
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 30, 2014

Or

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

For the transition period from _____ to _____.

Commission file number: 000-50865

MannKind Corporation
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

**28903 North Avenue Paine
Valencia, California**
(Address of principal executive offices)

13-3607736
(I.R.S. Employer
Identification No.)

91355
(Zip Code)

(661) 775-5300
(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of November 3, 2014, there were 405,699,862 shares of the registrant's common stock, \$0.01 par value per share, outstanding.

MANNKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended September 30, 2014

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AFREZZA®, MedTone® and Technosphere® are our registered trademarks in the United States. We have also applied for and have registered company trademarks in other jurisdictions, including Europe and Japan.

PART 1: FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share data)

	<u>September 30, 2014</u>	<u>December 31, 2013</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 172,465	\$ 70,790
State research and development tax credit exchange receivable – current	803	—
Prepaid expenses and other current assets	20,253	5,485
Total current assets	193,521	76,275
Property and equipment — net	190,923	176,557
State research and development credit exchange receivable	260	298
Other assets	2,114	5,516
Total	<u>\$ 386,818</u>	<u>\$ 258,646</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 17,389	\$ 3,860
Accrued expenses and other current liabilities	27,269	21,634
Facility financing obligation	—	102,300
Senior convertible notes – current	99,120	—
Deferred up-front payment from collaboration agreement	150,000	—
Total current liabilities	293,778	127,794
Facility financing obligation	72,625	—
Senior convertible notes	—	98,439
Note payable to principal stockholder	49,521	49,521
Other liabilities	11,572	13,605
Total liabilities	<u>427,496</u>	<u>289,359</u>
Commitments and contingencies		
Stockholders' deficit:		
Undesignated preferred stock, \$0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding at September 30, 2014 and December 31, 2013	—	—
Common stock, \$0.01 par value — 550,000,000 shares authorized at September 30, 2014 and December 31, 2013; 405,469,034 and 369,391,972 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	4,055	3,697
Additional paid-in capital	2,413,621	2,261,996
Accumulated other comprehensive loss	(11)	(4)
Deficit accumulated during the development stage	(2,458,343)	(2,296,402)
Total stockholders' deficit	<u>(40,678)</u>	<u>(30,713)</u>
Total	<u>\$ 386,818</u>	<u>\$ 258,646</u>

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,		Cumulative period from February 14, 1991 (date of inception) to September 30, 2014
	2014	2013	2014	2013	
Revenue	\$ —	\$ —	\$ —	\$ —	\$ 3,166
Operating expenses:					
Research and development	19,178	27,281	82,684	80,731	1,659,976
General and administrative	19,088	17,481	66,840	42,053	552,226
In-process research and development costs	—	—	—	—	19,726
Goodwill impairment	—	—	—	—	151,428
Total operating expenses	<u>38,266</u>	<u>44,762</u>	<u>149,524</u>	<u>122,784</u>	<u>2,383,356</u>
Loss from operations	(38,266)	(44,762)	(149,524)	(122,784)	(2,380,190)
Other income (expense)	7,898	10	1,638	48	(1,264)
Interest expense on note payable to principal stockholder	(729)	(1,745)	(2,164)	(5,123)	(47,298)
Interest expense on notes	(5,424)	(4,323)	(11,895)	(10,052)	(66,981)
Interest income	1	2	4	4	37,008
Loss before benefit for income taxes	(36,520)	(50,818)	(161,941)	(137,907)	(2,458,725)
Income tax benefit	—	—	—	—	382
Net loss	<u>(36,520)</u>	<u>(50,818)</u>	<u>(161,941)</u>	<u>(137,907)</u>	<u>(2,458,343)</u>
Deemed dividend related to beneficial conversion feature of convertible preferred stock	—	—	—	—	(22,260)
Accretion on redeemable preferred stock	—	—	—	—	(952)
Net loss applicable to common stockholders	<u>\$ (36,520)</u>	<u>\$ (50,818)</u>	<u>\$ (161,941)</u>	<u>\$ (137,907)</u>	<u>\$ (2,481,555)</u>
Net loss per share applicable to common stockholders — basic and diluted	<u>\$ (0.09)</u>	<u>\$ (0.17)</u>	<u>\$ (0.42)</u>	<u>\$ (0.48)</u>	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	<u>394,163</u>	<u>296,386</u>	<u>381,332</u>	<u>286,889</u>	

See notes to condensed consolidated financial statements.

MANKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)
(In thousands)

	Three months ended		Nine months ended		Cumulative period from February 14, 1991 (date of inception) to September 30, 2014
	September 30, 2014	2013	2014	2013	
Net Loss	\$(36,520)	\$(50,818)	\$(161,941)	\$(137,907)	\$ (2,458,343)
Other comprehensive loss:					
Cumulative translation (loss) gain	(7)	(1)	(7)	(3)	(11)
Unrealized gain (loss) on investments:					
Unrealized holding gain (loss) during the period	—	—	—	—	48
Less: reclassification adjustment for gains (losses) included in net loss	—	—	—	—	(48)
Net unrealized gain on investments	—	—	—	—	—
Other comprehensive loss	(7)	(1)	(7)	(3)	(11)
Comprehensive loss	<u>\$(36,527)</u>	<u>\$(50,819)</u>	<u>\$(161,948)</u>	<u>\$(137,910)</u>	<u>\$ (2,458,354)</u>

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine months ended September 30,		Cumulative Period from February 14, 1991 (Date of Inception) to September 30, 2014
	2014	2013	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$(161,941)	\$(137,907)	\$ (2,458,343)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and accretion	15,574	10,109	156,408
Stock-based compensation expense	46,755	31,304	229,859
Stock expense for shares issued pursuant to research agreement	—	—	3,018
(Gain) loss on sale, abandonment/disposal or impairment of property and equipment	—	686	25,070
Accrued interest on investments, net of amortization of discounts	—	—	(191)
In-process research and development	—	—	19,726
Goodwill impairment	—	—	151,428
Loss on available-for-sale securities	—	—	990
Write-off of derivative liability	(363)	—	(363)
Income from sale of intellectual property	(9,250)	—	(9,250)
Litigation settlement in stock	—	—	6,494
Fair value of forward purchase contract	—	—	1,237
Interest expense related to milestone payment	1,850	—	1,850
Other, net	(7)	(3)	1,094
Changes in assets and liabilities:			
State research and development credit exchange receivable	(765)	242	(1,062)
Prepaid expenses and other current assets	(14,768)	(708)	(18,303)
Other assets	(130)	—	(360)
Accounts payable	13,692	(1,929)	17,039
Accrued expenses and other current liabilities	(3,003)	3,525	35,721
Deferred up-front payment from collaboration agreement	150,000	—	150,000
Other liabilities	2,186	—	2,775
Net cash provided by (used in) operating activities	<u>39,830</u>	<u>(94,681)</u>	<u>(1,685,163)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities	—	—	(796,779)
Sales and maturities of marketable securities	—	—	796,393
Purchase of property and equipment	(19,134)	(1,821)	(354,867)
Proceeds from sale of intellectual property	9,250	—	9,250
Proceeds from sale of property and equipment	—	—	454
Net cash used in investing activities	<u>(9,884)</u>	<u>(1,821)</u>	<u>(345,549)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock and warrants, net of issuance costs	38,573	51,658	1,582,897
Collection of Series C convertible preferred stock subscriptions receivable	—	—	50,000
Issuance of Series B convertible preferred stock for cash	—	—	15,000
Cash received for common stock to be issued	—	—	3,900
Repurchase of common stock	—	—	(1,028)
Put shares sold to majority stockholder	—	—	623
Borrowings under lines of credit	—	—	4,220
Payment of 2013 notes	—	—	(115,000)
Proceeds from notes receivables	—	—	1,742
Proceeds from issuance of facility financing obligation & milestone rights	40,000	79,500	159,500
Proceeds from issuance of Tranche B of the facility financing obligation	20,000	—	20,000
Facility financing obligation & milestone rights issuance costs	—	(598)	(598)
Borrowings on notes payable to principal stockholder	—	—	387,750
Principal payments on notes payable to principal stockholder	—	—	(70,000)

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	Nine months ended September 30,		Cumulative Period from February 14, 1991 (Date of Inception) to September 30, 2014
	2014	2013	
Borrowings on notes payable	—	—	3,460
Principal payments on notes payable	—	—	(1,667)
Proceeds from senior convertible notes	—	—	207,050
Payment of employment taxes related to vested restricted stock units	(26,844)	(2,095)	(44,672)
Net cash provided by financing activities	71,729	128,465	2,203,177
NET INCREASE IN CASH AND CASH EQUIVALENTS	\$101,675	\$ 31,963	\$ 172,465
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	70,790	61,840	—
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$172,465	\$ 93,803	\$ 172,465
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	\$ —	\$ —	\$ 26
Interest paid in cash, net of amounts capitalized	9,740	7,862	82,344
Accretion on redeemable convertible preferred stock	—	—	(952)
Issuance of common stock upon conversion of notes payable	—	—	3,331
Increase in additional paid-in capital resulting from merger	—	—	171,154
Issuance of common stock for notes receivable	—	—	2,758
Issuance of common stock pursuant to conversion of facility financing obligation	93,500	—	100,000
Issuance of put option by stockholder	—	—	(2,949)
Put option redemption by stockholder	—	—	1,921
Issuance of Series C convertible preferred stock subscriptions	—	—	50,000
Issuance of Series A redeemable convertible preferred stock	—	—	4,296
Conversion of Series A redeemable convertible preferred stock	—	—	(5,248)
Non-cash construction in progress and property and equipment	3,809	5,523	3,089
Capitalization of interest on note payable to principal stockholder	—	—	22,105
Reduction of principal on note payable to principal stockholder upon issuance of common stock and exercise of warrants	—	—	290,334
Forward purchase contract contribution to APIC	—	—	29,317
Reclassification of forward purchase contract to APIC	—	—	28,080
Reclassification of share-based awards to liability	22,963	—	22,963
Tranche B Commitment Asset	1,753	—	1,753

In connection with the Company's initial public offering, all shares of Series B and Series C convertible preferred stock, in the amount of \$15.0 million and \$50.0 million, respectively, automatically converted into common stock in August 2004.

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Description of business and basis of presentation

The accompanying unaudited condensed consolidated financial statements of MannKind Corporation and its subsidiaries (“MannKind” or the “Company”), have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the “SEC”). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The information included in this quarterly report on Form 10-Q should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s annual report on Form 10-K for the fiscal year ended December 31, 2013 filed with the SEC on March 3, 2014 (the “Annual Report”).

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. Interim financial results may not be indicative of the results that may be expected for the full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in these accompanying financial statements involve assessing long-lived assets for impairment, accrued expenses, including clinical study expenses, valuation of forward purchase contracts, valuation of the facility financing obligation, commitment asset, milestone rights, valuation of stock-based compensation and the determination of the provision for income taxes and corresponding deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements.

Business — The Company is a biopharmaceutical company focused on the discovery and development of therapeutic products for diseases such as diabetes. The Company’s lead product, AFREZZA (insulin human) inhalation powder, is a rapid-acting inhaled insulin that was approved by the U.S. Food and Drug Administration (“FDA”) on June 27, 2014 to improve glycemic control in adult patients with diabetes.

Basis of Presentation — The Company is considered to be in the development stage as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, and raising capital. It is costly to develop therapeutic products and conduct clinical studies for these products. From its inception through September 30, 2014, the Company had accumulated net losses of \$2.5 billion, which include cumulative negative cash flow from operations of \$1.7 billion and a goodwill impairment charge of \$151.4 million.

On August 11, 2014, the Company entered into a license and collaboration agreement (the “Sanofi License Agreement”) with Sanofi-Aventis Deutschland GmbH (which subsequently assigned its rights and obligations under the agreement to Sanofi-Aventis U.S. LLC (“Sanofi”)), pursuant to which Sanofi will be responsible for global commercial, regulatory and development activities for AFREZZA. Under the Sanofi License Agreement, the Company received a \$150.0 million up-front fee and may earn up to an aggregate of \$775.0 million upon the achievement of certain development, manufacturing, regulatory and sales milestones. Worldwide profits and losses with respect to AFREZZA will be shared 65% by Sanofi and 35% by the Company. Pursuant to a supply agreement, the Company will manufacture AFREZZA at its manufacturing facility in Danbury, Connecticut to supply Sanofi’s demand for the product. The Sanofi License Agreement became effective on September 23, 2014 following completion of the U.S. Federal Trade Commission’s review of the transactions contemplated by the Sanofi License Agreement under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder (the “Hart-Scott-Rodino Act”) and the completion of documentation related to the \$175.0 million secured loan facility being provided to the Company by an affiliate of Sanofi (the “Sanofi Loan Facility”) to fund the Company’s share of net losses under the Sanofi License Agreement.

At September 30, 2014, the Company’s capital resources consisted of cash and cash equivalents of \$172.5 million. The Company expects to continue to incur significant expenditures to support commercial launch of AFREZZA and the development of other product candidates as contemplated under the Sanofi License Agreement. In addition, the Company’s 5.75% Senior Convertible Notes due 2015 (the “2015 notes”) in the aggregate principal amount of \$100.0 million have a maturity date of August 15, 2015, and payment on the outstanding amount is due in full on that date (see Note 10 – Senior convertible notes).

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The Company may need to raise additional capital, whether through the sale of equity or debt securities, additional strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means. Additional funding sources that are, or in certain circumstances may be available to the Company, include approximately \$30.1 million principal amount of available borrowings under its loan arrangement (the “Loan Arrangement”) with The Mann Group LLC (“The Mann Group”) (see note 9 – Related-party arrangements), potential proceeds from the exercise of warrants issued in its February 2012 public offering of approximately \$20 million, the Company’s at-the-market issuance sales agreements which allow the Company to sell up to \$50 million in common stock, and pursuant to the facility agreement (the “Facility Agreement”) with Deerfield Private Design Fund II, L.P. (“Deerfield Private Design Fund”) and Deerfield Private Design International II, L.P. (collectively, “Deerfield”) and the First Amendment to Facility Agreement and Registration Rights Agreement (the “First Amendment”) additional sales of an additional tranche of notes (the “Tranche B notes”) of up to \$70 million which must be purchased prior to December 30, 2014 (see Note 11 – Facility Agreement).

Although we believe that our existing cash and cash equivalents and available debt financing will be sufficient to finance our operational cash needs through at least the next twelve months, should our results not meet our current operating plan, it could negatively impact our liquidity and we may need to raise additional capital or seek additional financing sources as discussed above. There can be no assurance that we would be able to raise such additional financing or additional capital on acceptable terms, or at all, and if we are not able to raise adequate additional financing or capital to continue to fund our ongoing operations, we will need to defer, reduce or eliminate significant planned expenditures or significantly curtail our operations, and there may be substantial doubt about our ability to continue as a going concern.

Prepaid expenses and other current assets — Prepaid expenses and other current assets primarily consist of prepaid expenses for goods and services to be received. As of September 30, 2014, prepaid and other current assets had a balance of \$20.3 million, mainly comprised of a \$15.0 million prepayment for 2015 quantities of insulin, prepaid insurance, and prepaid clinical trial expenses.

On July 31, 2014, the Company entered into a Supply Agreement (the “Supply Agreement”) with Amphastar France Pharmaceuticals S.A.S., a French corporation (“Amphastar”), pursuant to which Amphastar will manufacture for and supply to the Company certain quantities of recombinant human insulin for use in AFREZZA. Under the terms of the Supply Agreement, Amphastar will be responsible for manufacturing the insulin in accordance with the Company’s specifications and agreed-upon quality standards. The Company has agreed to purchase annual minimum quantities of insulin under the Supply Agreement of an aggregate of approximately €120.1 million in calendar years 2015 through 2019. The Company may request to purchase additional quantities of insulin over such annual minimum quantities. As part of the Supply Agreement, the Company paid a \$15.0 million deposit to Amphastar as prepayment for 2015 quantities of insulin.

Unless earlier terminated, the term of the Supply Agreement expires on December 31, 2019 and can be renewed for additional, successive two year terms upon 12 months’ written notice, given prior to the end of the initial term or any additional two year term. The Company and Amphastar each have normal and customary termination rights, including termination for material breach that is

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not cured within a specific time frame or in the event of liquidation, bankruptcy or insolvency of the other party. In addition, the Company may terminate the Supply Agreement upon two years' prior written notice to Amphastar without cause or upon 30 days' prior written notice to Amphastar if a controlling regulatory authority withdraws approval for AFREZZA, provided, however, in the event of a termination pursuant to either of the latter two scenarios, the provisions of the Supply Agreement require the Company to pay the full amount of all unpaid purchase commitments due over the initial term within 60 calendar days of the effective date of such termination.

Sale of intellectual property — On July 18, 2014, the Company entered into an assignment agreement with a third party whereby the third party acquired all proprietary rights, technology and know-how that related to a small molecule inhibitor compound and all pre-clinical data and results related thereto. Under the terms of the assignment agreement, the Company received total consideration of \$9.3 million, which was offset by \$1.4 million of expense associated with the sale of the intellectual property related to oncology.

Fair Value of Financial Instruments — The carrying amounts reported in the accompanying financial statements for cash and cash equivalents, accounts payable and accrued liabilities approximate their fair value due to their relatively short maturities. The fair value of the cash equivalents, note payable to related party, senior convertible notes, and the elements of the Facility Agreement are discussed in Note 13, "Fair value of financial instruments."

Recently Issued Accounting Standards — In July 2013, the FASB issued ASU 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force)*. The amendments in this ASU provide guidance on the financial statements presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in this ASU do not require new recurring disclosures. The amendments in this ASU are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of the new requirement did not have a significant impact on the Company's consolidated financial statements.

In May 2014, a new standard was issued related to revenue recognition, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The new standard will replace most of the existing revenue recognition standards in U.S. GAAP when it becomes effective on January 1, 2017. Early adoption is not permitted. The new standard allows for either "full retrospective" adoption, whereby the new standard is applied to each prior reporting period presented or "modified retrospective" adoption, whereby the new standard is only applied to the most current period presented with the cumulative effect of the change recognized at the date of the initial application. The Company is assessing the potential impact of the new standard on its consolidated statements of financial position and results of operations and comprehensive income (loss) and has not yet selected a transition method.

In June 2014, the FASB issued ASU No. 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The amendments in this ASU remove all incremental financial reporting requirements from GAAP for development stage entities, including the removal of Topic 915, *Development Stage Entities*, from the FASB Accounting Standards Codification. In addition, the ASU: (a) adds an example disclosure in Topic 275, *Risks and Uncertainties*, to illustrate one way that an entity that has not begun planned principal operations could provide information about the risks and uncertainties related to the company's current activities; and (b) removes an exception provided to development stage entities in Topic 810, *Consolidation*, for determining whether an entity is a variable interest entity. The presentation and disclosure requirements in Topic 915 will no longer be required for the first annual period beginning after December 15, 2014. The revised consolidation standards are effective one year later, in annual periods beginning after December 15, 2015. Early adoption is permitted. The Company is evaluating the impact the adoption of ASU 2014-10 will have on its consolidated financial statements.

On August 27, 2014, the FASB issued ASU 2014-15, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is "substantial doubt about the entity's ability to continue as a going concern." The ASU is effective for annual periods ending after December 15, 2016, and interim periods thereafter; early adoption is permitted. The Company is evaluating the impact the adoption of ASU 2014-15 will have on its consolidated financial statements.

