weight of each mPEG molecule is about 5 kDa.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 1.143
Successful Expression Criteria

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 1.147
Third Party Agreements

Technology Assignment Agreement by and among Dow Global Technologies Inc., The Dow Chemical Company and Pfenex Inc. effective as of November 30, 2009

Technology Licensing Agreement by and among Dow Global Technologies Inc., The Dow Chemical Company and Pfenex Inc. effective as of November 30, 2009

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 6.3
Development Milestones for HemOnc Products

	Development Milestone Event	**Milestone Payment**		
		[***]	[***]	[***]
1)	[***]	[***]	[***]	[***]
2)	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]
3)	[***]	[***]	[***]	[***]
	[***]	[***]	[***]	[***]
4)	[***]	$ 13,500,000	[***]	[***]
5)	[***]	[***]	[***]	[***]
6)	[***]	[***]	[***]	[***]
7)	[***]	[***]	[***]	[***]
8)	[***]	[***]	[***]	[***]
9)	[***]	[***]	[***]	[***]
10)	[***]	[***]	[***]	[***]
	Total:	**$22,250,000**	**$58,750,000**	**$1,750,000 each**
				$3,500,000 total

[***]

[***]

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 6.4
Sales Milestones for HemOnc-NextGen

Sales Milestone Event	Milestone Payment
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
Total	**$ 120,000,000**

Under no circumstances shall Jazz be obligated to pay Pfenex more than one hundred twenty million Dollars ($120,000,000) pursuant to Section 6.4.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 6.5(a)
Royalties on HemOnc Products

		[***]	
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

[***]

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 10.4(b)
Joint Press Release

Attached.

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Jazz Pharmaceuticals and Pfenex Enter into a Worldwide License and Option Agreement Related to Product Candidates in Early Development for Hematological Malignancies

DUBLIN and SAN DIEGO July 27, 2016 — Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and Pfenex Inc. (NYSE MKT: PFNX) today announced an agreement under which Pfenex granted Jazz Pharmaceuticals worldwide rights to develop and commercialize multiple early stage hematology product candidates. The agreement also includes an option for Jazz Pharmaceuticals to negotiate a license for a recombinant pegaspargase product candidate with Pfenex. This early development stage collaboration demonstrates Jazz Pharmaceuticals' focus on identifying innovative technologies that may lead to the development of important therapeutic options for patients with hematological malignancies.

Under the agreement, Pfenex will receive upfront and option payments totaling $15 million and may be eligible to receive additional payments of up to $166 million based on the achievement of certain development-, regulatory-, and sales-related milestones, including up to $41 million for certain non-sales-related milestones. Pfenex may also be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration. Both parties will be contributing to development efforts.

"The collaboration with Pfenex, including access to its unique **protein expression technology,** demonstrates our emphasis on diversifying and strengthening our portfolio to provide improved therapeutic options for patients." said Karen Smith M.D., Ph.D, global head of research and development and chief medical officer at Jazz Pharmaceuticals plc. "We look forward to working with Pfenex on the development of multiple product candidates that have the potential to broaden our hematology/oncology portfolio."

"Our collaboration with Jazz further validates Pfenex's product development capability enabled by our protein expression platform technology. We look forward to working with Jazz on these assets in support of further advancement in clinical development," said Bertrand C. Liang, chief executive officer of Pfenex.

About Pfenex Inc.

Pfenex Inc. (NYSE MKT: PFNX) is a clinical-stage biotechnology company engaged in the development of biosimilar therapeutics and high-value and difficult to manufacture proteins. The company's lead product candidate is PF582, a biosimilar candidate to Lucentis (ranibizumab), for the potential treatment of patients with retinal diseases. Pfenex has leveraged its *Pf*ēnex Expression Technology® platform to build a pipeline of product candidates and preclinical products under development including other biosimilars, as well as vaccines, therapeutic equivalents to reference listed drug products, and next generation biologics. For more information, please visit www.pfenex.com.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. The company has a diverse portfolio of products and product candidates, with a focus in the areas of sleep and hematology/oncology. In these areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*) and Defitelio® (defibrotide sodium) in the U.S. and markets Erwinase® and Defitelio® (defibrotide) in countries outside the U.S. For more information, please visit www.jazzpharmaceuticals.com.