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2. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities were comprised of the following (in thousands):

	September 30, 2014	December 31, 2013
Salary and related expenses	\$ 10,287	\$ 12,193
Research and clinical trial costs	1,011	1,311
Accrued interest	958	2,082
Construction in progress	2,739	342
Other	12,274	5,706
Accrued expenses and other current liabilities	<u>\$ 27,269</u>	<u>\$ 21,634</u>

3. Accounting for stock-based compensation

Total stock-based compensation expense recognized in the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2014 and 2013 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Stock-based compensation	<u>\$(4,827)</u>	<u>\$15,943</u>	<u>\$46,755</u>	<u>\$31,304</u>

During the three months ended March 31, 2014, the Company issued stock awards to employees primarily with a four-year vesting schedule. The grant date fair value of the 46,400 restricted stock units and 17,700 stock options issued were \$296,000 and \$81,000, respectively, with a grant date fair value per share of \$6.39 and \$4.58, respectively.

During the three months ended June 30, 2014, the Company issued stock awards to employees primarily with a four-year vesting schedule as well as non-employee directors primarily with a three-year vesting schedule. The grant date fair value of the 158,600 restricted stock units and 252,600 stock options issued were \$1.23 million and \$1.32 million, respectively. The grant date fair value per share was \$7.76 for restricted stock units, \$5.31 for employee stock options and \$5.22 for non-employee director stock options.

On June 30, 2014, the Company modified certain performance grants to allow 124 employees to withhold in excess of the minimum statutory requirements for performance-based restricted stock units at the employee's discretion through December 31, 2014. The modification resulted in the reclassification of these performance grants from equity awards to liability awards, which require re-measurement at the end of each reporting period through settlement. Consequently, as of June 30, 2014, the reclassification and re-measurement of these performance-based restricted stock units resulted in an increase in stock-based compensation expense of \$35.9 million.

During the three months ended September 30, 2014, the performance shares related to the modification settled. The performance grants were re-measured on their respective settlement dates, which resulted in a credit to stock compensation expense of \$12.9 million. As of September 30, 2014, there were no remaining liability awards.

During the three months ended September 30, 2014, the Company issued stock awards to employees primarily with a four-year vesting schedule. The grant date fair value of the 720,000 restricted stock units and 1,053,900 stock options issued were \$5.1 million and \$4.9 million, respectively, with a grant date fair value per share of \$7.09 and \$4.66, respectively.

As of September 30, 2014, there was \$10.3 million of unrecognized compensation cost related to options and \$12.5 million of unrecognized compensation cost related to restricted stock units, which are expected to be recognized over the remaining weighted average vesting period of 3.0 years. The Company evaluates stock awards with performance conditions as to the probability that the performance conditions will be met and estimates the date at which the performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period. As of September 30, 2014, there were no awards with milestones not considered probable of achievement.

4. Net loss per common share

Basic net loss per share excludes dilution for potentially dilutive securities and is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period excluding the shares loaned to Bank of America, N.A. under a share lending arrangement (see Note 7 — Common and preferred stock). As of September 30, 2014, 9,000,000 shares of the Company's common stock loaned to Bank of America pursuant to the terms of a share lending agreement as described in Note 7, were issued and are outstanding, and the holder of the borrowed shares has all the rights of a holder of the Company's common stock. However, because the share borrower must return all borrowed shares to the Company (or, in certain circumstances, the cash value thereof), the borrowed shares are not considered outstanding for the purpose of computing and reporting basic or diluted earnings (loss) per share. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share for all of the periods presented in the accompanying condensed consolidated statements of operations because the reported net loss in each of these periods results in their inclusion being antidilutive. Antidilutive securities, which consist of stock options, restricted stock units, warrants, and shares that could be issued upon conversion of the senior convertible notes, that are not included in the diluted net loss per share calculation consisted of an aggregate of 47,820,744 shares and 133,944,425 shares as of September 30, 2014 and 2013, respectively, and exclude the 9,000,000 shares loaned under the share lending arrangement.

5. State research and development credit exchange receivable

The State of Connecticut provides certain companies with the opportunity to exchange certain research and development income tax credit carryforwards for cash in exchange for forgoing the carryforward of the research and development income tax credits. The program provides for an exchange of research and development income tax credits for cash equal to 65% of the value of corporation tax credit available for exchange. Current estimated amounts receivable under the program were \$803,000 at September 30, 2014, and there was no current portion at December 31, 2013. Long-term estimated amounts receivable under the program were \$260,000 and \$298,000 at September 30, 2014 and December 31, 2013, respectively.

6. Property and equipment

Property and equipment — net consisted of the following (dollar amounts in thousands):

	Estimated Useful Life (Years)	September 30, 2014	December 31, 2013
Land	—	\$ 5,273	\$ 5,273
Buildings	39-40	54,948	54,948
Building improvements	5-40	114,131	114,099
Machinery and equipment	3-15	82,068	82,189
Furniture, fixtures and office equipment	5-10	5,087	5,046
Computer equipment and software	3	11,335	11,289
Leasehold improvements	4	17	17
Construction in progress		36,214	14,756
		<u>309,073</u>	<u>287,617</u>
Less accumulated depreciation and amortization		(118,150)	(111,060)
Property and equipment — net		<u>\$ 190,923</u>	<u>\$ 176,557</u>

Leasehold improvements are amortized over four years which is the shorter of the term of the lease or the service lives of the improvements.

Depreciation and amortization expense related to property and equipment for the three and nine months ended September 30, 2014 and 2013 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Depreciation and amortization expense	<u>\$ 2,414</u>	<u>\$ 2,874</u>	<u>\$7,386</u>	<u>\$8,820</u>

7. Common and preferred stock

The Company is authorized to issue 550,000,000 shares of common stock, par value \$0.01 per share, and 10,000,000 shares of undesignated preferred stock, par value \$0.01 per share, issuable in one or more series designated by the Company's board of directors. No other class of capital stock is authorized. As of September 30, 2014 and December 31, 2013, 405,469,034 and 369,391,972 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding. Included in the common stock outstanding as of September 30, 2014 and December 31, 2013 are 9,000,000 shares of common stock loaned to Bank of America under a share lending agreement in connection with the offering of \$100.0 million aggregate principal amount of 2015 notes (see Note 10 — Senior convertible notes). Bank of America is obligated to return the borrowed shares (or, in certain circumstances, the cash value thereof) to the Company on or about the 45th business day following the date as of which the entire principal amount of the 2015 notes ceases to be outstanding, subject to extension or acceleration in certain circumstances or early termination at Bank of America's option. The Company did not receive any proceeds from the sale of the borrowed shares by Bank of America, but the Company did receive a nominal lending fee of \$0.01 per share from Bank of America for the use of borrowed shares.

On July 1, 2013, the Company entered into the Facility Agreement with Deerfield providing for the sale of up to \$160.0 million of 2019 notes to Deerfield in four equal tranches of \$40.0 million principal amount. On February 28, 2014, the Company amended the Facility Agreement to, among other things, allow Deerfield, subject to certain limitations, to convert up to an additional \$60.0 million principal amount under the then-outstanding 2019 notes into the Company's common stock after the effective date of the First Amendment. The Company also agreed to register for resale up to 12,000,000 shares of common stock issuable upon conversion of the outstanding 2019 notes, with a minimum conversion price of \$5.00 per share unless the Company otherwise consents. The conversion price was determined by the average of the volume weighted average prices per share during the three trading days immediately preceding the election to convert. As of September 30, 2014, Deerfield had converted \$100.0 million of 2019 notes into 18,616,304 shares of the Company's common stock which resulted in total expense of \$6.4 million for the nine months ended September 30, 2014 and \$0.6 million for the twelve months ended December 31, 2013 for the difference between the principal amount of the notes converted and their carrying amount (see Note 11 – Facility Agreement). No additional principal amount of 2019 notes is convertible.

8. Commitments and contingencies

Guarantees and Indemnifications — In the ordinary course of its business, the Company makes certain indemnities, commitments and guarantees under which it may be required to make payments in relation to certain transactions. The Company, as permitted under Delaware law and in accordance with its Bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. The Company has not recorded any liability for these indemnities in the accompanying condensed consolidated balance sheets. However, the Company accrues for losses for any known contingent liability, including those that may arise from indemnification provisions, when future payment is probable and the amount can be reasonably estimated.

Litigation — The Company is subject to legal proceedings and claims which arise in the ordinary course of its business. As of the date hereof, the Company believes that the final disposition of such matters will not have a material adverse effect on the financial position, results of operations or cash flows of the Company. The Company maintains liability insurance coverage to protect the Company's assets from losses arising out of or involving activities associated with ongoing and normal business operations. In accordance with ASC 450 *Contingencies*, the Company would record a provision for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

Contingencies — In connection with the Facility Agreement, on July 1, 2013 the Company also entered into a Milestone Rights Purchase Agreement (the "Milestone Agreement") with Deerfield Private Design Fund and Horizon Santé FLML SÁRL (collectively, the "Milestone Purchasers"), pursuant to which the Company sold the Milestone Purchasers certain rights (the "Milestone Rights") to receive payments of up to \$90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an AFREZZA product in the United States and the achievement of specified net sales figures (see Note 11 – Facility Agreement).

9. Related-party arrangements

In October 2007, the Company entered into a \$350.0 million loan arrangement with its principal stockholder. The Loan Arrangement has been amended from time to time. On October 31, 2013, the promissory note underlying the Loan Arrangement was amended to, among other things, extend the maturity date of the loan to January 5, 2020, extend the date through which the Company can borrow under the Loan Arrangement to December 31, 2019, increase the aggregate borrowing amount under the Loan Arrangement from \$350.0 million to \$370.0 million and provide that repayments or cancellations of principal under the Loan Arrangement will not be available for reborrowing.

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As of September 30, 2014, the total principal amount outstanding under the Loan Arrangement was \$49.5 million and the amount available for future borrowings was \$30.1 million. Interest, at a fixed rate of 5.84%, is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as the Company and The Mann Group mutually agree. All or any portion of accrued and unpaid interest that becomes due and payable may be paid-in-kind and capitalized as additional borrowings at any time upon mutual agreement of both parties and would be classified as non-current. As of September 30, 2014, the Company had accrued \$2.8 million of interest in other liabilities related to the Loan Arrangement. The Mann Group can require the Company to prepay up to \$200.0 million in advances that have been outstanding for at least 12 months (less approximately \$105.0 million aggregate principal amount that has been cancelled in connection with two common stock purchase agreements). If The Mann Group exercises this right, the Company will have 90 days after The Mann Group provides written notice (or the number of days to maturity of the note if less than 90 days) to prepay such advances. However, pursuant to a letter agreement entered into in August 2010, The Mann Group has agreed to not require the Company to prepay amounts outstanding under the amended and restated promissory note if the prepayment would require the Company to use its working capital resources. In addition, The Mann Group entered into a subordination agreement with Deerfield pursuant to which The Mann Group agreed with Deerfield not to demand or accept any payment under the Loan Arrangement until the Company's payment obligations to Deerfield under the Facility Agreement have been satisfied in full. Subject to the foregoing, in the event of a default under the Loan Arrangement, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at The Mann Group's option, and the interest rate will increase to the one-year LIBOR calculated on the date of the initial advance or in effect on the date of default, whichever is greater, plus 5% per annum. All borrowings under the Loan Arrangement are unsecured. The Loan Arrangement contains no financial covenants.

During the nine months ended September 30, 2014, there were no additional borrowings under or amendments to the Loan Arrangement.

10. Senior convertible notes

Senior convertible notes consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
2015 notes		
Principal amount	\$ 100,000	\$ 100,000
Unaccreted debt issuance expense	(880)	(1,561)
Net carrying amount	<u>\$ 99,120</u>	<u>\$ 98,439</u>

On August 18, 2010, the Company completed a Rule 144A offering of \$100.0 million aggregate principal amount of 2015 notes. The 2015 notes are governed by the terms of an indenture dated as of August 24, 2010 (the "2015 Note Indenture"). The 2015 notes bear interest at the rate of 5.75% per year on the principal amount, payable in cash semi-annually in arrears on February 15 and August 15 of each year, beginning February 15, 2011. In connection with the 2015 notes, the Company had accrued interest of \$1.0 million and \$2.4 million as of September 30, 2014 and December 31, 2013, respectively. The 2015 notes are general, unsecured, senior obligations of the Company and effectively rank junior in right of payment to all of the Company's secured debt, to the extent of the value of the assets securing such debt and to the debt and all other liabilities of the Company's subsidiaries. The maturity date of the 2015 notes is August 15, 2015 and payment is due in full on that date for unconverted securities. Because the 2015 notes are due within twelve months, the Company reclassified the 2015 notes from a long term liability to a current liability at September 30, 2014. Holders of the 2015 notes may convert, at any time prior to the close of business on the business day immediately preceding the stated maturity date, any outstanding principal into shares of the Company's common stock at an initial conversion rate of 147.0859 shares per \$1,000 principal amount, which is equal to a conversion price of approximately \$6.80 per share, subject to adjustment. Except in certain circumstances, if the Company undergoes a fundamental change: (1) the Company will pay a make-whole premium on the 2015 notes converted in connection with a fundamental change by increasing the conversion rate on such 2015 notes, which amount, if any, will be based on the Company's common stock price and the effective date of the fundamental change, and (2) each holder of 2015 notes will have the option to require the Company to repurchase all or any portion of such holder's 2015 notes at a repurchase price of 100% of the principal amount of the 2015 notes to be repurchased plus accrued and unpaid interest, if any. The Company may elect to redeem some or all of the 2015 notes if the closing stock price has equaled 150% of the conversion price for at least 20 of the 30 consecutive trading days ending on the trading day before the Company's redemption notice. The redemption price will equal 100% of

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the principal amount of the 2015 notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date, plus a make-whole payment equal to the sum of the present values of the remaining scheduled interest payments through and including August 15, 2015 (other than interest accrued up to, but excluding, the redemption date). The Company will be obligated to make the make-whole payment on all the 2015 notes called for redemption and converted during the period from the date the Company mailed the notice of redemption to and including the redemption date. The Company may elect to make the make-whole payment in cash or shares of its common stock, subject to certain limitations. Under the terms of the 2015 Note Indenture, the conversion option can be net-share settled and the maximum number of shares that could be required to be delivered under the contract, including the make-whole shares, is fixed and less than the number of authorized and unissued shares less the maximum number of shares that could be required to be delivered during the contract period under other existing commitments. Applying the Company's sequencing policy, the Company performed an analysis at the time of the offering of the 2015 notes and each reporting date since and has concluded that the number of available authorized shares at the time of the offering and each subsequent reporting date was sufficient to deliver the number of shares that could be required to be delivered during the contract period under existing commitments.

The Company incurred approximately \$4.2 million in issuance costs which are recorded as an offset to the 2015 notes in the accompanying condensed consolidated balance sheets. These costs are being accreted to interest expense using the effective interest method over the term of the 2015 notes.

The 2015 notes provide that upon an acceleration of certain indebtedness, including the 2019 notes and the Tranche B notes described in Note 11, the holders may elect to accelerate the Company's repayment obligations under the 2015 notes if such acceleration is not cured, waived, rescinded or annulled. There can be no assurance that the holders would not choose to exercise these rights in the event such events were to occur.

Accretion of debt issuance expense in connection with the 2015 notes during the three and nine months ended September 30, 2014 and 2013 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Accretion expense	\$ 231	\$ 216	\$ 681	\$ 637

11. Facility Agreement

The significant activity related to the Facility Agreement during the nine months ended September 30, 2014 consisted of the following (in thousands):

	September 30, 2014
Facility financing obligation	
Carrying value at December 31, 2013	\$ 102,300
Principal converted to equity	(93,500)
Accretion of debt discount and debt issuance expense	7,507
Adjustment to debt discount related to modification of the 2019 notes	2,921
Tranche B principal amount	20,000
Debt discount related to Tranche B purchase	(1,168)
Tranche 4 principal amount	40,000
Debt discount related to Tranche 4 purchase	(5,435)
Net carrying value of facility financing obligation	\$ 72,625
Commitment Asset	
Commitment asset balance at December 31, 2013	\$ 5,157
Tranche B commitment asset fair value	2,921
Less commitment asset portion associated with the receipt of Tranche 4 and Tranche B notes	(6,325)
Commitment asset value included in other assets	\$ 1,753

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Accretion of debt issuance cost and debt discount in connection with the Facility Agreement during the three and nine months ended September 30, 2014 were as follows (in thousands):

	Three months ended September 30, 2014	Nine months ended September 30, 2014
Accretion expense- debt issuance cost	\$ 9	\$ 318
Accretion expense- debt discount	\$ 306	\$ 7,189

On July 1, 2013, the Company entered into the Facility Agreement providing for the sale of up to \$160.0 million of 2019 notes to Deerfield in four equal tranches of \$40.0 million principal amount. The 2019 notes accrue interest at a rate of 9.75% per annum until maturity in 2019 or their earlier repayment, repurchase, or conversion. As of September 30, 2014, Deerfield had purchased the four tranches of 2019 notes in the aggregate principal amount of \$160.0 million.

On February 28, 2014, the Company entered into the First Amendment, which modified the terms of the Facility Agreement to provide for the issuance of Tranche B notes to Deerfield. Pursuant to the terms of the First Amendment and the subsequent occurrence of certain events specified in the First Amendment, prior to December 30, 2014, the Company may request that Deerfield purchase up to \$90.0 million aggregate principal amount of Tranche B notes. The Tranche B notes initially accrued interest at the rate of 9.75% per year on the outstanding principal amount, subject to reduction to 8.75% if the Company entered into a collaboration with a third party to commercialize AFREZZA. Pursuant to the terms of the First Amendment, the interest rate was subsequently reduced to 8.75% on September 23, 2014 following completion of the U.S. Federal Trade Commission's review of the transactions contemplated by the Sanofi License Agreement under the Hart-Scott-Rodino Act and the completion of documentation related to the \$175.0 million secured loan facility being provided to the Company. The interest on the outstanding principal amount of notes under the Facility Agreement is payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. The Company is required to repay 25% of the original principal amount of any Tranche B notes on the third, fourth, fifth and sixth anniversaries of the applicable issue dates of such notes, provided that the entire outstanding principal amount of all Tranche B notes will become due and payable no later than December 31, 2019. The Tranche B notes can be prepaid without penalty or premium commencing two years after issuance thereof. On May 6, 2014, Deerfield purchased an aggregate principal amount of \$20.0 million in Tranche B notes in accordance with the provisions of the Facility Agreement, as amended. On July 18, 2014, Deerfield purchased an aggregate principal amount of \$40.0 million of the fourth and final tranche of 2019 notes (the "Tranche 4 notes") in accordance with the provisions of the Facility Agreement, as amended, which contains a financial covenant that requires the Company's cash and cash equivalents which include available borrowings under the Loan Arrangement on the last day of each fiscal quarter to not be less than \$25.0 million.

In addition, pursuant to the First Amendment, the outstanding first tranche of 2019 notes (the "Tranche 1 notes") and third tranche of 2019 notes (the "Tranche 3 notes") held by Deerfield were amended and restated to permit Deerfield to convert up to an additional \$60.0 million principal amount under such 2019 notes into the Company's common stock after the effective date of the First Amendment. The Company also agreed to register for resale up to 12,000,000 shares of the Company's common stock issuable upon conversion of the outstanding 2019 notes, as amended and restated, as of the date of the First Amendment. In March 2014, Deerfield elected to convert the full \$40.0 million of outstanding principal amount of the Tranche 3 notes and \$12.5 million principal amount of the Tranche 1 notes. In April 2014, Deerfield elected to convert the remaining \$7.5 million principal amount of the Tranche 1 notes.

On August 11, 2014, the Company entered into a second amendment to the Facility Agreement to permit the incurrence of additional secured debt under the Sanofi Loan Facility.

Milestone Rights

In connection with the execution of the Facility Agreement, on July 1, 2013, the Company issued Milestone Rights to the Milestone Purchasers. The Milestone Rights provide the Milestone Purchasers certain rights to receive payments of up to \$90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an AFREZZA product in the United States and the achievement of specified net sales figures. The payments due under the Milestone Rights are subject to pro rata reduction in the event of certain funding failures by Deerfield under the Facility Agreement.

The Milestone Agreement includes customary representations and warranties and covenants by the Company, including restrictions on transfers of intellectual property related to AFREZZA. The Milestone Rights are subject to acceleration in the event the Company transfers its intellectual property related to AFREZZA in violation of the terms of the Milestone Agreement.

The Milestone Rights were initially recorded as a short-term liability equal to \$3.2 million included in accrued expenses and other current liabilities in the accompanying condensed consolidated balance sheet and a long-term liability equal to \$13.1 million included in other liabilities. As of September 30, 2014, the first milestone triggering event was achieved following the Company's entry into the Sanofi License Agreement, which resulted in a \$1.9 million incremental charge to interest expense due to the increase in carrying value of the liability to the required \$5.0 million payment, which was paid to Deerfield subsequent to September 30, 2014 pursuant to the terms of the Milestone Agreement. As of September 30, 2014, the short-term portion of the liability had a balance of \$9.2 million and the long-term portion of the liability had a balance of \$8.9 million.

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Commitment Asset

In connection with the issuance of the Tranche 1 notes and the Milestone Rights, the Company recorded a commitment asset (the “Commitment Asset”) on July 1, 2013. As a result of the First Amendment, the Company recorded an additional Tranche B notes commitment asset (the “Tranche B Commitment Asset”) with an estimated fair value equal to \$2.9 million. The Commitment Asset remaining as of September 30, 2014 represented the right to receive up to \$70.0 million of funding remaining under the Facility Agreement, as amended, from the sale of the Tranche B notes. The Commitment Asset is derecognized and recorded as a debt discount on the 2019 notes and Tranche B notes when issued and amortized using the effective interest rate method over the life of the respective notes. Prior to derecognition occurring, the Company monitors the Commitment Asset on an ongoing basis to determine whether an impairment indicator is present that would result in a full or partial write down of the Commitment Asset as a result of events that may lead to the subsequent tranches of notes not being issued. Based on the monitoring procedures performed through September 30, 2014, the Company did not identify any indicators of impairment.

Amendment to the outstanding Tranche 1 notes and Tranche 3 notes

The amendment and restatement of the outstanding Tranche 1 notes and Tranche 3 notes, pursuant to the First Amendment, did not represent a troubled debt restructuring of the 2019 notes because the First Amendment did not result in Deerfield granting a concession to the Company. In addition, the First Amendment did not result in a substantial modification to the terms of the Tranche 1 notes and Tranche 3 notes.

The impact of the First Amendment to the Tranche 1 notes and Tranche 3 notes is being accounted for as a prospective yield adjustment. Specifically, the value of the Tranche B Commitment Asset was considered a fee received from the creditor as consideration for the First Amendment and is being amortized as an adjustment of interest expense over the remaining term of the Tranche 1 notes and Tranche 3 notes using the effective interest method. Further, the value of the Tranche B Commitment Asset, which decreased the amount of debt discount in the Tranche 1 notes and Tranche 3 notes, was allocated between the Tranche 1 notes and Tranche 3 notes in a manner that resulted in the Tranche 1 notes and Tranche 3 notes having a new effective interest rate of 11.63%.

Conversion Option

For accounting purposes, the Company evaluated the embedded conversion option in the 2019 notes as a redemption feature because the number of shares issuable upon conversion was based on the volume weighted average prices for specified periods prior to the conversion date (as opposed to being fixed). Accordingly, conversions by Deerfield were treated as redemptions of the 2019 notes, and, the Company analyzed whether the conversion option required bifurcation as an embedded redemption feature. As of September 30, 2014, Deerfield had converted \$100.0 million of 2019 notes into 18,616,304 shares of the Company’s common stock and no additional principal amount of the 2019 notes is convertible.

12. Income taxes

As required by ASC 740 *Income Taxes* (“ASC 740”), management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets and concluded, in accordance with the applicable accounting standards, that net deferred tax assets should be fully reserved.

ASC 740-10-25 *Income Taxes Recognition* clarifies the accounting and disclosure for uncertainty in tax positions, as defined. This guidance seeks to reduce the diversity in practice associated with certain aspects of the recognition and measurement related to accounting for income taxes. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to this guidance. Tax years since 1993 remain subject to examination by the major tax jurisdictions in which the Company is subject to tax.

13. Fair value of financial instruments

The Company applies various valuation approaches in determining the fair value of its financial assets and liabilities within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company’s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

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Level 1— Quoted prices for identical instruments in active markets.

Level 2— Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3— Significant inputs to the valuation model are unobservable.

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level input that is significant to the overall fair value measurement.

Cash and cash equivalents

Cash equivalents consist of highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase, that are readily convertible into cash. As of September 30, 2014 and December 31, 2013, the Company held \$172.5 million and \$70.8 million, respectively, of cash and cash equivalents, consisting primarily of money market funds of \$169.7 million and \$67.7 million, respectively, and the remaining in non-interest bearing checking accounts. The carrying value approximates the fair value. The fair value of these money market funds was determined by using quoted prices for identical investments in an active market (Level 1 in the fair value hierarchy).

The following is a summary of the carrying values and estimated fair values of the 2015 notes and the facility financing obligation (i.e., the 2019 notes and Tranche B notes) (in millions):

	September 30, 2014		December 31, 2013	
	Carrying value	Estimated fair value	Carrying value	Estimated fair value
2015 notes	\$ 99.1	\$ 113.9	\$ 98.4	\$ 102.2
Facility financing obligation	\$ 72.6	\$ 75.3	\$ 102.3	\$ 107.0

Senior Convertible Notes

The estimated fair value of the 2015 notes was calculated based on model-derived valuations whose inputs were observable, such as the Company's stock price, and non-observable, such as the Company's longer-term historical volatility, which was estimated to be 85% (Level 3 in the fair value hierarchy). As there is no current observable market for the 2015 notes, the Company determined the estimated fair value using a convertible bond valuation model within a lattice framework. The convertible bond valuation model combined expected cash outflows with market-based assumptions regarding risk-adjusted yields, stock price volatility and recent price quotes and trading information regarding Company issued debt instruments and shares of common stock into which the notes are convertible.

Facility Agreement

As discussed in Note 11 — Facility Agreement, in connection with the Facility Agreement, the Company issued 2019 notes and Milestone Rights and recorded the Commitment Asset on July 1, 2013. In addition, on February 28, 2014, the Company entered into the First Amendment, and recorded the Tranche B Commitment Asset, which represented the increase in borrowing capacity that the Company received as consideration for the modifications made to the Facility Agreement and the Tranche 1 notes and Tranche 3 notes. As there is no current observable market for the 2019 notes or Tranche B notes, the Company determined the estimated fair value using a bond valuation model based on a discounted cash flow methodology. The bond valuation model combined expected cash flows associated with principal repayment and interest based on the contractual terms of the debt agreement discounted to present value using a selected market discount rate of 12.7% at December 31, 2013 for the 2019 notes and a selected market discount rate of 11.9% at the inception of the Tranche B notes (Level 3 in the fair value hierarchy). On September 30, 2014, the market discount rate was recalculated at 12.4% for the Tranche 1 notes and the Tranche 4 notes and 11.9% for the Tranche B notes. The Tranche 2 and Tranche 3 notes were fully converted by the end of the first quarter of 2014.

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The estimated fair value of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones discounted to present value using a selected market discount rate (Level 3 in the fair value hierarchy). The expected timing and probability of achieving the milestones, starting in 2014, was developed with consideration given to both internal data, such as progress made to date and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate (17.5%) was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. As of September 30, 2014, the fair value of the Milestone Rights is estimated at \$23.1 million.

The fair value of the Commitment Asset was estimated using the income approach by estimating the fair value of the future tranches using a market debt rate (12.0%) commensurate with the risk of the future tranches and the fair value of the cash expected to be received by the Company and assessing the probability of the commitments being funded in the future based on the operational hurdles required for funding being met (Level 3 in the fair value hierarchy). At September 30, 2014, as Deerfield had purchased all four tranches of 2019 notes in the aggregate principal amount of \$160.0 million, the carrying value of the Commitment Asset was zero.

The fair value of the Tranche B Commitment Asset was estimated using a discounted cash flow analysis under the income approach. Specifically, the fair value was determined by estimating the fair value of the future tranche using a market yield (11.9%) commensurate with the risk of the future tranche and the fair value of the cash expected to be received by the Company and assessing the probability of the commitment being funded in the future based on the operational hurdles required for funding being met as well as consideration of alternative funding options (Level 3 in the fair value hierarchy). As of the date it was recorded, the Tranche B Commitment Asset was valued at \$2.9 million.

On May 6, 2014, Deerfield purchased \$20.0 million aggregate principal amount of Tranche B notes in accordance with the provisions of the Facility Agreement, as amended. Accordingly, the \$1.2 million portion of the Commitment Asset associated with the \$20.0 million purchased was derecognized and recorded as debt discount on the Tranche B notes. Consequently, the remaining carrying value of the Tranche B Commitment Asset was \$1.8 million. As of September 30, 2014, because there have been no material changes to the established estimates, the carrying value of the Tranche B Commitment Asset approximates its respective estimated fair value.

There were no material re-measurements to fair value during the nine months ended September 30, 2014 and 2013 of financial assets and liabilities that are not measured at fair value on a recurring basis. There were no transfers of assets or liabilities between the fair value measurement levels during the nine months ended September 30, 2014 and 2013.

14. Collaboration arrangement

On August 11, 2014, the Company and Sanofi entered into a license and collaboration agreement, which became effective on September 23, 2014. Under the terms of the Sanofi License Agreement, the Company granted to Sanofi exclusive, worldwide licenses to certain of the Company's patents, trademarks and know-how for the development and commercialization of AFREZZA. Under the terms of the Sanofi License Agreement, Sanofi has the exclusive right and responsibility to develop AFREZZA worldwide, subject to certain development activities that will be performed by the Company. Sanofi will also be obligated to use commercially reasonable efforts to file for, obtain and maintain marketing approvals for AFREZZA in certain major markets and countries. In addition, Sanofi will have exclusive, worldwide rights to commercialize AFREZZA and will be obligated to use commercially reasonable efforts to market, promote and commercialize AFREZZA in all countries in the world where regulatory approval for AFREZZA has been received. Pursuant to the terms of a supply agreement that the Company entered into with Sanofi concurrently with the Sanofi License Agreement, the Company will be responsible for the manufacture and supply to Sanofi of its requirements of AFREZZA.

Under the Sanofi License Agreement, Sanofi paid the Company an up-front cash payment of \$150.0 million in the third quarter of 2014. If certain manufacturing, regulatory and sales milestones are achieved, the Company will also be eligible to receive up to \$775.0 million in milestone payments, of which \$75.0 million relates to certain development and manufacturing milestone events, \$50.0 million relates to the filing and completion of regulatory approvals and \$650.0 million relates to the achievement of certain product sales milestones. In addition, worldwide profits and losses, which are determined based on the difference between the net sales of AFREZZA and the costs and expenses incurred by the Company and Sanofi that are specifically attributable or related to the development, improvement, regulatory filings, manufacturing, and commercialization of AFREZZA will be shared 65% by Sanofi and 35% by the Company. In accordance with the terms of the Sanofi License Agreement, profit and loss sharing will commence the first full calendar quarter subsequent to the execution date of the agreement.

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On September 23, 2014, the Company entered into the Sanofi Loan Facility, consisting of a senior secured revolving promissory note (the “Note”) and a guaranty and security agreement (the “Security Agreement”) with an affiliate of Sanofi which provides the Company with a secured loan facility of up to \$175.0 million to fund the Company’s share of net losses under the Sanofi License Agreement.

The obligations of the Company under the Sanofi Loan Facility are guaranteed by the Company’s wholly-owned subsidiary, MannKind LLC, and are secured by a first priority security interest in certain insulin inventory located in the United States and any contractual rights and obligations pursuant to which the Company purchases or has purchased such insulin, and a second priority security interest in the Company’s assets that secure the Company’s obligations under the Facility Agreement, as amended. In addition, the Company agreed to grant to Sanofi, as additional security for the obligations under the Sanofi Loan Facility, a first priority mortgage on the Company’s facility in Valencia, California, by December 22, 2014.

Advances under the Sanofi Loan Facility bear interest at a rate of 8.5% per annum and are payable in-kind and compounded quarterly and added to the outstanding principal balance under the Sanofi Loan Facility. The Company is required to make mandatory prepayments on the outstanding loans under the Sanofi Loan Facility from its share of any Profits (as defined in the Sanofi License Agreement) under the Sanofi License Agreement within 30 days of receipt of its share of any such Profits. No advances may be made under the Sanofi Loan Agreement if Deerfield has commenced enforcement proceedings in connection with an event of default under the Facility Agreement.

The outstanding principal of all loans under the Sanofi Loan Facility, if not prepaid, will become due and payable on September 23, 2024 unless accelerated pursuant to the terms of the Sanofi Loan Facility. Additionally, if the Company sells its Valencia facility, the Company is required to prepay the loans under the Sanofi Loan Facility in an amount equal to 100% of the net cash proceeds of the sale within five business days of receipt.

The Sanofi Loan Facility includes customary representations, warranties and covenants by the Company, including restrictions on its ability to incur additional indebtedness, grant certain liens and make certain changes to its organizational documents. Events of default under the Sanofi Loan Facility include: the Company’s failure to timely make payments due under the Sanofi Loan Facility; inaccuracies in the Company’s representations and warranties to the noteholder; the Company’s failure to comply with any of its covenants under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility, subject to a cure period with respect to most covenants; the Company’s insolvency or the occurrence of certain bankruptcy-related events; termination by Sanofi of the Sanofi License Agreement as a result of the Company’s breach of the Sanofi License Agreement; and the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect. If one or more events of default occurs and is continuing, Sanofi may terminate its obligation to make advances under the Sanofi Loan Facility, and, if certain specified events of default (including the Company’s failure to timely make payments due under the Sanofi Loan Facility; the Company’s failure to comply with the negative covenants under the Sanofi Loan Facility limiting the Company’s ability to incur additional indebtedness or grant certain liens; the Company’s insolvency or the occurrence of certain bankruptcy-related events; termination by Sanofi of the Sanofi License Agreement as a result of the Company’s breach of the non-compete provisions of the Sanofi License Agreement; or the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect) occur and are continuing, the noteholder may accelerate all of the Company’s repayment obligations under the Sanofi Loan Facility and otherwise exercise any of its remedies as a secured creditor. There can be no assurance that the noteholder would not choose to exercise these rights in the event such events were to occur.

The Company analyzed the up-front cash payment of \$150.0 million under the provisions of ASC 605, *Revenue Recognition*, to determine whether the up-front cash payment, or a portion thereof, could be recognized as revenue. ASC 605 provides that revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured. In addition, revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price of each deliverable and the appropriate revenue recognition principles are applied to each unit.

The assessment of multiple element arrangements requires judgment in order to determine the appropriate units of accounting and the points in time that, or periods over which, revenue should be recognized. Under the terms of the Sanofi License Agreement, the Company determined that the arrangement contained significant deliverables including (i) licenses to develop and commercialize AFREZZA and to use the Company’s trademarks, (ii) transfer of know-how, (iii) development activities, and (iv) manufacture and supply services for AFREZZA. Due to the proprietary nature of the manufacturing services being provided by the Company, the Company determined that all of the significant deliverables should be combined into a single unit of accounting. The Company believes that the manufacturing services are proprietary due to the fact that over the past twelve years, the Company has developed proprietary knowledge and patented equipment and tools that are used in the manufacturing process of AFREZZA. Due to the complexities of particle formulation and the specialized knowledge and equipment needed to handle the AFREZZA powder, neither Sanofi nor any third-party contract manufacturing organization currently possesses the capability of manufacturing AFREZZA.

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In order for revenue to be recognized, the seller's price to the buyer must be fixed and determinable and thus not subject to refund or adjustment. Given that as of September 30, 2014, the Company did not have the ability to estimate the amount of costs that would potentially be incurred under the loss share provision related to the Sanofi License Agreement, the Company believes this requirement for revenue recognition is not met.

As such, the Company did not recognize any revenue pursuant to the Sanofi License Agreement for the three months ended September 30, 2014. The Company recorded the \$150.0 million up-front payment as a deferred up-front payment from the Sanofi License Agreement.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in Part II, Item 1A Risk Factors and elsewhere in this quarterly report on Form 10-Q. The preceding interim condensed consolidated financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and related notes for the year ended December 31, 2013 and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K, or the Annual Report. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

OVERVIEW

We are a biopharmaceutical company focused on the discovery and development of therapeutic products for diseases such as diabetes. Our only approved product, AFREZZA, is a rapid-acting inhaled insulin that was approved by the U.S. Food and Drug Administration, or FDA, on June 27, 2014 to improve glycemic control in adult patients with diabetes. On August 11, 2014, we executed a license and collaboration agreement, or the Sanofi License Agreement, with Sanofi-Aventis Deutschland GmbH (which subsequently assigned its rights and obligations under the agreement to sanofi-aventis U.S. LLC, or Sanofi), pursuant to which Sanofi will be responsible for global commercial, regulatory and development activities for AFREZZA. The Sanofi License Agreement became effective on September 23, 2014. We will manufacture AFREZZA at our manufacturing facility in Danbury, Connecticut to supply Sanofi's demand for the product. In addition, the companies are planning to collaborate to expand manufacturing capacity to meet global demand as necessary. In connection with the Sanofi License Agreement, an affiliate of Sanofi provided us with a secured loan facility, or the Sanofi Loan Facility, of up to \$175.0 million to fund our share of net losses under the Sanofi License Agreement.

Under the Sanofi License Agreement, Sanofi paid us an up-front cash payment of \$150.0 million in the third quarter of 2014. As of September 30, 2014, no products or services had been delivered or performed pursuant to the agreement. In addition, the up-front cash payment of \$150.0 million does not represent a fixed fee, as a result of the loss share provision, and because we do not have the ability to estimate the amount of costs that would potentially be incurred related to the Sanofi License Agreement, the amount of up-front cash payment that could be recognized as revenue is not fixed or determinable. Based on these factors, the requirements for revenue recognition had not been met as of September 30, 2014. Accordingly, the entire \$150.0 million up-front payment was recorded on the balance sheet as a liability.

If certain manufacturing, regulatory and sales milestones are achieved we will also be eligible to receive up to \$775.0 million in milestone payments under the Sanofi License Agreement. None of the milestones have been met as of September 30, 2014.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of September 30, 2014, we have incurred a cumulative net loss of \$2.5 billion and have stockholders' deficit of \$40.7 million. To date, we have not generated any product revenues and have funded our operations through the sale of equity securities and convertible debt securities; through our facility agreement, or the Facility Agreement, with Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P., referred to collectively as Deerfield; and through borrowings under our loan arrangement with The Mann Group LLC, or the Loan Arrangement, and through the \$150.0 million up-front payment we received pursuant to the Sanofi License Agreement.

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As of September 30, 2014, we and our marketing partner, Sanofi, have not yet begun to commercialize AFREZZA. We anticipate that commercialization of AFREZZA will commence in the first quarter of 2015. We currently do not have the required approvals to market any of our other product candidates, and we may not receive such approvals. We may not be able to achieve positive cash flow from operations even if we succeed in commercializing our product candidates. We expect to make substantial expenditures and to incur additional operating losses for at least the next several years as we:

- support the launch of AFREZZA through our marketing partner;
- expand our manufacturing capabilities as dictated by the growth in demand for AFREZZA; and
- develop additional applications of our proprietary Technosphere formulation technology for the pulmonary delivery of other drugs.