Jazz Pharmaceuticals' "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements, including, but not limited to, statements related to the potential benefits of certain preclinical product candidates and related development activities, potential future payments to Pfenex by Jazz Pharmaceuticals, the potential broadening of Jazz Pharmaceuticals' product portfolio and other statements that are not historical facts. These forward- looking statements are based on Jazz Pharmaceuticals' current plans, objectives, estimates, expectations and intentions, and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with the difficulty and uncertainty of pharmaceutical product development and the uncertainty of preclinical and clinical success, and the risks and uncertainties described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and future filings and reports by the company. Other risks and uncertainties of which Jazz Pharmaceuticals is not currently aware may also affect its forward-looking statements and may cause actual results and timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by Jazz Pharmaceuticals on its website or otherwise. Jazz Pharmaceuticals does not undertake any obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

Pfenex Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or Pfenex's future financial or operating performance. In some cases, forward-looking statements can be identified because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern Pfenex's expectations, strategy, plans or intentions.

Forward-looking statements in this press release include, but are not limited to, statements regarding the future potential of the hematology product candidates, including future plans to develop, manufacture and commercialize these product candidates; the potential to receive future milestone and royalty payments under Pfenex's agreements with Jazz Pharmaceuticals; and the belief that these product candidates may lead to therapeutic options for patients with hematological malignancies. Actual results may differ materially from those indicated by these forward- looking statements as a result of the uncertainties inherent in the clinical drug development process, including, without limitation, challenges in successfully demonstrating the efficacy and safety of product candidates; the pre-clinical and clinical results for product candidates, which may not support further development of product candidates or may require additional clinical trials or modifications of ongoing clinical trials or regulatory pathways; challenges related to commencement, patient enrollment, completion, and analysis of clinical trials; Pfenex's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and new business initiatives; Pfenex's dependence on third parties for development, manufacture, marketing, sales and distribution of products; unexpected expenditures; and difficulties in obtaining and maintaining intellectual property protection for product candidates. Information on these and additional risks, uncertainties, and other information affecting Pfenex's business and operating results is contained in Pfenex's Annual Report on Form 10-K for the year ended December 31, 2015, Pfenex's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, and in Pfenex's subsequent reports filed with the Securities and Exchange Commission. The forward-looking statements in this press release are based on information available to Pfenex as of the date hereof, and Pfenex disclaims any obligation to update any forward-looking statements, except as required by law.

[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Pfenex investors and others should note that Pfenex announces material information to the public about Pfenex through a variety of means, including its website (http://www.pfenex.com/), investor relations website (http://pfenex.investorroom.com/), press releases, SEC filings, public conference calls, corporate Twitter account (https://twitter.com/pfenex), Facebook page (https://www.facebook.com/Pfenex-Inc-105908276167776/timeline/), and LinkedIn page (https://www.linkedin.com/company /pfenex-inc) in order to achieve broad, non-exclusionary distribution of information to the public and to comply with its disclosure obligations under Regulation FD. Pfenex encourages its investors and others to monitor and review the information Pfenex makes public in these locations as such information could be deemed to be material information. Please note that this list may be updated from time to time.

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[***] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

[Jazz Pharmaceuticals Letterhead]

July 30, 2025

Renee Gala
Address on File

Re: CEO Employment Agreement

Dear Renee,

This letter agreement ("**Agreement**") memorializes the terms and conditions of your promotion to the position of President and Chief Executive Officer ("**CEO**") of Jazz Pharmaceuticals. This Agreement will be effective as of August 11, 2025 (the "**Effective Date**").

1. Employment Duties and Board Position; Best Efforts; Work Location.

(a) **Employment Duties and Board Position.** You will serve as the President and CEO of Jazz Pharmaceuticals, Inc. (the "**Company**"), the Company's parent entity, Jazz Pharmaceuticals plc ("**PLC**"), and of PLC's other subsidiary entities (collectively, the "**Jazz Group**"). You will report to the Board of Directors of PLC (the "**Board**"), and you will perform all duties and accept all responsibilities incident to such position as may be reasonably assigned to you. You will also be appointed and serve as a Director on the Board.