Our business is subject to significant risks, including but not limited to the risks inherent in our potential inability to support the commercialization of AFREZZA in a timely manner. Additional significant risks also include the results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

RESEARCH AND DEVELOPMENT EXPENSES

To date, our research and development expenses have consisted mainly of costs associated with the clinical trials of our product candidates. This includes the salaries, benefits and stock-based compensation of research and development personnel, raw materials, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees, and depreciation of equipment. Our recent research and development expenses have also included certain commercial readiness costs. We track research and development costs by the type of cost incurred. We partially offset research and development expenses with the recognition of estimated amounts receivable from the State of Connecticut pursuant to a program under which we can exchange qualified research and development income tax credits for cash.

Our research and development staff conducts our internal research and development activities, which include research, product development, clinical development, manufacturing and related activities. This staff is located in our facilities in Valencia, California; Paramus, New Jersey; and Danbury, Connecticut. We expense research and development costs as we incur them.

Clinical development timelines, likelihood of success and total costs vary widely. Prior to the FDA's approval of AFREZZA, we focused on advancing AFREZZA through regulatory approval.

At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product candidates other than AFREZZA, which was recently approved by the FDA, we are unable to estimate with any certainty the costs that we will incur in the continued development of our product candidates.

GENERAL AND ADMINISTRATIVE EXPENSES

Our general and administrative expenses consist primarily of salaries, benefits and stock-based compensation for administrative, finance, business development, human resources, legal and information systems support personnel. In addition, general and administrative expenses include professional service fees and business insurance costs.

CRITICAL ACCOUNTING POLICIES

The preparation of our condensed consolidated financial statements in conformity with generally accepted accounting principles in the United States, or GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes to the financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. A summary of our critical accounting policies is presented in Item 7 of our Annual Report for the year ended December 31, 2013. There has been one material change to our critical accounting policies during the three and nine months ended September 30, 2014.

License and collaboration agreements

Pursuant to the Sanofi License Agreement, we granted to Sanofi exclusive, worldwide licenses to certain of our patents, trademarks and know-how for the development and commercialization of AFREZZA. The terms of the Sanofi License Agreement provide for consideration to us in the form of a non-refundable up-front payment, manufacturing, regulatory and sales milestone payments and profit and loss sharing.

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We analyze consideration received under the provisions of ASC 605, Revenue Recognition, to determine whether the consideration, or a portion thereof, could be recognized as revenue. ASC 605 provides that revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured.

In arrangements involving the delivery of more than one element, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has “stand-alone value” to the customer. The arrangement’s consideration that is fixed and determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price and (iii) best estimate of selling price (BESP). The BESP reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables.

The assessment of multiple element arrangements requires judgment in order to determine the appropriate units of accounting and the points in time that, or periods over which, revenue should be recognized. Given that, as of September 30, 2014, we did not have the ability to estimate the amount of costs that would potentially be incurred under the loss share provision related to the Sanofi License Agreement, we believe the fixed and determinable fee requirement for revenue recognition was not met.

Recently Issued Accounting Standards — In July 2013, the FASB issued ASU 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force)*. The amendments in this ASU provide guidance on the financial statements presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in this ASU do not require new recurring disclosures. The amendments in this ASU are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of the new requirement did not have a significant impact on our consolidated financial statements.

In May 2014, a new standard was issued related to revenue recognition, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The new standard will replace most of the existing revenue recognition standards in U.S. GAAP when it becomes effective on January 1, 2017. Early adoption is not permitted. The new standard allows for either “full retrospective” adoption, whereby the new standard is applied to each prior reporting period presented or “modified retrospective” adoption, whereby the new standard is only applied to the most current period presented with the cumulative effect of the change recognized at the date of the initial application. We are assessing the potential impact of the new standard on its consolidated statements of financial position and results of operations and comprehensive income (loss) and has not yet selected a transition method.

In June 2014, the FASB issued ASU No. 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The amendments in this ASU remove all incremental financial reporting requirements from GAAP for development stage entities, including the removal of Topic 915, *Development Stage Entities*, from the FASB Accounting Standards Codification. In addition, the ASU: (a) adds an example disclosure in Topic 275, *Risks and Uncertainties*, to illustrate one way that an entity that has not begun planned principal operations could provide information about the risks and uncertainties related to the company’s current activities; and (b) removes an exception provided to development stage entities in Topic 810, *Consolidation*, for determining whether an entity is a variable interest entity. The presentation and disclosure requirements in Topic 915 will no longer be required for the first annual period beginning after December 15, 2014. The revised consolidation standards are effective one year later, in annual periods beginning after December 15, 2015. Early adoption is permitted. We are evaluating the impact the adoption of ASU 2014-10 will have on our consolidated financial statements.

On August 27, 2014, the FASB issued ASU 2014-15, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date of issuance of the entity’s financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is “substantial doubt about the entity’s ability to continue as a going concern.” The ASU is effective for annual periods ending after December 15, 2016, and interim periods thereafter; early adoption is permitted. We are evaluating the impact the adoption of ASU 2014-15 will have on its consolidated financial statements.

RESULTS OF OPERATIONS**Three and nine months ended September 30, 2014 and 2013****Revenue**

We did not recognize any revenue for the nine months ended September 30, 2014 or 2013. We do not anticipate sales of any product prior to the commercialization of AFREZZA.

Research and Development Expenses

The following table provides a comparison of the research and development expense categories for the three and nine months ended September 30, 2014 and 2013 (dollars in thousands):

	Three months ended September 30,		\$ Change	% Change
	2014	2013		
Clinical	\$ 6,255	\$ 8,249	\$ (1,994)	(24%)
Manufacturing	13,167	10,240	2,927	29%
Research	1,349	1,601	(252)	(16%)
Research and development tax credit	(600)	(51)	(549)	1076%
Stock-based compensation expense	(993)	7,242	(8,235)	(114%)
Research and development expenses	<u>\$19,178</u>	<u>\$27,281</u>	<u>\$ (8,103)</u>	(30%)
	Nine months ended September 30,			
	2014	2013	\$ Change	% Change
Clinical	\$22,170	\$32,509	\$(10,339)	(32%)
Manufacturing	35,017	29,354	5,663	19%
Research	4,608	4,690	(82)	(2%)
Research and development tax credit	(766)	(207)	(559)	270%
Stock-based compensation expense	21,655	14,385	7,270	51%
Research and development expenses	<u>\$82,684</u>	<u>\$80,731</u>	<u>\$ 1,953</u>	2%

The decrease in research and development expenses of \$8.1 million for the three months ended September 30, 2014 compared to the three months ended September 30, 2013 was primarily due to decreased stock-based compensation expense of \$8.2 million resulting from a credit of \$5.5 million for the settlement value of modified performance awards and an overall decrease in stock-based compensation expense of \$2.7 million related to performance milestones that were substantially recorded in 2013 but were achieved and settled in 2014.

Overall research and development expenses for the nine months ended September 30, 2014 increased by \$2.0 million compared to the nine months ended September 30, 2013 primarily due to increased stock-based compensation expense of \$7.3 million and increased spending on commercial readiness of \$5.7 million partially offset by decreased clinical expenses of \$10.3 million with the completion of two Phase 3 clinical studies of AFREZZA in 2013. The net effect of \$10.4 million in increased stock-based compensation expense resulted from the modification and subsequent settlement value of performance awards which was partially offset by an overall decrease in stock-based compensation of \$3.1 million. Manufacturing spending increased \$5.7 million due to development supply purchases and increased headcount in preparation for commercialization offset by decreased clinical expenses of \$10.3 million as a result of the completion of two Phase 3 studies in 2013.

We anticipate our overall research and development expenses will increase in 2014 compared to 2013 due to the ongoing preparation for the commercialization of AFREZZA and increased stock compensation expense.

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General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the three and nine months ended September 30, 2014 and 2013 (dollars in thousands):

	Three months ended September 30,		\$ Change	% Change
	2014	2013		
Salaries and employee related expenses	\$ 4,552	\$ 4,028	\$ 524	13%
Professional fees and other general expenses	18,370	4,752	13,618	287%
Stock-based compensation expense	(3,834)	8,701	(12,535)	(144%)
General and administrative expenses	<u>\$19,088</u>	<u>\$17,481</u>	<u>\$ 1,607</u>	9%

	Nine months ended September 30,		\$ Change	% Change
	2014	2013		
Salaries and employee related expenses	\$13,221	\$11,763	\$ 1,458	12%
Professional fees and other general expenses	28,519	13,371	15,148	113%
Stock-based compensation expense	25,100	16,919	8,181	48%
General and administrative expenses	<u>\$66,840</u>	<u>\$42,053</u>	<u>\$ 24,787</u>	59%

The increase in general and administrative expenses of \$1.6 million for the three months ended September 30, 2014 compared to the three months ended September 30, 2013 was primarily due to increased professional fees of \$13.6 million associated with the closing of the Sanofi License Agreement offset by a decrease in stock compensation expense of \$12.5 million resulting from a credit of \$7.4 million for the settlement value of modified performance awards and an overall decrease in stock-based compensation expense of \$5.1 million related to performance milestones that were substantially recorded in 2013 but were achieved and settled in 2014.

General and administrative expenses for the nine months ended September 30, 2014 increased by \$24.8 million compared to the nine months ended September 30, 2013 primarily due to an \$8.2 million increase in stock-based compensation resulting from the net effect of \$12.6 million in increased stock-based compensation expense due to the modification and subsequent settlement value of performance awards, partially offset by an overall decrease in stock-based compensation of \$4.4 million, increased professional fees of \$13.6 million associated with the Sanofi License Agreement, and an increase of \$1.5 million in professional fees related to financing transactions and associated filings.

General and administrative expenses overall will be higher in 2014 as compared to 2013 as a result of increased stock compensation expense due to milestone achievements and the modification and re-measurement of performance shares in the third quarter of 2014.

Other Income (Expense)

Other income increased by \$7.9 million for the three months ended September 30, 2014 compared to the three months ended September 30, 2013 and by \$1.6 million for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013. The increase for the three months ended September 30, 2014 was due to \$7.9 million of other income, net of expenses, associated with the sale of intellectual property in the third quarter. The increase for the nine months ended September 30, 2014 was due to income associated with the sale of intellectual property related to oncology in the third quarter, partially offset by the \$6.4 million loss on the conversion of Deerfield debt into equity.

Interest Income and Expense

Interest expense increased by \$0.1 million for the three months ended September 30, 2014 compared to the three months ended September 30, 2013 and decreased by \$1.1 million for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013. The decrease for the nine months ended September 30, 2014 was primarily due to a decrease of \$3.0 million in interest expense on the Loan Arrangement with The Mann Group due to a lower carrying value in 2014, partially offset by incremental interest expense of \$1.9 million resulting from the achievement and re-measurement of the first milestone under the Milestone Rights Purchase Agreement dated July 1, 2013, or the Milestone Agreement, by and between us and Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL, referred to collectively as the Milestone Purchasers, in the third quarter.

LIQUIDITY AND CAPITAL RESOURCES

To date, we have funded our operations through the sale of equity securities and convertible debt securities, borrowings under the Loan Arrangement with The Mann Group and the Facility Agreement with Deerfield.

As of September 30, 2014, the total principal amount outstanding under the Loan Arrangement was \$49.5 million, and the amount available for future borrowings was \$30.1 million. We anticipate using a portion of these available borrowings to capitalize accrued interest into principal, upon mutual agreement of the parties, as it becomes due and payable under the Loan Arrangement.

On July 1, 2013, we entered into the Facility Agreement with Deerfield providing for the sale of up to \$160.0 million of 9.75% Senior Convertible Notes due 2019, or the 2019 notes, in four equal tranches of \$40.0 million principal amount.

As of September 30, 2014, Deerfield had purchased all four tranches of 2019 notes in the aggregate principal amount of \$160.0 million.

On February 28, 2014, we amended the Facility Agreement to provide for the issuance of an additional tranche of notes, or the Tranche B notes, to Deerfield. Pursuant to the terms of the amendment, prior to December 30, 2014, we may issue to Deerfield up to \$90.0 million aggregate principal amount of Tranche B notes, subject to the satisfaction of certain conditions, \$20.0 million of which had been issued as of September 30, 2014. As of September 30, 2014, the Tranche B notes bear interest at the rate of 8.75% per year on the outstanding principal amount, payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. The Tranche B notes initially accrued interest at the rate of 9.75% per year on the outstanding principal amount, subject to reduction to 8.75% if we entered into a collaboration with a third party to commercialize AFREZZA. Pursuant to the terms of the amendment, the interest rate was subsequently reduced to 8.75% on September 23, 2014 following completion of the U.S. Federal Trade Commission's review of the transaction under the Hart-Scott-Rodino Act and the completion of documentation related to the \$175.0 million secured loan facility being provided to MannKind. The amended Facility Agreement also provided Deerfield with the option, subject to certain limitations, to convert up to an additional \$60.0 million of the 2019 notes issued and outstanding on the date of the amendment into shares of our common stock following the effective date of the amendment.

On April 2, 2014, Deerfield elected to convert an aggregate of \$7.5 million of principal amount of the outstanding first tranche of the 2019 notes, or the Tranche 1 notes, pursuant to which we issued Deerfield 1,500,000 shares of our common stock. As a result of this election, Deerfield has fully exercised the conversion option under the Facility Agreement, as amended, by converting \$20.0 million of the Tranche 1 notes and the full \$40.0 million of the outstanding third tranche of the 2019 notes, or the Tranche 3 notes, allowable into 10,763,829 shares of our common stock in the aggregate.

In connection with the execution of the Facility Agreement, on July 1, 2013, we issued Milestone Rights to the Milestone Purchasers. The Milestone Rights provide the Milestone Purchasers certain rights to receive payments of up to \$90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an AFREZZA product and the achievement of specified net sales figures. The payments due under the Milestone Rights are subject to pro rata reduction in the event of certain funding failures by Deerfield under the Facility Agreement.

As of September 30, 2014, the first milestone triggering event was achieved following our entry into the Sanofi License Agreement. Subsequent to September 30, 2014, in connection with the milestone triggering event, we paid a \$5.0 million payment to Deerfield pursuant to the terms of the Milestone Agreement.

In March 2014, we entered into an At-The-Market Issuance Sales Agreement with MLV & Co. LLC, or MLV, and an At-The-Market Issuance Sales Agreement with Meyers Associates, L.P. (doing business as Brinson Patrick, a division of Meyers Associates, L.P.), or Brinson Patrick. We refer to the foregoing agreements as the "ATM Agreements." Under each ATM Agreement, we may issue or sell shares of our common stock having an aggregate offering price of up to \$50.0 million from time to time through MLV or Brinson Patrick, as our sales agents, provided in no event may we sell more than \$50.0 million of common stock under both agreements in the aggregate. We expect that all or substantially all sales of our common stock made under the ATM Agreements will be made in "at the market" offerings as defined in Rule 415 of the Securities Act of 1933, as amended. We have not yet sold or issued any shares of our common stock under the ATM Agreements. There can be no assurance that we will be able to access capital through the ATM Agreements on a timely basis, or at all.

On August 11, 2014, we and Sanofi executed the Sanofi License Agreement, which subsequently became effective on September 23, 2014. Pursuant to the Sanofi License Agreement, we received a \$150.0 million up-front fee and may earn potential payments of up to an aggregate of \$775.0 million upon the achievement of certain development, manufacturing, regulatory and sales milestones. Worldwide profits and losses will be shared 65% by Sanofi and 35% by us. Pursuant to a separate supply agreement, we will manufacture AFREZZA at our manufacturing facility in Danbury, Connecticut to supply Sanofi's demand for the product.

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In addition, an affiliate of Sanofi has provided us with a secured loan facility of up to \$175.0 million to fund our share of net losses under the Sanofi License Agreement. On August 11, 2014, we entered into a second amendment to the Facility Agreement to permit the incurrence of additional debt under the Sanofi Loan Facility. Advances under the Sanofi Loan Facility will bear interest at a rate of 8.5% per year and will be payable-in-kind and compounded quarterly. We will be required to make mandatory prepayments on any outstanding loans under the Sanofi Loan Facility from our share of any profits under the Sanofi License Agreement. We have not yet incurred any indebtedness under the Sanofi Loan Facility.

During the nine months ended September 30, 2014, our operations provided \$39.8 million of cash, and we had a net loss of \$161.9 million, which included \$62.3 million of non-cash charges consisting of depreciation and accretion, and stock-based compensation. By comparison, during the nine months ended September 30, 2013, we used \$94.7 million of cash for our operations and had a net loss of \$137.9 million, which included \$41.4 million of non-cash charges consisting of depreciation and accretion, and stock-based compensation. The operating cash outflow decreased by \$134.5 million primarily due to the \$150.0 million deferred up-front payment recorded from the up-front fee associated with the Sanofi License Agreement being partially offset by the \$15.0 million deposit to Amphastar as prepayment for 2015 quantities of insulin as part of the Supply Agreement. Going forward, we expect our operating cash flow to be negative at least until we achieve commercialization of AFREZZA.

We used \$9.9 million of cash for investing activities during the nine months ended September 30, 2014, compared to \$1.8 million for the nine months ended September 30, 2013. The \$8.1 million increase was primarily due to \$19.1 million in purchases of machinery and equipment for the preparation for commercialization of AFREZZA, offset by \$9.3 million proceeds from the sale of intellectual property.

Our financing activities provided \$71.7 million of cash for the nine months ended September 30, 2014, compared to \$128.5 million for the nine months ended September 30, 2013. Cash provided by financing activities during the nine months ended September 30, 2014 was comprised of \$40.0 million in proceeds received from the issuance of the fourth tranche of 2019 notes to Deerfield, \$20.0 million from the sale of Tranche B notes to Deerfield, \$27.8 million from warrant exercises, and \$10.1 million from the exercise of stock options, which were partially offset by \$26.8 million paid for employment taxes related to vested restricted stock units. For the nine months ended September 30, 2013, cash provided by financing activities was primarily comprised of \$79.5 million from the sale of the first two tranches under the Facility Agreement with Deerfield and \$49.2 million in warrant exercises.

As of September 30, 2014, we had \$172.5 million in cash and cash equivalents. Based upon our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital requirements for at least the next 12 months. We may need to raise additional capital in the future, whether through the sale of equity or debt securities, additional strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to support our ongoing activities related to the commercialization of AFREZZA and the development of other product candidates. However, we cannot provide assurances that such additional capital, if needed, will be available through these or other means.

We intend to use our capital resources to support the commercialization of AFREZZA. We are expending a portion of our capital resources to scale up our manufacturing capabilities in our Danbury facilities and to develop our other product candidates. We also intend to use our capital resources for general corporate purposes.

If we enter into strategic business collaborations with respect to our other product candidates, we would expect, as part of the transaction, to receive additional capital. In addition, we expect to pursue the sale of equity and/or debt securities, including sales of our common stock through the ATM Agreements, or the establishment of other funding facilities. Issuances of debt or additional equity could impact the rights of our existing stockholders, dilute the ownership percentages of our existing stockholders and may impose restrictions on our operations. These restrictions could include limitations on additional borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing, sale or divestiture of certain intellectual property and other assets, including our Technosphere technology platform. There can be no assurance, however, that any strategic collaboration, sale of securities or sale or license of assets will be available to us on a timely basis or on acceptable terms, if at all. If we are unable to raise additional capital, we may be required to enter into agreements with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such agreements may not be on terms as commercially favorable to us.

We cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. If planned operating results are not achieved or we are not successful in raising additional capital, if needed, through equity or debt financing or entering business collaborations, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration, and there could be substantial doubt about our ability to continue as a going concern.

Contractual Obligations and Commitments

As of September 30, 2014, in addition to the obligations and commitments disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operation contained in our Annual Report, we incurred additional contractual obligations pursuant to our issuance of \$20.0 million aggregate principal amount of Tranche B notes in accordance with the provisions of the Facility Agreement, as amended, to Deerfield on May 6, 2014; the issuance of the fourth tranche of \$40.0 million aggregate principal amount of 2019 notes to Deerfield on July 28, 2014; the entry into our supply agreement with Amphastar France Pharmaceuticals S.A.S., or Amphastar, on July 31, 2014, which contains annual minimum purchase obligations of an aggregate of approximately €120.1 million in calendar years 2015 through 2019; the entry into the Sanofi License Agreement, under which we are responsible for 35% of worldwide losses with respect to AFREZZA; and additional contractual obligations pursuant to the Sanofi Loan Facility.

Off-Balance Sheet Arrangements

As of September 30, 2014, we did not have any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Due to the fixed interest rates of our debt, we do not currently have any exposure to changes in our interest expense as a result of changes in interest rates. The interest rate on amounts borrowed under our loan arrangement with The Mann Group for the year ended December 31, 2013 and the nine months ended September 30, 2014 was a fixed rate equal to 5.84%. As of December 31, 2013, the total principal amount outstanding under the Loan Arrangement was \$49.5 million. We also have debt related to our 5.75% Senior Convertible Notes due 2015, or the 2015 notes, at a fixed interest rate of 5.75%, debt related to the 2019 notes at a fixed interest rate of 9.75% and debt related to the Tranche B notes at a fixed interest rate of 8.75%. In addition, any advances under the Sanofi Loan Facility will bear interest at a rate of 8.5%.

Our current policy requires us to maintain a highly liquid short-term investment portfolio consisting mainly of U.S. money market funds and investment-grade corporate, government and municipal debt. None of these investments are entered into for trading purposes. Our cash is deposited in and invested through highly rated financial institutions in North America.

If a change in interest rates equal to 10% of the interest rates on September 30, 2014 were to have occurred, this change would not have had a material effect on the value of our short-term investment portfolio or on our interest expense obligations with respect to outstanding borrowed amounts.

Foreign Currency Exchange Risk

We will incur significant expenses, including for insulin supply purchases, outside the United States based on contractual obligations denominated in the euro. At the end of each reporting period, these liabilities are converted to U.S. dollars at the then-applicable foreign exchange rate. As a result, our business is affected by fluctuations in exchange rates between the U.S. dollar and foreign currencies. We have not entered into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks, but may enter into foreign currency hedging transactions in the future. Exchange rate fluctuations may adversely affect our expenses, results of operations, financial position and cash flows. If a minimum quarterly supply purchase under our supply agreement with Amphastar and if a movement of 10% in the U.S. dollar to euro exchange rate were to have occurred on September 30, 2014, this movement would not have had a material effect on our results of operations or financial condition.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of September 30, 2014. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

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Management determined that, as of September 30, 2014, there were no changes in our internal control over financial reporting that occurred during the fiscal quarter then ended 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

None.

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this quarterly report on Form 10-Q before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this quarterly report. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. The risk factors set forth below with an asterisk () next to the title contain changes to the description of the risk factors previously disclosed in Item 1A to our Annual Report. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.*

RISKS RELATED TO OUR BUSINESS

We depend heavily on the successful commercialization of our only approved product, AFREZZA.*

To date, we have not commercialized any products. We have expended significant time, money and effort in the development of our only approved product, AFREZZA. We anticipate that in the near term, our ability to generate revenues will depend on the successful commercialization of AFREZZA in the United States, which we have not yet begun to commercialize. On August 11, 2014, we executed the Sanofi License Agreement, which became effective on September 23, 2014. Pursuant to the Sanofi License Agreement, Sanofi will be responsible for global commercial, regulatory and development activities for AFREZZA. We will manufacture AFREZZA at our manufacturing facility in Danbury, Connecticut to supply Sanofi's demand for the product. In addition, the companies are planning to collaborate to expand manufacturing capacity to meet global demand as necessary. We must receive the necessary approvals from foreign regulatory agencies before AFREZZA can be marketed outside of the United States.

Even with regulatory approval, we and our marketing partner, Sanofi, ultimately may be unable to gain market acceptance of AFREZZA for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, the availability of alternative treatments and lack of coverage or adequate reimbursement. If we fail to commercialize AFREZZA successfully, our business, financial condition and results of operations will be materially and adversely affected.

We have sought to develop our other product candidates through our internal research programs. Our product candidates are generally in early clinical or preclinical development. All of our product candidates will require additional research and development and, in some cases, significant preclinical, clinical and other testing prior to seeking regulatory approval to market them. Accordingly, these product candidates will not be commercially available for a number of years, if at all.

A significant portion of the research that we have conducted involves new compounds and technologies, including our Technosphere platform technology. Even if our research programs identify product candidates that initially show promise, these candidates may fail to progress to clinical development for any number of reasons, including discovery upon further research that these candidates have adverse effects or other characteristics that indicate they are unlikely to be effective. In addition, the clinical results we obtain at one stage are not necessarily indicative of future testing results. If we fail to successfully commercialize AFREZZA or develop our other product candidates, or if we are significantly delayed in doing so, our business and results of operations will be harmed and the value of our stock could decline.

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We are dependent on our collaboration with Sanofi to further develop and to commercialize AFREZZA worldwide. This collaboration may place the development and commercialization largely outside our control, and poor performance under or failure to maintain the collaboration agreement between us and Sanofi could have a material and adverse impact on our business.*

We have entered into the Sanofi License Agreement to provide for the future development and commercialization of AFREZZA. We cannot be certain that our collaboration with Sanofi will continue for as long as there is a potential market for AFREZZA. Both we and Sanofi have certain rights to terminate the collaboration agreement, in certain circumstances, including a right by Sanofi to terminate the agreement upon specified prior written notice. If the agreement is terminated prior to the end of the commercial life of AFREZZA, we may not be able to find another collaborator for the development and commercialization of AFREZZA, and even if we elected to pursue further development and commercialization of AFREZZA on our own, we might not be able to do so successfully and would experience substantially increased capital requirements that we might not be able to fund. Our dependence on Sanofi and the Sanofi License Agreement will subject us to a number of risks, including:

- Sanofi may not perform as expected and we may not be able to control the amount and timing of resources that Sanofi may devote to the development or commercialization of AFREZZA;
- we and Sanofi could disagree as to development plans and Sanofi may delay clinical trials or stop a clinical trial;
- there may be disputes between us and Sanofi, including disagreements regarding the Sanofi License Agreement, that may result in (a) the delay of (or prevent entirely) the achievement of regulatory and commercial objectives that would result in milestone payments, (b) the delay or termination of the development or commercialization of AFREZZA, and/or (c) costly litigation or arbitration that diverts our management's attention and resources;
- Sanofi may not comply with applicable regulatory guidelines with respect to the development or commercialization of AFREZZA, which could adversely impact the development of or sales of AFREZZA and could result in administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizures or detention, product recalls, total or partial suspension of production and refusal to approve any new drug applications;
- Sanofi may not provide us with timely and accurate information regarding sales activities and supply forecasts, which could adversely impact our ability to comply with our manufacturing and supply obligations under our supply agreement with Sanofi and our and Sanofi's ability to launch and commercialize AFREZZA;
- Sanofi may experience financial difficulties;
- business combinations or significant changes in Sanofi's business strategy may also adversely affect Sanofi's ability to perform its obligations under the Sanofi License Agreement;
- Sanofi may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation; and
- notwithstanding the non-competition requirements in the Sanofi License Agreement, Sanofi could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

Any failure of Sanofi to adequately perform its obligations under the Sanofi License Agreement or the termination of such agreement could have a material and adverse impact on our business.

We have a history of operating losses, we expect to continue to incur losses and we may never generate positive cash flow from operations.*

Although we had a positive cash flow from operations during the nine months ended September 30, 2014, due to the \$150.0 million up-front payment received from Sanofi, we expect negative cash flows from operations for the full year. We have never been profitable or generated positive cash flow from cumulative operations to date and, as of September 30, 2014, we had incurred a cumulative net loss of \$2.5 billion. The cumulative net loss has resulted principally from costs incurred in our research and development programs, the write-off of goodwill and general operating expenses. We expect to make substantial expenditures and to incur increasing operating losses in the future in order to support the commercialization of AFREZZA, including costs and expenses to manufacture AFREZZA on a commercial scale. In addition, we have agreed to purchase annual minimum quantities of insulin under our supply agreement with Amphastar of an aggregate of approximately €120.1 million in calendar years 2015 through 2019. We may not have the necessary capital resources on hand in order to service this contractual commitment, and we may become obligated to make additional payments under the supply agreement in the event of its termination under certain scenarios. Our cumulative net loss may therefore increase significantly. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. As of September 30, 2014, we had stockholders' deficit of \$40.7 million. Our ability to achieve and sustain positive cash flow from operations and profitability depends upon successfully commercializing AFREZZA in collaboration with our marketing partner. We may not generate positive cash flow from operations or be profitable even if we succeed in commercializing any of our product candidates. As a result, we cannot be sure when we will generate positive cash flow from operations or become profitable, if at all.

In the future we may need to raise additional capital to fund our operations.*

In the future, we may need to raise additional capital, whether through the sale of equity or debt securities, additional strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to support our ongoing activities related to the commercialization of AFREZZA and the development of other product candidates. It may be difficult for us to raise additional funds on favorable terms, or at all. As of September 30, 2014, we had stockholders' deficit of \$40.7 million, which may raise concerns about our solvency and affect our ability to raise additional capital. The extent of our additional funding requirements will depend on a number of factors, including:

- the election of any or all of the holders of the 2015 notes or the 2019 notes to require us to repay or repurchase such notes if and when required;
- our ability to refinance existing indebtedness, including indebtedness under the 2015 notes which mature in August 2015;
- the extent to which the 2015 notes are converted into shares of our common stock;
- the rate of progress and costs of our clinical studies and research and development activities;
- the costs of procuring raw materials and operating our manufacturing facilities;
- our obligation to make milestone payments pursuant to the milestone rights issued to the Milestone Purchasers pursuant to the Milestone Agreement;
- our obligation to bear our share of net losses under the Sanofi License Agreement;
- our success in establishing strategic business collaborations or other sales or licensing of assets, and the timing and amount of any payments we might receive from any such transactions;
- the degree of success in commercializing AFREZZA;
- actions taken by the FDA and other regulatory authorities affecting AFREZZA and our product candidates and competitive products;
- the costs of preparing applications for regulatory approvals for our product candidates, either ourselves or with any commercialization partner;
- the emergence of competing technologies and products and other market developments;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others;
- the level of our legal and litigation expenses; and
- the costs of discontinuing projects and technologies, and/or decommissioning existing facilities, if we undertake any such activities.

We have raised capital in the past through the sale of equity and debt securities. We may in the future pursue the sale of additional equity and/or debt securities, including sales of our common stock through the ATM Agreements, or the establishment of other funding facilities including asset-based borrowings. There can be no assurances, however, that we will be able to raise additional capital on acceptable terms, or at all. Issuances of additional debt or equity securities or the conversion of any of our currently outstanding convertible debt securities into shares of our common stock or the exercise of our currently outstanding warrants for shares of our common stock could impact the rights of the holders of our common stock and may dilute their ownership percentage. Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets. We cannot offer assurances, however, that any strategic collaborations, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case.

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In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration. As of the date hereof, we have not obtained a solvency opinion or otherwise conducted a valuation of our properties to determine whether our debts exceed the fair value of our property within the meaning of applicable solvency laws. If we are or become insolvent, investors in our stock may lose the entire value of their investment.

We do not anticipate generating operating cash flow prior to commercial launch of AFREZZA, and therefore cannot provide assurances that changed or unexpected circumstances, including, among other things, delays in manufacturing on a commercial scale, will not result in the depletion of our capital resources more rapidly than we currently anticipate, in which case we may be required to raise additional capital. There can be no assurances that we will be able to raise additional capital, if needed, on favorable terms, or at all. If we need but cannot raise adequate additional capital in the future we will be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration, and there may be substantial doubt about our ability to continue as a going concern.

We have a substantial amount of debt pursuant to our 2015 notes, 2019 notes and Tranche B notes, may incur additional indebtedness under the Sanofi Loan Facility and may be unable to make required payments of interest and principal as they become due.*

As of September 30, 2014, we had \$180.0 million of outstanding debt pursuant to our 2015 notes and 2019 notes, consisting of:

- \$100.0 million principal amount of 2015 notes bearing interest at 5.75% per annum and maturing on August 15, 2015;
- \$60.0 million principal amount of 2019 notes bearing interest at 9.75% per annum and maturing between 2016 and December 31, 2019; and
- \$20.0 million principal amount of Tranche B notes bearing interest at 8.75% per annum and maturing between 2017 and December 31, 2019.

Prior to December 30, 2014, we may request that Deerfield purchase up to \$70.0 million principal amount of additional Tranche B notes under the Facility Agreement. In addition, an affiliate of Sanofi has provided the Sanofi Loan Facility to us, the proceeds of which will be used by us to fund our share of net losses under the Sanofi License Agreement.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the 2015 notes, 2019 notes or Tranche B notes when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2015 notes, or certain Major Transactions as defined in the Facility Agreement in respect of the 2019 notes and the Tranche B notes, the holders of the respective notes will have the option to require us to repurchase all or any portion of such notes at a repurchase price of 100% of the principal amount of such notes to be repurchased plus accrued and unpaid interest, if any. The 2015 notes bear interest at the rate of 5.75% per year on the outstanding principal amount, payable in cash semiannually in arrears on February 15 and August 15 of each year, and the 2019 notes bear interest at the rate of 9.75% per year on the outstanding principal amount, payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. The Tranche B notes bear interest at the rate of 8.75% on the outstanding principal amount, payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. Loans under the Sanofi Loan Facility will bear interest at a rate of 8.5% per annum, paid-in-kind on a quarterly basis (2.06% per quarter compounded). While we have been able to timely make our required interest payments to date, we cannot guarantee that we will be able to do so in the future. If we fail to pay interest on the 2015 notes, 2019 notes, Tranche B notes, or on the loans under the Sanofi Loan Facility, or if we fail to repay or repurchase the 2015 notes, 2019 notes, Tranche B notes, or the loans under the Sanofi Loan Facility when required, we will be in default under the indenture or other applicable instrument for such note(s) or loans, and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the note holders initiating bankruptcy proceedings or causing us to cease operations altogether.

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The agreements governing our indebtedness contain covenants that we may not be able to meet and place restrictions on our operating and financial flexibility.*

Our indebtedness under the Facility Agreement, including any indebtedness under the 2019 notes and the Tranche B notes and any additional indebtedness we incur as the result of our sale of additional Tranche B notes, is secured by substantially all of our assets, including our intellectual property, accounts receivables, equipment, general intangibles, inventory (excluding the insulin inventory) and investment property, and all of the proceeds and products of the foregoing. Our obligations under the Facility Agreement and the Milestone Agreement are also secured by a certain mortgage on our facility in Danbury, Connecticut. Our obligations under the Sanofi Loan Facility are secured by a first priority mortgage on our facility in Valencia, California, a first priority security interest in certain insulin inventory located in the United States and any contractual rights and obligations pursuant to which we purchase or have purchased such insulin, and a second priority security interest in our assets that secure our obligations under the Facility Agreement.

The Facility Agreement includes customary representations, warranties and covenants by us, including restrictions on our ability to incur additional indebtedness, grant certain liens, engage in certain mergers and acquisitions, make certain distributions and make certain voluntary prepayments. Events of default under the Facility Agreement include: our failure to timely make payments due under the 2019 notes or the Tranche B notes; inaccuracies in our representations and warranties to Deerfield; our failure to comply with any of our covenants under any of the Facility Agreement, Milestone Agreement or certain other related security agreements and documents entered into in connection with the Facility Agreement, subject to a cure period with respect to most covenants; our insolvency or the occurrence of certain bankruptcy-related events; certain judgments against us; the suspension, cancellation or revocation of governmental authorizations that are reasonably expected to have a material adverse effect on our business; the acceleration of a specified amount of our indebtedness; our cash and cash equivalents, including amounts available to us under our loan arrangement with The Mann Group, falling below \$25.0 million as of the last day of any fiscal quarter. If one or more events of default under the Facility Agreement occurs and continues beyond any applicable cure period, the holders of the 2019 notes and Tranche B notes may declare all or any portion of the 2019 notes and Tranche B notes to be immediately due and payable. The Milestone Agreement includes customary representations and warranties and covenants by us, including restrictions on transfers of intellectual property related to AFREZZA. The milestones are subject to acceleration in the event we transfer our intellectual property related to AFREZZA in violation of the terms of the Milestone Agreement. Similarly, the Sanofi Loan Facility includes customary representations, warranties and covenants by us, including restrictions on our ability to incur additional indebtedness, grant certain liens and make certain changes to our organizational documents. Events of default under the Sanofi Loan Facility include: our failure to make timely payments due under the Sanofi Loan Facility; inaccuracies in our representations and warranties to the noteholder; our failure to comply with any of our covenants under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility, subject to a cure period with respect to most covenants; our insolvency or the occurrence of certain bankruptcy-related events; termination by Sanofi of the Sanofi License Agreement as a result of our breach of the Sanofi License Agreement; and the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect. If one or more events of default occurs and is continuing, the noteholder may terminate its obligation to make advances under the Sanofi Loan Facility, and, if certain specified events of default (including our failure to timely make payments due under the Sanofi Loan Facility; our failure to comply with the negative covenants under the Sanofi Loan Facility limiting our ability to incur additional indebtedness or grant certain liens; our insolvency or the occurrence of certain bankruptcy-related events; termination by Sanofi of the Sanofi License Agreement as a result of our breach of the non-compete provisions of the Sanofi License Agreement; or the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect) occur and are continuing, the noteholder may accelerate all of our repayment obligations under the Sanofi Loan Facility and otherwise exercise any of its remedies as a secured creditor.

There can be no assurance that we will be able to comply with the covenants under any of the foregoing agreements, and we cannot predict whether the holders of the 2019 notes or Tranche B notes or the lender under the Sanofi Loan Facility would demand repayment of the outstanding balance of the 2019 notes, the Tranche B notes or the loans under the Sanofi Loan Facility as appointed or exercise any other remedies available to such holders if we were unable to comply with these covenants. The covenants and restrictions contained in the foregoing agreements could significantly limit our ability to respond to changes in our business or competitive activities or take advantage of business opportunities that may create value for our stockholders. In addition, our inability to meet or otherwise comply with the covenants under these agreements could have an adverse impact on our financial position and results of operations and could result in an event of default under the terms of our other indebtedness, including our indebtedness under the 2015 notes. In the event of certain future defaults under the foregoing agreements for which we are not able to obtain waivers, the holders of the 2015 notes, 2019 notes and Tranche B notes and the lender under the Sanofi Loan Facility may accelerate all of our repayment obligations, and, with respect to the 2019 notes and Tranche B notes and the loans under the Sanofi Loan Facility, take control of our pledged assets, potentially requiring us to renegotiate the terms of our indebtedness on terms less favorable to us, or to immediately cease operations.

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If we enter into additional debt arrangements, the terms of such additional arrangements could further restrict our operating and financial flexibility. In the event we must cease operations and liquidate our assets, the rights of any holders of our outstanding debt would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, our business will be harmed and the market price of our common stock could decline.*

For planning purposes, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical studies and the submission of regulatory filings. From time to time, we publicly announce the expected timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of the achievement of these milestones can vary dramatically from our estimates, in many cases for reasons beyond our control, depending on numerous factors, including:

- the rate of progress, costs and results of our clinical studies and research and development activities;
- our ability to identify and enroll patients who meet clinical study eligibility criteria;
- our ability to access sufficient, reliable and affordable supplies of components used in the manufacture of our product candidates;
- the costs of expanding and maintaining manufacturing operations, as necessary;
- the extent to which our clinical studies compete for clinical sites and eligible subjects with clinical studies sponsored by other companies; and
- actions by regulators.