(b) **Best Efforts.** During your employment, you will devote your best efforts and full time and attention to promote the business and affairs of the Company and the Jazz Group, and you may be engaged in other business activities only to the extent you have received the prior written consent of the Board and such activities do not materially interfere or conflict with your obligations hereunder. The foregoing shall not be construed as preventing you from (i) serving on civic, educational, philanthropic or charitable boards or committees, (ii) managing personal investments, or (iii) serving in the position included on **Schedule A** attached hereto, in each case, so long as such activities are permitted under the global Code of Conduct and applicable employment policies.

(c) **Working Location; Business Travel.** The Company has a flexible work location policy, Jazz Remix, which permits employees to work remotely, as well as within corporate offices, as appropriate for their job duties. Accordingly, you will have flexibility to work from your home and will also be expected to work from the corporate offices of the Jazz Group as appropriate for satisfactory completion of your duties. You will also be expected to travel for business in the course of performing your duties.

2. Compensation and Benefits.

(a) **Base Salary.** From the Effective Date, your base salary shall be increased to an annualized rate of $1,200,000.00 USD, payable in accordance with the regular payroll practices of the Company ("**Base Salary**"). Your Base Salary shall be reviewed annually by the Board and may be adjusted from time to time as the Board deems appropriate, provided that your Base Salary will not be decreased by more than ten percent (10%) without your consent, unless such reduction is made in connection with a Base Salary reduction which generally affects all executive level employees of the Company.

(b) **Annual Bonus.** Pursuant to the Jazz Pharmaceuticals Global Cash Bonus Plan, you will be eligible for consideration of an annual bonus, and in this position, your annual bonus target will be one hundred ten percent (110%) of your annual base salary rate, starting with your 2025 annual bonus which, for the sake of clarity, will not be pro-rated based on your start date as CEO during the 2025 calendar year. Your annual bonus target shall be reviewed annually by the Board and may be adjusted from time to time as the Board deems appropriate, provided that your annual bonus target will not be decreased by more than ten percent (10%) without your consent, unless such reduction is made in connection with an annual bonus target reduction which generally affects all executive level employees of the Company. The amount of your bonus is determined at the discretion of the Board and takes into consideration various factors, including Company

and individual performance. Bonuses are not guaranteed, and whether there will be a bonus in any year, and the amount of any bonus, is within the discretion of the Board.

(c) **Equity Compensation.** In connection with your promotion, you will receive a one-time equity award with a total grant value of $6,500,000, which will consist of the following: (a) 67% of the equity award will be in the form of Performance Stock Units ("**PSUs**"); and (b) 33% will be in the form of Restricted Stock Units ("**RSUs**"). This equity award will give you a right to receive PLC ordinary shares at a future date, subject to the terms and conditions of the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan, and the terms and conditions of the applicable award agreements. Your PSUs will vest based on achievement of the financial and strategic goals previously established by the Compensation & Management Development Committee (the "**Compensation Committee**") for the 2025 - 2027 performance period. Your RSUs will vest in four equal annual installments, subject to your continued employment through each vesting date.

Your PSUs and RSUs will be granted on the second trading day following the filing date of the Company's quarterly report filed with the U.S. Securities and Exchange Commission for the second quarter of 2025. Each of your new PSUs and RSUs will be converted from the dollar value shown above to a number of units based on the average closing price of PLC common shares for the 30-day period ending the day prior to the grant date.

As part of the annual compensation review, you will be eligible to receive annual equity awards subject to approval by the Board.

(d) **Benefits.** You will be eligible to participate in such health and other group insurance and other employee benefit plans and programs of the Company as in effect from time to time, in each case, which are generally made available to other similarly situated executive officers of the Company. Your participation will be subject to the terms of the applicable plan documents and generally applicable Company policies. The Company reserves the right to amend or terminate any employee benefit plan, program and policy in its discretion at any time.

(e) **Paid Time Off.** You will be entitled to paid time off in accordance with applicable policies governing paid time off, including Company holidays, vacation, and paid sick time, as may be in effect from time to time.