In addition, if we do not obtain sufficient additional funds through sales of securities, strategic collaborations or the license or sale of certain of our assets on a timely basis, we may be required to reduce expenses by delaying, reducing or curtailing our development of product candidates. If we fail to commence or complete, or experience delays in or are forced to curtail, our proposed clinical programs or otherwise fail to adhere to our projected development goals in the timeframes we announce and expect (or within the timeframes expected by analysts or investors), our business and results of operations will be harmed and the market price of our common stock may decline.

We may not be able to compete successfully, and AFREZZA may be rendered obsolete by rapid technological change.*

A number of established pharmaceutical companies have or are developing technologies for the treatment of diabetes.

The rapid rate of scientific discoveries and technological changes could result in AFREZZA or one or more of our product candidates becoming obsolete or noncompetitive. Our competitors may develop or introduce new products that render our technology and AFREZZA less competitive, uneconomical or obsolete. Our future success will depend not only on our ability to develop our product candidates but to improve them and keep pace with emerging industry developments. We cannot assure you that we will be able to do so.

We also expect to face competition from universities and other non-profit research organizations. These institutions carry out a significant amount of research and development in various areas of unmet medical need. These institutions are becoming increasingly aware of the commercial value of their findings and are more active in seeking patent and other proprietary rights as well as licensing revenues.

Continued testing of AFREZZA or our product candidates may not yield successful results, and even if it does, we may still be unable to commercialize our product candidates.*

Forecasts about the effects of the use of drugs, including AFREZZA, over terms longer than the clinical studies or in much larger populations may not be consistent with the earlier clinical results. For example, with the approval of AFREZZA, the FDA has required a five-year, randomized, controlled trial in 8,000 - 10,000 patients with type 2 diabetes, the primary objective of which is to compare the incidence of pulmonary malignancy observed with AFREZZA to that observed in a standard of care control group. If long-term use of a drug results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our ability to market and sell the drug, may narrow the approved indications for use or otherwise require restrictive product labeling or marketing, or may require further clinical studies, which may be time-consuming and expensive and may not produce favorable results.

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Our research and development programs are designed to test the safety and efficacy of our product candidates through extensive nonclinical and clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or impact commercialization of any of our product candidates, including the following:

- safety and efficacy results obtained in our nonclinical and early clinical testing may be inconclusive or may not be predictive of results that we may obtain in our future clinical studies or following long-term use, and we may as a result be forced to stop developing a product candidate or alter the marketing of an approved product;
- the analysis of data collected from clinical studies of our product candidates may not reach the statistical significance necessary, or otherwise be sufficient to support FDA or other regulatory approval for the claimed indications;
- after reviewing clinical data, we or any collaborators may abandon projects that we previously believed were promising; and
- our product candidates may not produce the desired effects or may result in adverse health effects or other characteristics that preclude regulatory approval or limit their commercial use once approved.

As a result of any of these events, we, any collaborator, the FDA, or any other regulatory authorities, may suspend or terminate clinical studies or marketing of the drug at any time. Any suspension or termination of our clinical studies or marketing activities may harm our business and results of operations and the market price of our common stock may decline.

If our suppliers fail to deliver materials and services needed for the production of AFREZZA in a timely and sufficient manner, or they fail to comply with applicable regulations, our business and results of operations would be harmed and the market price of our common stock could decline.*

For AFREZZA to be commercially viable, we need access to sufficient, reliable and affordable supplies of insulin, our AFREZZA inhaler, the related cartridges and other materials. Our primary supplier of insulin is Amphastar. We must rely on our suppliers to comply with relevant regulatory and other legal requirements, including the production of insulin in accordance with the FDA's current Good Manufacturing Practices, or cGMPs for drug products, and the production of the AFREZZA inhaler and related cartridges in accordance with Quality System Regulations, or QSRs. The supply of any of these materials may be limited or any of the manufacturers may not meet relevant regulatory requirements, and if we are unable to obtain any of these materials in sufficient amounts, in a timely manner and at reasonable prices, or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, the production of AFREZZA may be delayed. Any such events could delay market introduction and subsequent sales of AFREZZA and, if so, our business and results of operations will be harmed and the market price of our common stock may decline.

We have never manufactured AFREZZA in commercial quantities, and if we fail to develop an effective manufacturing capability or to engage third-party manufacturers with this capability, we may be unable to support commercialization of this product.*

We use our Danbury, Connecticut facility to formulate AFREZZA inhalation powder, fill plastic cartridges with the powder, package the cartridges in blister packs, and place the blister packs into foil pouches. We will utilize a contract packager to do the final kitting and cartoning of foil pouched blisters containing cartridges, as well as inhalers and the package insert. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. If we engage a third-party manufacturer, we would need to transfer our technology to that third-party manufacturer and gain FDA approval, potentially causing delays in product delivery. In addition, our third-party manufacturer may not perform as agreed or may terminate its agreement with us.

Any of these factors could cause us to delay or suspend production, could entail higher costs and may result in our being unable to effectively support commercialization of AFREZZA. Furthermore, if we or a third-party manufacturer fail to deliver the required commercial quantities of the product or any raw material on a timely basis, and at commercially reasonable prices and acceptable quality, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and quality on a timely basis, we would likely be unable to meet demand for AFREZZA and we would lose potential revenues.

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If any product that we develop does not become widely accepted by physicians, patients, third-party payors and the healthcare community, we may be unable to generate significant revenue, if any. *

AFREZZA and our other product candidates may not gain market acceptance among physicians, patients, third-party payors and the healthcare community. Failure to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

The degree of market acceptance of AFREZZA and our other product candidates will depend on many factors, including the:

- approved labeling claims;
- effectiveness of efforts by us or our marketing partner(s) to educate physicians about the benefits and advantages of AFREZZA or our other products and to provide adequate support for them, and the perceived advantages and disadvantages of competitive products;
- willingness of the healthcare community and patients to adopt new technologies;
- ability to manufacture the product in sufficient quantities with acceptable quality and cost;
- perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits compared to competing products or therapies;
- convenience and ease of administration relative to existing treatment methods;
- coverage and pricing and reimbursement relative to other treatment therapeutics and methods; and
- marketing and distribution support.

Because of these and other factors, AFREZZA and any other product that we get approved may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

If third-party payors do not cover AFREZZA or any of our product candidates for which we receive regulatory approval, AFREZZA or such product candidates might not be prescribed, used or purchased, which would adversely affect our revenues. *

Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of governments and third-party payors to contain or reduce the costs of healthcare through various means. For example, in certain foreign markets the pricing of prescription pharmaceuticals is subject to governmental control. In the United States, there has been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services may take in response to any drug pricing reform proposals or legislation. Such reforms may limit our ability to generate revenues from sales of AFREZZA or our other product candidates and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of our marketing partner for AFREZZA, Sanofi, and companies that are prospective collaborators for our product candidates, our ability to commercialize AFREZZA and our product candidates under development may be adversely affected.

In the United States and elsewhere, sales of prescription pharmaceuticals still depend in large part on the availability of reimbursement to the consumer from third-party payors, such as governmental and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. The market for AFREZZA and our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. In addition, because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We would be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing one or more products to market, we cannot be certain that any such products would be considered cost-effective or that coverage and adequate reimbursement to the consumer would be available. Patients will be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

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In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for AFREZZA or any of our other product candidates that receives marketing approval from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

If we are unable to obtain coverage of, and adequate payment levels for, AFREZZA or any of our other product candidates that receive marketing approval from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our and our marketing partner's ability to successfully commercialize AFREZZA and our ability to successfully commercialize any of our other product candidates that receives regulatory approval and impact our profitability, results of operations, financial condition, and prospects.

Healthcare legislation may make it more difficult to receive revenues.*

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the healthcare industry. Among the provisions of PPACA of importance to us are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- a 2.3% medical device excise tax on certain transactions, including many U.S. sales of medical devices, which currently includes and we expect will continue to include U.S. sales of drug-device combination products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in 2014 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any "payments or transfers of value" made or distributed to prescribers, teaching hospitals and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with reporting to the Centers for Medicare & Medicaid Services, or CMS, required by March 31, 2014 and by the 90th day of each subsequent calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable

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to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

We expect that PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

If we or our marketing partner fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.*

As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal physician sunshine requirements under PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. To the extent that AFREZZA or any of our product candidates that receives marketing approval is ultimately sold in a foreign country, we may be subject to similar foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, individual imprisonment, disgorgement, exclusion of products from reimbursement under U.S. federal or state healthcare programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If product liability claims are brought against us, we may incur significant liabilities and suffer damage to our reputation.*

The testing, manufacturing, marketing and sale of AFREZZA and our other product candidates expose us to potential product liability claims. A product liability claim may result in substantial judgments as well as consume significant financial and management resources and result in adverse publicity, decreased demand for a product, injury to our reputation, withdrawal of clinical studies volunteers and loss of revenues. We currently carry worldwide liability insurance in the amount of \$10.0 million. In addition, we carry local policies per study in each country in which we conduct clinical studies that require us to carry coverage based on local statutory requirements. We intend to obtain product liability coverage for commercial sales of AFREZZA. However, we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise, and because insurance coverage in our industry can be very expensive and difficult to obtain, we cannot assure you that we will be able to obtain sufficient coverage at an acceptable cost, if at all. If losses from such claims exceed our liability insurance coverage, we may ourselves incur substantial liabilities. If we are required to pay a product liability claim our business and results of operations would be harmed and the market price of our common stock may decline.

If we lose any key employees or scientific advisors, our operations and our ability to execute our business strategy could be materially harmed.*

We face intense competition for qualified employees among companies in the biotechnology and biopharmaceutical industries. Our success depends upon our ability to attract, retain and motivate highly skilled employees. We may be unable to attract and retain these individuals on acceptable terms, if at all. In addition, in order to commercialize AFREZZA successfully, we may be required to expand our work force, particularly in the areas of manufacturing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel, and we cannot assure you that we will be able to attract or retain any such new personnel on acceptable terms, if at all.

The loss of the services of any principal member of our management and scientific staff could significantly delay or prevent the achievement of our scientific and business objectives. All of our employees are “at will” and we currently do not have employment agreements with any of the principal members of our management or scientific staff, and we do not have key person life insurance to cover the loss of any of these individuals. Replacing key employees may be difficult and time-consuming because of the limited number of individuals in our industry with the skills and experience required to develop, gain regulatory approval of and commercialize products successfully.

We have relationships with scientific advisors at academic and other institutions to conduct research or assist us in formulating our research, development or clinical strategy. These scientific advisors are not our employees and may have commitments to, and other obligations with, other entities that may limit their availability to us. We have limited control over the activities of these scientific advisors and can generally expect these individuals to devote only limited time to our activities. Failure of any of these persons to devote sufficient time and resources to our programs could harm our business. In addition, these advisors are not prohibited from, and may have arrangements with, other companies to assist those companies in developing technologies that may compete with AFREZZA or our product candidates.

If our Chairman and Chief Executive Officer is unable to devote sufficient time and attention to our business, our operations and our ability to execute our business strategy could be materially harmed.

Alfred Mann, our Chairman and Chief Executive Officer, is involved in many other business and charitable activities. As a result, the time and attention Mr. Mann devotes to the operation of our business varies, and he may not expend the same time or focus on our activities as other, similarly situated chief executive officers. If Mr. Mann is unable to devote the time and attention necessary to running our business, we may not be able to execute our business strategy and our business could be materially harmed.

If our internal controls over financial reporting are not considered effective, our business and stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal controls over financial reporting in our annual report on Form 10-K for that fiscal year. Section 404 also requires our independent registered public accounting firm to attest to, and report on, our internal controls over financial reporting.

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Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls in the future. A material weakness in our internal controls over financial reporting would require management and our independent registered public accounting firm to evaluate our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business and on the market price of our common stock.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.*

We expect that at least for the foreseeable future, our manufacturing facility in Danbury, Connecticut will be the sole location for the manufacturing of AFREZZA. This facility and the manufacturing equipment we use would be costly to replace and could require substantial lead time to repair or replace. In addition, we are headquartered in Valencia, California. This facility contains our principal executive offices and is used to provide support for the development of our Technosphere technology programs. We depend on our facilities and on collaborators, contractors and vendors for the continued operation of our business, some of whom are located in other countries. Natural disasters or other catastrophic events, including interruptions in the supply of natural resources, political and governmental changes, severe weather conditions, wildfires and other fires, explosions, actions of animal rights activists, terrorist attacks, volcanic eruptions, earthquakes and wars could disrupt our operations or those of our collaborators, contractors and vendors. We might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors' insurance policies or for which we or our contractors do not have coverage. For example, we are not insured against a terrorist attack. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our research and development programs and adversely affect, which may include stopping, our readiness for commercial production.

We deal with hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development work involves the controlled storage and use of hazardous materials, including chemical and biological materials. In addition, our manufacturing operations involve the use of a chemical that may form an explosive mixture under certain conditions. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations (i) governing how we use, manufacture, store, handle and dispose of these materials (ii) imposing liability for costs of cleaning up, and damages to natural resources from past spills, waste disposals on and off-site, or other releases of hazardous materials or regulated substances, and (iii) regulating workplace safety. Moreover, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated, and in the event of an accident, we could be held liable for any damages that may result, and any liability could fall outside the coverage or exceed the limits of our insurance. Currently, our general liability policy provides coverage up to \$1.0 million per occurrence and \$2.0 million in the aggregate and is supplemented by an umbrella policy that provides a further \$4.0 million of coverage; however, our insurance policy excludes pollution liability coverage and we do not carry a separate hazardous materials policy. In addition, we could be required to incur significant costs to comply with environmental laws and regulations in the future. Finally, current or future environmental laws and regulations may impair our research, development or production efforts or have an adverse impact on our business, results of operations and financial condition.

When we purchased the facilities located in Danbury, Connecticut in 2001, a soil and groundwater investigation and remediation was being conducted by a former site operator (the responsible party) under the oversight of the Connecticut Department of Environmental Protection. During the construction of our expanded manufacturing facility, we excavated contaminated soil under the footprint of our building expansion location. The responsible party reimbursed us for our increased excavation and disposal costs of contaminated soil in the amount of \$1.6 million. It has conducted at its expense all work and will make all filings necessary to achieve closure for the environmental remediation conducted at the site, and has agreed to indemnify us for any future costs and expenses we may incur that are directly related to the final closure. If we are unable to collect these future costs and expenses, if any, from the responsible party, our business and results of operations may be harmed.

RISKS RELATED TO GOVERNMENT REGULATION

Our product candidates must undergo costly and time-consuming rigorous nonclinical and clinical testing and we must obtain regulatory approval prior to the sale and marketing of any product in each jurisdiction. The results of this testing or issues that develop in the review and approval by a regulatory agency may subject us to unanticipated delays or prevent us from marketing any products.*

Our research and development activities, as well as the manufacturing and marketing of AFREZZA and our product candidates, are subject to regulation, including regulation for safety, efficacy and quality, by the FDA in the United States and comparable authorities in other countries. FDA regulations and the regulations of comparable foreign regulatory authorities are wide-ranging and govern, among other things:

- product design, development, manufacture and testing;
- product labeling;
- product storage and shipping;
- pre-market clearance or approval;
- advertising and promotion; and
- product sales and distribution.

The requirements governing the conduct of clinical studies and manufacturing and marketing of AFREZZA and our product candidates outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical study designs. Foreign regulatory approval processes include essentially all of the risks associated with the FDA approval processes. Some of those agencies also must approve prices of the products. Approval of a product by the FDA does not ensure approval of the same product by the health authorities of other countries. In addition, changes in regulatory policy in the United States or in foreign countries for product approval during the period of product development and regulatory agency review of each submitted new application may cause delays or rejections.

Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. We cannot be certain if or when regulatory agencies might request additional studies, under what conditions such studies might be requested, or what the size or length of any such studies might be. The clinical studies of our product candidates may not be completed on schedule, regulatory agencies may order us to stop or modify our research, or these agencies may not ultimately approve any of our product candidates for commercial sale. The data collected from our clinical studies may not be sufficient to support regulatory approval of our product candidates. Even if we believe the data collected from our clinical studies are sufficient, regulatory agencies have substantial discretion in the approval process and may disagree with our interpretation of the data. Our failure to adequately demonstrate the safety and efficacy of any of our product candidates would delay or prevent regulatory approval of our product candidates, which could prevent us from achieving profitability.

Questions that have been raised about the safety of marketed drugs generally, including pertaining to the lack of adequate labeling, may result in increased cautiousness by regulatory agencies in reviewing new drugs based on safety, efficacy, or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Such regulatory considerations may also result in the imposition of more restrictive drug labeling or marketing requirements as conditions of approval, which may significantly affect the marketability of our drug products.

If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to criminal prosecution, fined or forced to remove a product from the market or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval.*

Even if we comply with regulatory requirements, we may not be able to obtain the labeling claims necessary or desirable for product promotion. We may also be required to undertake post-marketing studies. For example, the FDA is requiring the following post-marketing studies for AFREZZA:

- a clinical trial to evaluate pharmacokinetics, safety and efficacy in pediatric patients;
- a clinical trial to evaluate the potential risk of pulmonary malignancy with AFREZZA (as well as cardiovascular risk and the long-term effect of AFREZZA on pulmonary function); and
- two pharmacokinetic-pharmacodynamic studies, one to characterize dose-response and one to characterize within-subject variability.

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In addition, if we or other parties identify adverse effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and a reformulation of our products, additional clinical studies, changes in labeling of, or indications of use for, our products and/or additional marketing applications may be required. If we encounter any of the foregoing problems, our business and results of operations will be harmed and the market price of our common stock may decline.

We are subject to stringent, ongoing government regulation.*

The manufacture, marketing and sale of AFREZZA are subject to stringent and ongoing government regulation. The FDA may also withdraw product approvals if problems concerning the safety or efficacy of a product appear following approval. We cannot be sure that FDA and United States Congressional initiatives or actions by foreign regulatory bodies pertaining to ensuring the safety of marketed drugs or other developments pertaining to the pharmaceutical industry will not adversely affect our operations.

We also are required to register our establishments and list our products with the FDA and certain state agencies. We and any third-party manufacturers or suppliers must continually adhere to federal regulations setting forth requirements, known as cGMP (for drugs) and QSR (for medical devices), and their foreign equivalents, which are enforced by the FDA and other national regulatory bodies through their facilities inspection programs. In complying with cGMP and foreign regulatory requirements, we and any of our potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that our products meet applicable specifications and other requirements. QSR requirements also impose extensive testing, control and documentation requirements. State regulatory agencies and the regulatory agencies of other countries have similar requirements. In addition, we will be required to comply with regulatory requirements of the FDA, state regulatory agencies and the regulatory agencies of other countries concerning the reporting of adverse events and device malfunctions, corrections and removals (e.g., recalls), promotion and advertising and general prohibitions against the manufacture and distribution of adulterated and misbranded devices. Failure to comply with these regulatory requirements could result in civil fines, product seizures, injunctions and/or criminal prosecution of responsible individuals and us. Any such actions would have a material adverse effect on our business and results of operations.