3. Employment Termination.

(a) **At-Will Employment**. Your employment relationship with the Company is at-will. This means that you will have the right to terminate your employment relationship with the Company at any time. Similarly, the Company will have the right to terminate its employment relationship with you at any time, with or without Cause (defined below). As discussed below, you may be entitled to certain severance benefits in the event of a qualifying termination of employment.

(b) **Severance Benefits for Involuntary Termination other than for Cause.** If your employment is terminated by the Company other than for Cause (excluding due to death or Disability) (the "**Involuntary Termination**"), in addition to any amounts by which you are entitled by law, you will be entitled to the following severance benefits (the "**Severance Benefits for Involuntary Termination**"):

(A) **Base Salary Severance Payment:** A cash severance payment equal to eighteen (18) months of your Base Salary.

(B) **Bonus Severance Payment:** If you have been employed with the Company or another Affiliate (defined below) through at least January 31 of the calendar year in which the Involuntary Termination occurs, an amount equal to (A) your target bonus for such calendar year, multiplied by (B) a ratio, the numerator of which is the number of calendar days that you were employed by the Company or an Affiliate

during such calendar year and the denominator of which is the total number of calendar days in such calendar year. In addition, if the date of Involuntary Termination occurs in the first quarter of the calendar year and such date is prior to the scheduled payment date for previous year annual bonus(es), you will receive payment of the annual bonus for such previous calendar year at the target amount.

(C) **COBRA Payments:** Provided that (i) you are eligible to continue coverage under a health, dental or vision insurance plan sponsored by the Company or an Affiliate upon the Involuntary Termination pursuant to COBRA, and (ii) you make an election to continue such coverage pursuant to COBRA within the time period prescribed under COBRA, then you shall be entitled to payment by the Company (on your behalf directly to the COBRA provider) of all of the applicable COBRA premiums for such health, dental or vision insurance plan coverage from the date of the Involuntary Termination through the earliest of (i) a period of eighteen (18) months following such date, (ii) your death or (iii) the effective date of your coverage by a health, dental or vision insurance plan of a subsequent employer (such period from the date of the Involuntary Termination through the earliest of (i) through (iii), the "**COBRA Payment Period**"), with such coverage counted as coverage pursuant to COBRA. Such COBRA premium payments shall be inclusive of premiums for your eligible dependents for such health, dental or vision insurance plan coverage as in effect immediately prior to the date of the Involuntary Termination, provided that such dependents continue to be eligible for such coverage during the COBRA Payment Period.

(D) **Outplacement Services:** Following the Involuntary Termination, the Company shall provide you with outplacement services through an agency selected by the Company in its sole discretion and commensurate with your position until the earlier of (i) the date eighteen (18) months following the Involuntary Termination and (ii) your acceptance of an offer of full-time employment from a subsequent employer.

(E) **Continued Equity Vesting:** You will be eligible for continued vesting of outstanding RSUs and PSUs to the extent such awards were granted to you at least twelve (12) months prior to the date of the Involuntary Termination, as follows:

(i) Unvested RSUs will continue to vest on each vesting date(s) scheduled to occur (pursuant to the original vesting schedule under which such RSUs were granted, as provided in the grant notice evidencing such RSUs) during the twelve (12) month period following the Involuntary Termination; and

(ii) Unvested PSUs that are subject to vesting based on the achievement of performance goals during a performance period that is scheduled to end during the twelve (12) month period following the Involuntary Termination will vest on the Certification Date (as defined below) in an amount, if any, equal to (a) the number of such PSUs that are otherwise eligible to vest based on actual performance measured against the performance goals for the applicable performance period, as certified by the Compensation Committee (pursuant to the original vesting terms under which such PSUs were granted, as provided in the grant notice evidencing such PSUs) (the date of such certification, the "**Certification Date**"), multiplied by (b) a ratio, the numerator of which is the number of calendar days during the performance period for such PSUs that had elapsed prior to the Involuntary Termination and the denominator of which is the total number of calendar days in such performance period, with the resulting number rounded up to the nearest

whole PSU; provided, however, that if such PSUs were granted to you after the standard grant date for such PSUs, then for purposes of the foregoing ratio, the term "performance period" will mean the period commencing on the date such PSUs were granted to you and ending on the last day of the performance period.

Notwithstanding the foregoing, the Severance Benefits for Involuntary Termination shall be conditioned upon your continued compliance with your obligations under your Employee Confidential Information and Inventions Agreement (discussed below) and your execution and nonrevocation of a general release of all known and unknown claims in favor of the Company, PLC, the other entities in the Jazz Group, and related parties, in a form provided by the Company which may be incorporated into a separation agreement at the Company's election ("**Release**"). Provided the Release is effective, the cash severance payments set forth in Sections 3(b)(A) and (B) shall be paid in a lump sum within 60 days following the Termination Date.

For purposes of this Section 3(b), "**Cause**" is defined as means the occurrence of any one or more of the following: (i) your unauthorized use or disclosure of the confidential information or trade secrets of the Company or an Affiliate which use or disclosure causes or could cause material harm to the Company or an Affiliate; (ii) your material breach of any written agreement between you and the Company or an Affiliate, or your material violation of any statutory duty owed to the Company or an Affiliate; (iii) your material failure to comply with the written policies or rules of the Company or an Affiliate; (iv) your conviction of, or plea of "guilty" or "no contest" to, any crime involving fraud or dishonesty under the laws of any jurisdiction; (v) your gross misconduct, including but not limited to attempted or actual commission of, participation or cooperation in, fraud or act of dishonesty against the Company or an Affiliate; (vi) your continuing failure to perform assigned duties after receiving notification of the failure from the Board or its designee; or (vii) your failure to reasonably cooperate in good faith with a governmental or internal investigation of the Company or any of its Affiliates, directors, officers or employees, if your cooperation has been requested by the Board or its designee. "**Affiliate**" is defined as any corporate entity within the Jazz Group.

(c) **Change in Control Termination.** You shall continue to be considered a "Participant" in the Jazz Pharmaceuticals plc Amended & Restated Executive Change in Control and Severance Benefit Plan (the "**Change in Control Plan**"), and if you are subject to a Covered Termination (as defined in and pursuant to the terms of the Change in Control Plan), you shall be eligible for either (i) the severance benefits as provided thereunder, or (ii) the severance benefits provided in Section 3(b) of this Agreement, in each case, whichever of clause (i) or (ii) provides greater value to you. The Change in Control Plan may be amended from time to time, and in the event that it is terminated and no successor plan is implemented, your entitlement to severance benefits (if any) shall be pursuant to this Agreement.

(d) **Resignation of Positions.** Upon your termination of employment with the Company for any reason, you will be automatically deemed to have resigned, as of the Termination Date, from all positions and offices you then hold within the Jazz Group, including as an officer and director of the Company and PLC. If requested, you shall execute all documents necessary to effectuate same, which may include letters of resignation.

(e) **Cooperation.** Following the termination of your employment with the Company for any reason, you will reasonably cooperate with the Company and other entities within the Jazz Group upon request of the Board, including being reasonably available to the Company (taking into account your other business endeavors) with respect to matters arising out of your services, including, in connection with any legal proceeding, providing testimony and affidavits; provided, that, the Company shall make reasonable efforts to minimize disruption of your other activities. The Company shall reimburse you for reasonable expenses incurred in connection with such cooperation.

4. Employee Confidential Information and Inventions Agreement.

Your previously signed Employee Confidential Information and Inventions Agreement shall remain in effect.

5. Section 409A.

(a) To the extent applicable, it is intended that this Agreement (including all amendments hereto, if any) either meets the requirements for exclusion from coverage under Section 409A, or alternatively complies with the requirements of Section 409A, so that the income inclusion provisions of Section 409A(a)(1) of the Code (defined below) do not apply to you. This Agreement shall be interpreted and administered in a manner consistent with this intent.

(b) To the extent required so that payments under this Agreement that are payable upon termination of employment are exempt from or compliant with Section 409A, such amounts shall only be payable if such termination also constitutes a "separation from service," within the meaning of Section 409A, from the Company and its affiliates. If you are deemed on the date of your separation from service to be a "specified employee" (within the meaning of Section 409A(a)(2)(B) of the Code) of the Company, then, notwithstanding any other provision herein, with regard to any payment that is "nonqualified deferred compensation" subject to Section 409A and that is payable on account of your "separation from service," such payment shall not be made prior to the earlier of (i) the expiration of six (6) months following the date of your separation from service, and (ii) the date of your death, following which all payments so delayed shall be paid to you in a lump sum without interest.