Our suppliers will be subject to FDA inspection.*

We depend on suppliers for insulin and other materials that comprise AFREZZA, including our AFREZZA inhaler and cartridges. Each supplier must comply with relevant regulatory requirements including QSR, and is subject to inspection by the FDA. There can be no assurance, in the conduct of an inspection of any of our suppliers that the agency would find that the supplier substantially complies with the QSR or cGMP requirements, where applicable. If we or any potential third-party manufacturer or supplier fails to comply with these requirements or comparable requirements in foreign countries, regulatory authorities may subject us to regulatory action, including criminal prosecutions, fines and suspension of the manufacture of our products. Amphastar is our primary supplier of insulin. If we are required to find a new or additional supplier of insulin, we will be required to evaluate the new supplier's ability to provide insulin that meets regulatory requirements, including cGMP requirements as well as our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and commercialization of AFREZZA.

Reports of side effects or safety concerns in related technology fields or in other companies' clinical studies could delay or prevent us from obtaining regulatory approval for our product candidates or negatively impact public perception of AFREZZA or our other product candidates.*

At present, there are a number of clinical studies being conducted by other pharmaceutical companies involving insulin delivery systems. If other pharmaceutical companies announce that they observed frequent adverse events in their studies involving insulin therapies, we may be subject to class warnings in the label for AFREZZA. In addition, the public perception of AFREZZA might be adversely affected, which could harm our business and results of operations and cause the market price of our common stock to decline, even if the concern relates to another company's products or product candidates.

There are also a number of clinical studies being conducted by other pharmaceutical companies involving compounds similar to, or competitive with, our other product candidates. Adverse results reported by these other companies in their clinical studies could delay or prevent us from obtaining regulatory approval or negatively impact public perception of our product candidates, which could harm our business and results of operations and cause the market price of our common stock to decline.

RISKS RELATED TO INTELLECTUAL PROPERTY

If we are unable to protect our proprietary rights, we may not be able to compete effectively, or operate profitably.*

Our commercial success depends, in large part, on our ability to obtain and maintain intellectual property protection for our technology. Our ability to do so will depend on, among other things, complex legal and factual questions, and it should be noted that the standards regarding intellectual property rights in our fields are still evolving. We attempt to protect our proprietary technology through a combination of patents, trade secrets and confidentiality agreements. We own a number of domestic and international patents, have a number of domestic and international patent applications pending and have licenses to additional patents. We cannot assure you that our patents and licenses will successfully preclude others from using our technologies, and we could incur substantial costs in seeking enforcement of our proprietary rights against infringement. Even if issued, the patents may not give us an advantage over competitors with alternative technologies.

Moreover, the term of a patent is limited and, as a result, the patents protecting our products expire at various dates. For example, some patents providing protection for our AFREZZA inhalation powder expired in 2012 and 2014. Other patents providing protection for AFREZZA have terms extending into 2020, 2030 and 2031. In addition, patents providing protection for our inhaler and cartridges have terms extending into 2023, 2031 and 2032, and we have method of treatment claims that extend into 2026 and 2029. As and when these different patents expire, AFREZZA could become subject to increased competition. As a consequence, we may not be able to recover our development costs.

Moreover, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be afforded by our patents. A third party may challenge the validity or enforceability of a patent after its issuance by various proceedings such as oppositions in foreign jurisdictions or re-examinations or other review in the United States. In some instances we may seek re-examination or reissuance of our own patents. If we attempt to enforce our patents, they may be challenged in court where they could be held invalid, unenforceable, or have their breadth narrowed to an extent that would destroy their value.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted, subjected to post-grant challenge, and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO is continuing to develop regulations and procedures to govern administration of the Leahy-Smith Act, and while all of the substantive changes to patent law associated with the Leahy-Smith Act have become effective, many changes have only recently become effective. Moreover there will be a transitional period of many years during which some applications may be eligible for prosecution under the previous rules. There are many ambiguities in this new law and how the courts will interpret it cannot be predicted with confidence. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, patent law continues to evolve. Several further changes to patent law are before Congress. The United States Supreme Court has exhibited an increased interest in patent law and several of its recent decisions have tended to narrow the scope of patentable subject matter related to medical products and methods. In March 2014 the USPTO, in response to Supreme Court decisions, issued new examination guidelines which call into question the patentability of biological inventions that had previously been considered patentable. While none of this has an immediately apparent impact on our core technology and patents, the full and ultimate effect of these developments is not yet known. We also rely on unpatented technology, trade secrets, know-how and confidentiality agreements. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. We also execute confidentiality agreements with outside collaborators. There can be no assurance, however, that these agreements will provide meaningful protection for our inventions, trade secrets, know-how or other proprietary information in the event of unauthorized use or disclosure of such information. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business, results of operations and financial condition could be adversely affected.

If we become involved in lawsuits to protect or enforce our patents or the patents of our collaborators or licensors, we would be required to devote substantial time and resources to prosecute or defend such proceedings.

Competitors may infringe our patents or the patents of our collaborators or licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. A court may also decide to award us a royalty from an infringing party instead of issuing an injunction against the infringing activity. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

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Interference proceedings brought by the USPTO, may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Additionally, the Leahy-Smith Act has greatly expanded the options for post-grant review of patents that can be brought by third parties. Litigation, post-grant review, or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. We may not prevail in any litigation, post-grant review, or interference proceeding in which we are involved. Even if we do prevail, these proceedings can be very expensive and distract our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price of our common stock may decline.

If our technologies conflict with the proprietary rights of others, we may incur substantial costs as a result of litigation or other proceedings and we could face substantial monetary damages and be precluded from commercializing our products, which would materially harm our business.

Biotechnology patents are numerous and may, at times, conflict with one another. As a result, it is not always clear to industry participants, including us, which patents cover the multitude of biotechnology product types. Ultimately, the courts must determine the scope of coverage afforded by a patent and the courts do not always arrive at uniform conclusions.

A patent owner may claim that we are making, using, selling or offering for sale an invention covered by the owner's patents and may go to court to stop us from engaging in such activities. Such litigation is not uncommon in our industry.

Patent lawsuits can be expensive and would consume time and other resources. There is a risk that a court would decide that we are infringing a third party's patents and would order us to stop the activities covered by the patents, including the commercialization of our products. In addition, there is a risk that we would have to pay the other party damages for having violated the other party's patents (which damages may be increased, as well as attorneys' fees ordered paid, if infringement is found to be willful), or that we will be required to obtain a license from the other party in order to continue to commercialize the affected products, or to design our products in a manner that does not infringe a valid patent. We may not prevail in any legal action, and a required license under the patent may not be available on acceptable terms or at all, requiring cessation of activities that were found to infringe a valid patent. We also may not be able to develop a non-infringing product design on commercially reasonable terms, or at all.

Moreover, certain components of AFREZZA may be manufactured outside the United States and imported into the United States. As such, third parties could file complaints under 19 U.S.C. Section 337(a)(1)(B), or a 337 action, with the International Trade Commission, or the ITC. A 337 action can be expensive and would consume time and other resources. There is a risk that the ITC would decide that we are infringing a third party's patents and either enjoin us from importing the infringing products or parts thereof into the United States or set a bond in an amount that the ITC considers would offset our competitive advantage from the continued importation during the statutory review period. The bond could be up to 100% of the value of the patented products. We may not prevail in any legal action, and a required license under the patent may not be available on acceptable terms, or at all, resulting in a permanent injunction preventing any further importation of the infringing products or parts thereof into the United States. We also may not be able to develop a non-infringing product design on commercially reasonable terms, or at all.

Although we own a number of domestic and foreign patents and patent applications relating to AFREZZA, we have identified certain third-party patents having claims relating to pulmonary insulin delivery that may trigger an allegation of infringement upon the commercial manufacture and sale of AFREZZA. If a court were to determine that AFREZZA was infringing any of these patent rights, we would have to establish with the court that these patents were invalid or unenforceable in order to avoid legal liability for infringement of these patents. However, proving patent invalidity or unenforceability can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in a non-infringement or invalidity action we will have to either acquire the third-party patents outright or seek a royalty-bearing license. Royalty-bearing licenses effectively increase production costs and therefore may materially affect product profitability. Furthermore, should the patent holder refuse to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and/or design around the patents, if possible. In either event, our business would be harmed and our profitability could be materially adversely impacted.

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Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price of our common stock may decline.

In addition, patent litigation may divert the attention of key personnel and we may not have sufficient resources to bring these actions to a successful conclusion. At the same time, some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products or result in substantial monetary damages, which would adversely affect our business and results of operations and cause the market price of our common stock to decline.

We may not obtain trademark registrations for our potential trade names.

We have not selected trade names for some of our product candidates; therefore, we have not filed trademark registrations for all of our potential trade names for our product candidates in all jurisdictions, nor can we assure that we will be granted registration of those potential trade names for which we have filed. No assurance can be given that any of our trademarks will be registered in the United States or elsewhere, or once registered that, prior to our being able to enter a particular market, they will not be cancelled for non-use. Nor can we give assurances, that the use of any of our trademarks will confer a competitive advantage in the marketplace.

Furthermore, even if we are successful in our trademark registrations, the FDA has its own process for drug nomenclature and its own views concerning appropriate proprietary names. It also has the power, even after granting market approval, to request a company to reconsider the name for a product because of evidence of confusion in the marketplace. We cannot assure you that the FDA or any other regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks at some time in the future.

RISKS RELATED TO OUR COMMON STOCK

Our stock price is volatile.*

The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks, and this trend may continue. The volatility of pharmaceutical and biotechnology stocks often does not relate to the operating performance of the companies represented by the stock. Our business and the market price of our common stock may be influenced by a large variety of factors, including:

- the progress and results of our clinical studies;
- general economic, political or stock market conditions;
- legislative developments;
- announcements by us, our collaborators, or our competitors concerning clinical study results, acquisitions, strategic alliances, technological innovations, newly approved commercial products, product discontinuations, or other developments;
- the availability of critical materials used in developing and manufacturing AFREZZA or other product candidates;
- developments or disputes concerning our patents or proprietary rights;
- the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;
- announcements by us concerning our financial condition or operating performance;
- changes in securities analysts' estimates of our financial condition or operating performance;
- general market conditions and fluctuations for emerging growth and pharmaceutical market sectors;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- the status of any legal proceedings or regulatory matters against or involving us or any of our executive officers and directors;
- the existence of, and the issuance of shares of our common stock pursuant to, the share lending agreement and the short sales of our common stock effected in connection with the sale of our 2015 notes;

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- the conversion of any of our 2015 notes into shares of our common stock; and
- discussion of AFREZZA, our other product candidates, competitors' products, or our stock price by the financial and scientific press, the healthcare community and online investor communities such as chat rooms. In particular, it may be difficult to verify statements about us and our investigational products that appear on interactive websites that permit users to generate content anonymously or under a pseudonym and statements attributed to company officials may, in fact, have originated elsewhere.

Any of these risks, as well as other factors, could cause the market price of our common stock to decline.

If other biotechnology and biopharmaceutical companies or the securities markets in general encounter problems, the market price of our common stock could be adversely affected.

Public companies in general and companies included on the NASDAQ Global Market in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. There has been particular volatility in the market prices of securities of biotechnology and other life sciences companies, and the market prices of these companies have often fluctuated because of problems or successes in a given market segment or because investor interest has shifted to other segments. These broad market and industry factors may cause the market price of our common stock to decline, regardless of our operating performance. We have no control over this volatility and can only focus our efforts on our own operations, and even these may be affected due to the state of the capital markets.

In the past, following periods of large price declines in the public market price of a company's securities, securities class action litigation has often been initiated against that company. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

Our Chairman and Chief Executive Officer and principal stockholder can individually control our direction and policies, and his interests may be adverse to the interests of our other stockholders. After his death, his stock will be left to his funding foundations for distribution to various charities, and we cannot assure you of the manner in which those entities will manage their holdings.*

At September 30, 2014, our Chairman and Chief Executive Officer, Alfred E. Mann beneficially owned 37.8% of our outstanding shares of capital stock. By virtue of his holdings, Mr. Mann may be able to continue to effectively control the election of the members of our board of directors, our management and our affairs and prevent corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders or cause a transaction that we or our other stockholders may view as unfavorable.

Subject to compliance with United States federal and state securities laws, Mr. Mann is free to sell the shares of our stock he holds at any time. Upon his death, we have been advised by Mr. Mann that his shares of our capital stock will be left to the Alfred E. Mann Medical Research Organization, or AEMMRO, and AEM Foundation for Biomedical Engineering, or AEMFBE, not-for-profit medical research foundations that serve as funding organizations for Mr. Mann's various charities, including the Alfred Mann Foundation, or AMF, and the Alfred Mann Institutes at the University of Southern California, the Technion-Israel Institute of Technology, and Purdue University, and that may serve as funding organizations for any other charities that he may establish. The AEMMRO is a membership foundation consisting of nine members, including Mr. Mann, his wife, three of his children and Dr. Joseph Schulman, the chief scientist of the AEMFBE. The AEMFBE is a membership foundation consisting of five members, including Mr. Mann, his wife, and the same three of his children. Although we understand that the members of AEMMRO and AEMFBE have been advised of Mr. Mann's objectives for these foundations, once Mr. Mann's shares of our capital stock become the property of the foundations, we cannot assure you as to how those shares will be distributed or how they will be voted.

The future sale of our common stock, the conversion of our 2015 notes into common stock or the exercise of our warrants for common stock could negatively affect our stock price.*

As of November 3, 2014, we had 405,699,862 shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock may decline. Likewise the issuance of additional shares of our common stock upon the conversion of some or all of our 2015 notes, or upon the exercise of some or all of the warrants we issued in February 2012, could adversely affect the trading price of our common stock. In addition, the existence of these notes and warrants may encourage short selling of our common stock by market participants. Furthermore, if we were to include in a company-initiated registration statement shares held by our stockholders pursuant to the exercise of their registration rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

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In addition, we may need to raise substantial additional capital in the future to fund our operations. If we raise additional funds by issuing equity securities, including through the ATM Agreements, or additional convertible debt, the market price of our common stock may decline and our existing stockholders may experience significant dilution.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

We are incorporated in Delaware. Certain anti-takeover provisions under Delaware law and in our certificate of incorporation and amended and restated bylaws, as currently in effect, may make a change of control of our company more difficult, even if a change in control would be beneficial to our stockholders. Our anti-takeover provisions include provisions such as a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning 15% or more of our outstanding voting stock from merging or combining with us in certain circumstances. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some of our stockholders. In addition, they may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Because we do not expect to pay dividends in the foreseeable future, you must rely on stock appreciation for any return on your investment.

We have paid no cash dividends on any of our capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, the success of your investment in our common stock will likely depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate or maintain its current price. You could lose the entire value of your investment in our common stock.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.5 to MannKind's Registration Statement on Form S-1 (File No. 333-115020), originally filed with the SEC on April 30, 2004, as amended).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2007).

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Exhibit Number	Description of Document
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to MannKind's Quarterly report on Form 10-Q (File No. 000-50865), originally filed with the SEC on August 2, 2010).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.4 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 4, 2011).
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on December 24, 2012).
3.6	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on November 19, 2007).
4.1	Form of common stock certificate (incorporated by reference to Exhibit 4.4 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 18, 2013).
4.2	Registration Rights Agreement, dated October 15, 1998 by and among CTL Immuno Therapies Corp., Medical Research Group, LLC, McLean Watson Advisory Inc. and Alfred E. Mann, as amended (incorporated by reference to Exhibit 4.2 to MannKind's Registration Statement on Form S-1 (File No. 333-115020), filed with the SEC on April 30, 2004, as amended).
4.3	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated August 24, 2010 (incorporated by reference to Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), y filed with the SEC on August 24, 2010).
4.4	Form of 5.75% Senior Convertible Note due 2015 (incorporated by reference to Exhibit 4.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 24, 2010).
4.5	Form of Warrant to Purchase Common Stock issued February 8, 2012 (incorporated by reference to Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on February 6, 2012).
4.6	Form of 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.7	Form of Amended and Restated 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to Exhibit 4.7 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
4.8	Form of Tranche B Senior Secured Note due 2019 (incorporated by reference to Exhibit 4.8 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on May 12, 2014).
4.9	Milestone Rights Purchase Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to Exhibit 99.3 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.10	Guaranty and Security Agreement, dated as of July 1, 2013, by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to Exhibit 99.4 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.11	Registration Rights Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.5 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.12	Facility Agreement, dated as of July 1, 2013, by and among MannKind Corporation, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.13	First Amendment to Facility Agreement and Registration Rights Agreement, dated as of February 28, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 4.12 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
4.14	Second Amendment to Facility Agreement and Registration Rights Agreement, dated as of August 11, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P.
4.15	Senior Secured Revolving Promissory Note, dated as of September 23, 2014, by and between MannKind Corporation and Aventisub LLC (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 29, 2014).

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<u>Exhibit Number</u>	<u>Description of Document</u>
4.16	Guaranty and Security Agreement, dated as of September 23, 2014, by and among MannKind Corporation, MannKind LLC and Aventisub LLC (incorporated by reference to Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 29, 2014).
10.1†	License and Collaboration Agreement, dated as of August 11, 2014, by and among MannKind Corporation, Technosphere International C.V., MannKind Netherlands B.V. and Sanofi-Aventis Deutschland GmbH.
10.2†	Supply Agreement, dated as of August 11, 2014, by and between MannKind Corporation and Sanofi-Aventis Deutschland GmbH.
10.3†	Supply Agreement, dated as of July 31, 2014, by and between MannKind Corporation and Amphastar France Pharmaceuticals S.A.S.
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

† Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: November 10, 2014

MANKIND CORPORATION

By: _____ /s/ MATTHEW J. PFEFFER

Matthew J. Pfeffer
Corporate Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

SECOND AMENDMENT TO FACILITY AGREEMENT

SECOND AMENDMENT TO FACILITY AGREEMENT (this "Amendment"), dated as of August 11, 2014, by and among MANNKIND CORPORATION, a Delaware corporation (the "Borrower"), DEERFIELD PRIVATE DESIGN FUND II, L.P. ("DPDF") and DEERFIELD PRIVATE DESIGN INTERNATIONAL II, L.P. (together with DPDF collectively referred to as the "Purchasers" and together with the Borrower, the "Parties").

RECITALS:

A. Borrower and Purchasers have entered into that certain Facility Agreement dated as of July 1, 2013, as amended by that the First Amendment to Facility Agreement and Registration Rights Agreement, dated as of February 28, 2014 (as the same may be amended, modified, restated or otherwise supplemented from time to time, the "Facility Agreement").

B. In connection with the Borrower's proposed entry into (i) that certain License and Collaboration Agreement with Sanofi-Aventis Deutschland GmbH ("Sanofi"), Technosphere International C.V., a wholly-owned subsidiary of the Borrower ("TICV"), and MannKind Netherlands BV, a wholly-owned subsidiary of TICV ("MNBV" and, collectively with TICV, "Borrower Subsidiaries"), relating to Borrower's Afrezza® rapid-acting inhaled insulin product (the "License Agreement"), (ii) that certain Supply Agreement with Sanofi related to such product (the "Supply Agreement" and, together with the License Agreement, the "Collaboration Agreements"), and (iii) that certain loan commitment letter with Sanofi regarding a loan facility to be made available by Sanofi to the Borrower in connection with the Collaboration Agreements, a copy of which is attached hereto as Exhibit A (the "Commitment Letter") pursuant to a loan agreement and related loan documents to be entered into by the Borrower and Sanofi after entry into the Collaboration Agreements and prior to the time the Collaboration Agreements become effective (the "Loan Documents"), the Parties desire to amend the Facility Agreement to permit the incurrence by the Borrower of additional indebtedness and liens securing such indebtedness contemplated by the Commitment Letter and the Loan Documents, on the terms set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements contained herein, the Parties agree as follows:

1. Defined Terms. Capitalized terms used herein which are defined in the Facility Agreement, unless otherwise defined herein, shall have the meanings ascribed to them in the Facility Agreement. The Recitals to this Amendment are incorporated herein in their entirety by this reference thereto.