(c) All taxable reimbursements of business or other expenses or in-kind benefits provided for under this Agreement that are subject to Section 409A shall be subject to the following conditions where applicable: (i) the expenses eligible for reimbursement or the in-kind benefits to be provided in one taxable year shall not affect the expenses eligible for reimbursement or the in-kind benefits to be provided in any other taxable year; (ii) the reimbursement of an eligible expense shall be made no later than the end of the year after the year in which such expense was incurred; and (iii) the right to reimbursement or in-kind benefit shall not be subject to liquidation or exchange for another benefit.

(d) In applying Section 409A to amounts paid pursuant to this Agreement, each payment shall be treated as a separate payment and any right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments. Whenever a payment under this Agreement specifies a payment period within a specified number of days, the actual date of payment within the specified period shall be within the sole discretion of the Company. If the consideration and revocation period for the Release spans two taxable years and any amount hereunder is “nonqualified deferred compensation” subject to Section 409A and payable on account of your separation from service, such payment shall not be made or commence until the second taxable year.

6. Section 280G.

(a) If any payment or benefit (including payments and benefits pursuant to this Agreement) that you would receive in connection with a Change in Control (as defined in the Change in Control Plan) from the Company or otherwise (“**Transaction Payment**”) would (a) constitute a “parachute payment” within the meaning of Section 280G of the Internal Revenue Code (the “**Code**”); and (b) the net after-tax benefit that you would receive by reducing the Transaction Payments to three times the “base amount,” as defined in Section 280G(b)(3) of the Code, (the “**Parachute Threshold**”) is greater than the net after-tax benefit you would receive if the full amount of the Transaction Payments were paid to you, then the Transaction Payments payable to you shall be reduced (but not below zero) so that the Transaction Payments due to you do not exceed the amount of the Parachute Threshold.

(b) Unless you and the Company otherwise agree in writing, any determination required under this section shall be made in writing by the Company’s independent public accountants (the “**Accountants**”),

whose determination shall be conclusive and binding upon you and the Company for all purposes. The Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Accountants shall provide detailed supporting calculations to the Company and you as requested by the Company or you at least thirty (30) days prior to the date the excise tax imposed by Section 4999 of the Code (including any interest, penalties or additions to tax relating thereto) is required to be paid by you or withheld by the Company. You and the Company shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this section. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this section as well as any costs incurred by you with the Accountants for tax planning under Sections 280G and 4999 of the Code.

(c) The Company hereby agrees that, for purposes of determining whether any Transaction Payment would be subject to the excise tax under Section 4999 of the Code, any non-competition restrictive covenant which you may be subject to shall be treated as an agreement for the performance of personal services. The Company hereby agrees to indemnify, defend, and hold you harmless from and against any adverse impact, tax, penalty, or excise tax resulting from the Company or Accountants' attribution of a value to any non-competition restrictive covenant applicable to you that is less than the total compensation amount disclosed under Item 402(c) of Securities and Exchange Commission Regulation S-K in the immediately preceding year of the event that triggers the excise tax, to the extent the use of such lesser amount results in a larger excise tax under Section 4999 of the Code than you would have been subject to had the Company or Accountants attributed a value to any applicable non-competition restrictive covenant that is at least equal to the total compensation amount disclosed under Item 402(c) of Securities and Exchange Commission Regulation S-K for such year.

7. Miscellaneous.

(a) This Agreement shall be governed by and construed and enforced in accordance with the procedural and substantive laws of the Commonwealth of Pennsylvania, without regard to its conflicts of laws provisions that would result in the application of the laws of another jurisdiction. The litigation of any disputes arising out of this Agreement shall take place in the appropriate federal or state court located in Philadelphia County, Pennsylvania. Each of you and the Company hereby consent to service of process, and to be sued in the Commonwealth of Philadelphia and consent to the exclusive jurisdiction of the courts of the state courts located in Philadelphia County, Pennsylvania and the United States District Court for the Eastern District of Pennsylvania, as well as to the jurisdiction of all courts to which an appeal may be taken from such courts, for the purpose of any suit, action or other proceeding arising out of any of their obligations hereunder or with respect to the transactions contemplated hereby, and expressly waive any and all objections they may have to venue in such courts.

(b) All amounts paid to you under this Agreement during or following your employment shall be subject to withholding and other employment taxes imposed by applicable law, and the Company shall withhold from any payments under this Agreement all federal, state and local taxes as the Company is required to withhold pursuant to any law or governmental rule or regulation. You shall be solely responsible for the payment of all taxes imposed on you relating to the payment or provision of any amounts or benefits hereunder.

(c) This Agreement may be executed electronically (including via DocuSign), by .pdf and/or facsimile signatures in any number of counterparts, each of which shall be deemed an original, but all such counterparts shall together constitute one and the same instrument.

(d) From and after the Effective Date, this Agreement, your Employee Confidential Information and Inventions Agreement, and the Indemnification Agreement to be provided to you, constitutes the entire agreement on the subject matters hereof, and supersedes all other representations, agreements and

understandings (including any prior course of dealings), both written and oral, between you and the Company, PLC, or any other entity within the Jazz Group, with respect to the subject matters hereof.

(e) This Agreement and any of the provisions hereof may be amended, waived (either generally or in a particular instance and either retroactively or prospectively), modified or supplemented, in whole or in part, only by written agreement signed by you and the Company. This Agreement and your rights and obligations hereunder, may not be assigned by you, and any purported assignment by you in violation hereof shall be null and void. The Company is authorized to assign this Agreement to a successor to substantially all of its assets or business. Nothing in this Agreement shall confer upon any person not a party hereof, or the legal representatives of such person, any rights or remedies of any nature or kind whatsoever under or by reason of this Agreement, except the personal representative of the deceased. This Agreement shall inure to the benefit of, and be binding on, the successors and assigns of each of the parties, including, without limitation, your heirs and the personal representatives of your estate and any successor to all or substantially all of the business and/or assets of the Company.

(f) No remedy conferred upon a party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given under this Agreement or now or hereafter existing at law or in equity. Except as explicitly provided herein, no delay or omission by a party in exercising any right, remedy or power under this Agreement or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in its sole discretion.

(g) This Agreement and the compensation payable hereunder shall be subject to the Jazz Pharmaceuticals PLC Incentive Compensation Recoupment Policy, and any other applicable clawback or recoupment policies, share trading policies, and other policies that may be implemented by the Board from time to time with respect to officers of the Company.

(h) Any notices required or permitted hereunder or necessary or convenient in connection herewith shall be in writing and shall be deemed to have been given when hand delivered, when emailed, or when mailed by registered or certified mail if to the Company, to the Chairman of the Board, with a copy to the Chief Legal Officer, and if to you at your most recent home address in the Company's records.

Please acknowledge your acceptance of these terms and conditions by returning a signed copy of this Agreement at your earliest convenience. On behalf of the Board, we are very excited about your promotion to the position of President and CEO!

Very Truly yours,

/s/ Heidi Manna
Heidi Manna
Chief People Officer

I hereby accept these terms and conditions of employment as President and CEO of Jazz Pharmaceuticals:

Signature:	Date:
/s/ Renee Gala	30 July 2025
Renee Gala	

SCHEDULE A

Permitted Outside Activities

· Member, Board of Directors of DexCom, Inc.

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: August 6, 2025

By: /s/ Bruce C. Cozadd

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

Exhibit 31.2

CERTIFICATION

I, Philip L. Johnson, 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: August 6, 2025

By: /s/ Philip L. Johnson

Philip L. Johnson
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION[(1)]

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), Bruce C. Cozadd, Chief Executive Officer of Jazz Pharmaceuticals public limited company (the "Company"), and Philip L. Johnson, 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 June 30, 2025, 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: August 6, 2025

/s/ Bruce C. Cozadd

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

/s/ Philip L. Johnson

Philip L. Johnson
Executive Vice President and Chief Financial Officer
(Principal 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.