2. Amendments to Facility Agreement. Upon the satisfaction of the conditions set forth in Section 3 of this Amendment:

a. Section 1.1 of the Facility Agreement is hereby amended to add the following additional defined terms:

“Collaboration Agreements” shall have the meaning provided therefor in the Second Amendment.

“Commitment Letter” shall have the meaning provided therefor in the Second Amendment.

“Intercreditor Agreement” means an Intercreditor Agreement in form and substance reasonably acceptable to Purchasers and consistent with the terms set forth in Exhibit B to the Second Amendment, among Borrower, Purchasers and Sanofi or its affiliate providing the loans to Borrower under the Loan Documents.

“Loan Documents” shall have the meaning provided therefor in the Second Amendment.

“Sanofi” shall have the meaning provided therefor in the Second Amendment.

“Second Amendment” means the Second Amendment to Facility Agreement dated as of August 11, 2014 between Borrower and Purchasers.

b. The defined term “Permitted Indebtedness” in Section 1.1 of the Facility Agreement is amended to renumber subsection “(xxvi)” as “(xxvii)” and insert a new subsection (xxvi) to read as follows:

“(xxvi) Indebtedness to Sanofi or its affiliates incurred in connection with the transactions contemplated by the Collaboration Agreements, the Commitment Letter and the Loan Documents (which shall be consistent with the terms set forth in the Commitment Letter) in an aggregate principal amount of up to One Hundred Seventy-Five Million Dollars (\$175,000,000) plus any PIK interest that may be accrued and added to such principal that (a) may be secured (i) on a first lien basis by Insulin Inventory located in the United States, and the property and improvements located at 28903 North Avenue Paine, Valencia, CA, and (ii) on a second lien basis by all other Collateral pursuant to the Intercreditor Agreement, and (b) may be prepaid at any time (x) with distributions allocable to Borrower under the Collaboration Agreements, or (y) with any other funds of Borrower if, Borrower first offers to prepay the Obligations in the amount of the proposed prepayment to Sanofi, and Purchasers decline such prepayment; and”.

c. The defined term “Permitted Liens” in Section 1.1 of the Facility Agreement is amended to renumber subsection “(xxvi)” as “(xxvii)” and insert a new subsection (xxvi) to read as follows:

“(xxvi) Liens securing Indebtedness permitted by clause (xxvi) of the definition of Permitted Indebtedness with the priority set forth therein; and”.

3. Conditions Precedent. The effectiveness of this Amendment is subject to the following conditions precedent:

a. Delivery of Documents. The Borrowers and the Purchasers shall each execute and deliver this Amendment.

b. Performance; No Default. The Borrower shall have performed and complied with all agreements and conditions contained in the Facility Agreement and the other Transaction Documents to be performed by or complied with by the Borrower prior to the date hereof in all material respects.

4. Representations and Warranties. The Borrower hereby represents and warrants to Purchasers as follows:

a. As of the date hereof, the representations and warranties of the Borrower contained in the Transaction Documents are (i) in the case of representations and warranties qualified by "materiality," "Material Adverse Effect" or similar language, true and correct in all respects and (ii) in the case of all other representations and warranties, true and correct in all material respects, in each case on and as of the date hereof, except to the extent that any such representation or warranty relates to a specific date, in which case such representation and warranty shall be true and correct in all respects or all material respects, as applicable, as of such earlier date;

b. The execution, delivery and performance by the Borrower of this Amendment (i) are within the Borrower's corporate powers, (ii) have been duly authorized by all necessary action pursuant to its Organizational Documents, (iii) require no further action by or in respect of, or filing with, any Government Authority, and (iv) do not violate, conflict with or cause a breach or a default under any provision of applicable law or regulation or of Borrower's Organizational Documents or of any agreement, judgment, injunction, order, decree or other instrument binding upon Borrower, except to the extent such violation, conflict, breach or default would not individually or in the aggregate reasonably be expected to have a Material Adverse Effect;

c. This Amendment constitutes the valid and binding obligation of the Borrower, enforceable against the Borrower in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, or similar laws relating to the enforcement of creditor's rights generally and by general equitable principles; and

d. Subject to the effectiveness of this Amendment, no Event of Default exists.

5. No Further Amendments; Ratification of Liability. Except as amended hereby, the Facility Agreement and each of the other Transaction Documents shall remain in full force and effect in accordance with their respective terms. Borrower as debtor, grantor, pledgor, guarantor or assignor, or in any similar capacity in which it has granted Liens or acted as an accommodation party or guarantor, as the case may be, hereby ratifies, confirms and reaffirms its liabilities, its payment and performance obligations (contingent or otherwise) and its agreements under the Facility Agreement and the other Transaction Documents, all as amended by this Amendment, and the liens and security interests granted, created and perfected thereby. The Purchasers' agreement to the terms of this Amendment or any other amendment of the Facility

Agreement or any other Transaction Document shall not be deemed to establish or create a custom or course of dealing among Borrower, Purchasers, Assignees, or any of them. This Amendment, together with the other Transaction Documents, contains the entire agreement among Borrower and Purchasers contemplated by this Amendment.

6. Covenants. Borrower covenants and agrees (i) not to enter into the Loan Documents unless and until Borrower and Sanofi enter into the Intercreditor Agreement with Purchasers consistent with the terms set forth in Exhibit B attached hereto and (ii) to provide Purchasers with executed copies of all Loan Documents upon their execution.

7. Incorporation by Reference. The provisions of Article 6 of the Facility Agreement are incorporated herein by reference *mutatis mutandis*.

[Remainder of Page Intentionally Left Blank, signature page follows]

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date set forth above.

BORROWER:

MANKIND CORPORATION

By: /s/ David Thomson

Name: David Thomson

Title: General Counsel

PURCHASERS:

DEERFIELD PRIVATE DESIGN FUND II, L.P.

By: Deerfield Mgmt., L.P., its General Partner

By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ David J. Clark

Name: David J. Clark

Title: Authorized Signatory

**DEERFIELD PRIVATE DESIGN INTERNATIONAL II,
L.P.**

By: Deerfield Mgmt., L.P., its General Partner

By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ David J. Clark

Name: David J. Clark

Title: Authorized Signatory

HOECHST GMBH
Industriepark Hoechst
Gebäude K703
D-65926 Frankfurt am Main

PERSONAL AND CONFIDENTIAL

August 11, 2014

MannKind Corporation
28903 North Avenue Paine
Valencia, California 91355

Attention: General Counsel

Commitment Letter

Ladies and Gentlemen:

Reference is made to the License and Collaboration Agreement dated as of August 11, 2014 (the "License Agreement") by and among MannKind Corporation, a Delaware corporation ("MannKind"), Technosphere International C.V., a Dutch limited partnership ("TICV" and, together with MannKind, the "Licensors"), and Sanofi-Aventis Deutschland GmbH, a company organized and existing under the laws of Germany ("Sanofi"). In connection with the consummation of the transactions contemplated by the License Agreement you have requested that Hoechst GmbH (the "Lender") provide a \$175.0 million senior secured revolving credit facility (the "Facility") to MannKind (in such capacity, the "Borrower" or "you") on the terms and subject to the conditions set forth in this Commitment Letter and Exhibit A (collectively, the "Commitment Letter").

1. Commitments

The Lender is pleased to advise you of its commitment to provide to the Borrower the Facility on the terms and subject to the conditions set forth in this Commitment Letter.

2. Conditions Precedent

The Lender's commitment hereunder is subject to the following conditions: (i) the definitive loan documents relating to the Facility, including without limitation a credit agreement (or promissory note), security agreements and other related definitive documents (collectively, the "Loan Documents") shall have been prepared based upon and substantially consistent with the terms set forth in this Commitment Letter and otherwise reasonably satisfactory to the Lender and the Borrower and shall have been executed and delivered by the Borrower, (ii) the Lender shall be reasonably satisfied that the Borrower has complied with all other customary closing conditions, including: (A) the delivery of customary corporate records and documents from public officials and officer's certificates; (B) evidence of authority; and (C) grant and perfection of liens on the collateral to secure the Facility, (iii) the accuracy of the representations and warranties specified in Exhibit A and (iv) the absence of any default or event of default specified in Exhibit A. Notwithstanding the forgoing, the Borrower shall be required only to use commercially reasonable efforts to obtain account control agreements with its depository banks in form and substance reasonably satisfactory to the Lender within 90 days after the Closing Date (as defined in

Exhibit A) and a failure to obtain such account control agreements shall not result in a default provided the Borrower has used commercially reasonable efforts.

3. Indemnification

You hereby agree to indemnify upon demand and hold harmless the Lender and each partner, trustee, shareholder, director, officer, employee, advisor, representative, agent, attorney and controlling person thereof (each of the above, an "Indemnified Person") from and against any and all actions, suits, proceedings (including any investigations or inquiries), claims, losses, damages, liabilities or expenses (including legal expenses), joint or several, of any kind or nature whatsoever that may be brought or threatened by the Borrower, the Guarantors (as defined in Exhibit A), any of their respective affiliates or any other person or entity and which may be incurred by or asserted against or involve any Indemnified Person (whether or not any Indemnified Person is a party to such action, suit, proceeding or claim) arising solely from this Commitment Letter, the Facility, any other Loan Document or any use or intended use of the proceeds of the Facility other than those relating to the License Agreement; provided that you will not have to indemnify an Indemnified Person against any claim, loss, damage, liability or expense to the extent the same resulted directly and primarily from (i) the gross negligence or willful misconduct of such Indemnified Person (to the extent determined by a court of competent jurisdiction in a final and non-appealable judgment) and (ii) a material breach of the obligations of such Indemnified Person under this Commitment Letter (to the extent determined by a court of competent jurisdiction in a final and non-appealable judgment).

Your indemnity and reimbursement obligations under this Section 3 will be in addition to any liability which you may otherwise have and will be binding upon and inure to the benefit of the successors, assigns, heirs and personal representatives of you and the Indemnified Persons.

Neither party nor any other Indemnified Person will be responsible or liable to the other party or any other person or entity for any indirect, special, punitive or consequential damages which may be alleged as a result of this Commitment Letter, the Facility or any related transaction contemplated hereby or thereby or any use or intended use of the proceeds of the Facility; provided that nothing in this paragraph shall limit your indemnity obligations hereunder.

4. Assignments

This Commitment Letter may not be assigned by either party without the prior written consent of the other party (and any purported assignment without such consent will be null and void), is intended to be solely for the benefit of the parties hereto and is not intended to confer any benefits upon, or create any rights in favor of, any person (including either party's equity holders, employees or creditors) other than the parties hereto (and any Indemnified Person). The Lender may assign its commitments and agreements hereunder, in whole or in part, to any of its affiliates (other than to Sanofi-Aventis Deutschland GmbH). Notwithstanding the prior sentence, the parties agree that the Lender shall remain liable for the performance of its obligations hereunder in the case of an assignment by the Lender to any of its affiliates. This Commitment Letter may not be amended or any term or provision hereof waived or modified except by an instrument in writing signed by each of the parties hereto.

5. Waiver of Jury Trial; Governing Law; Submission to Jurisdiction; Surviving Provisions

ANY RIGHT TO TRIAL BY JURY WITH RESPECT TO ANY ACTION, SUIT, PROCEEDING OR CLAIM ARISING IN CONNECTION WITH OR AS A RESULT OF ANY MATTER REFERRED TO IN THIS COMMITMENT LETTER IS HEREBY IRREVOCABLY WAIVED BY THE PARTIES HERETO. THIS COMMITMENT LETTER WILL BE GOVERNED BY

AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK. Each of the parties hereto hereby irrevocably (i) submits, for itself and its property, to the exclusive jurisdiction of (a) the Supreme Court of the State of New York, New York County, located in the Borough of Manhattan and (b) the United States District Court for the Southern District of New York and any appellate court from any such court, in any action, suit, proceeding or claim arising out of or relating to this Commitment Letter the transactions related thereto or the performance of services contemplated hereunder, or for recognition or enforcement of any judgment, and agrees that all claims in respect of any such action, suit, proceeding or claim may be heard and determined in such New York State court or such Federal court, (ii) waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of venue of any action, suit, proceeding or claim arising out of or relating to this Commitment Letter, the transactions related thereto or the performance of services contemplated hereunder in any such New York State or Federal court and (iii) waives, to the fullest extent permitted by law, the defense of an inconvenient forum to the maintenance of any such action, suit, proceeding or claim in any such court. Each of the parties hereto agrees to commence any such action, suit, proceeding or claim either in the United States District Court for the Southern District of New York or in the Supreme Court of the State of New York, New York County located in the Borough of Manhattan.

This Commitment Letter is issued for the benefit of the parties hereto and no other person or entity may rely hereon (other than the Indemnified Persons).

The provisions of Section 3 and this Section 5 of this Commitment Letter will survive any termination or completion of the arrangements contemplated by this Commitment Letter, including without limitation whether or not the Loan Documents are executed and delivered and whether or not the Facility is made available or any loans under the Facility are disbursed; provided, however, that, to the extent covered by the Loan Documents, your obligations under this Commitment Letter shall automatically terminate and be superseded by the corresponding provisions of the Loan Documents upon the effectiveness thereof.

6. Termination

Our commitments hereunder will terminate upon (i) the abandonment or termination of the License Agreement in accordance with the last sentence of Section 15.16 of the License Agreement or (ii) the Lender's receipt from you of written notice of termination of this Commitment Letter.

This Commitment Letter may be executed in any number of counterparts, each of which when executed will be an original and all of which, when taken together, will constitute one agreement. Delivery of an executed counterpart of a signature page of this Commitment Letter by facsimile or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

[The remainder of this page is intentionally left blank.]

Very truly yours,

HOECHST GMBH

By: _____

Name: _____

Title: _____

By: _____

Name: _____

Title: _____

Commitment Letter

ACCEPTED AND AGREED TO AS OF THE DATE FIRST WRITTEN ABOVE:

MANKIND CORPORATION

By: _____
Name:
Title:

Commitment Letter

Exhibit A

Summary of Terms and Conditions of the Facility

This Summary of Terms and Conditions outlines the material terms and conditions of the Facility.

Borrower:	MannKind Corporation (the " <u>Borrower</u> ").
Guarantors:	The entities that are guarantors under that certain Facility Agreement dated as of July 1, 2013, by and among MannKind and the purchasers party thereto (as amended, restated, supplemented or otherwise modified from time to time, the " <u>Deerfield Facility</u> ").
Lender:	Hoechst GmbH (the " <u>Lender</u> ").
Purpose/Use of Proceeds:	The proceeds of the Facility will be used to fund MannKind's Sharing Percentage of any Losses (each as defined in the License Agreement) (the " <u>Loss Amount</u> ").
Facility:	A \$175.0 million senior secured revolving credit facility (the " <u>Facility</u> ").
Availability:	Amounts available under the Facility may be borrowed, repaid and reborrowed after the Closing Date (as defined below) until the Maturity Date (as defined below); <u>provided</u> that, no amounts under the Facility may be borrowed after the occurrence or during the continuance of an "Event of Default" under the Deerfield Facility that has resulted in the lender under the Deerfield Facility commencing enforcement proceedings with respect to its rights thereunder. The Facility shall only be borrowed on a quarterly basis and each borrowing shall not exceed the Loss Amount for the fiscal quarter most recently ended. No Loss Amount may be carried forward to the next succeeding fiscal quarter.
Closing Date:	The date on which the Loan Documents are executed in accordance with the Commitment Letter (the " <u>Closing Date</u> ") which in no event shall be later than the "Effective Date" as that term is defined in the License Agreement (the " <u>License Effective Date</u> ").
Maturity:	The maturity date (the " <u>Maturity Date</u> ") will be the tenth anniversary of the License Effective Date.
Amortization:	None. Payable in full on the Maturity Date.
Interest Rate:	All amounts outstanding under the Facility will bear interest at a rate <i>per annum</i> equal to 8.5% (2.06% per quarter compounded), and shall be paid-in-kind.
Default Interest:	Upon the occurrence and during the continuance of any payment or insolvency event of default, interest will accrue at a rate of 2.0% <i>per</i>

annum plus the rate otherwise applicable thereto on any amount then outstanding and will be payable on demand.

Interest Payments:

Quarterly; payable in-kind in arrears and computed on the basis of a 360-day year.

Voluntary Prepayments:

The Facility may be prepaid in whole or in part upon 5 business day's prior written notice without premium or penalty.

Mandatory Prepayments:

The Borrower shall prepay the Facility in an amount equal to 100% of MannKind's Sharing Percentage of any Profit (as defined in the License Agreement), payable no later than 30 days following the date of receipt; provided that any voluntary prepayments made by the Borrower during the relevant quarter shall be credited against any amount payable as a result of MannKind's Sharing Percentage of any Profit.

Collateral:

The obligations of the Borrower and the Guarantors under the Facility will be secured by a perfected (x) first priority security interest in any insulin located in Danbury, CT owned by the Borrower and its subsidiaries and any contractual rights and obligations pursuant to which the Borrower purchases or has purchased such insulin and (y) second priority security interest in all assets of the Borrower and the Guarantors required to be secured pursuant to the Deerfield Facility; provided that the Lender shall have a first priority mortgage on the real property and improvements thereon located at 28903 North Avenue Paine, Valencia, California 91355; provided further that Lender agrees to release the mortgage on the Valencia facility if the Valencia facility is sold as long as the net cash proceeds of such sale are used to prepay the loan under the Facility and the maximum limit available to be borrowed under the Facility is reduced accordingly.

Intercreditor Agreement:

The Lender and the lender under the Deerfield Facility shall agree to negotiate in good faith an intercreditor agreement reflecting the principles set forth in the attachment to the Intercreditor Principles Agreement dated as of August 11, 2014, between the Lender and the lender under the Deerfield Facility.

Representations and Warranties:

The Facility will contain only the following representations and warranties by the Borrower and the Guarantors (subject to customary exceptions, baskets and thresholds to be agreed): organization, requisite power and authority, qualification; due authorization; no conflict with any material agreements listed on the Borrower's most recently filed annual report on Form 10-K or subsequent quarterly reports on Form 10-Q; any governmental consents related to the Loan Documents; compliance with laws; binding obligation; adverse proceedings relating to any Loan Document or the performance by the Borrower or any Guarantor thereunder; payment of taxes; no defaults; solvency; and security documents.

Exhibit A-2

Covenants:

The Facility will contain only the following affirmative and negative covenants by the Borrower and the Guarantors (subject to customary exceptions, baskets and thresholds to be agreed and including, without limitation, any exceptions, baskets or carve-outs included in the Deerfield Facility):

Affirmative covenants: existence; payment of taxes and claims; compliance with laws; use of proceeds; notices; additional collateral; and further assurances.

Negative covenants: indebtedness (which shall permit the Deerfield Facility and any refinancing thereof in an amount not to exceed \$160,000,000 and shall include the ability to reborrow such amounts upon the conversion of some or all of the existing indebtedness under the Deerfield Facility into equity); liens; and amendments or waivers of organizational documents in a manner that is materially adverse to the interest of the Lender.

Events of Default:

The Facility will include only the following events of default (subject to customary exceptions, baskets, thresholds and cure periods to be agreed): failure to make payments when due; breach of certain covenants; breach of representations; other defaults under Loan Documents; involuntary bankruptcy; voluntary bankruptcy; dissolution; failure to maintain the valid perfected security interest having the applicable priority purported to be granted under the security documents, the failure of any other Loan Document to be a valid binding obligation of the parties thereto enforceable in accordance with its terms or the Borrower or any guarantor shall so state in writing; and termination of the License Agreement by Sanofi as a result of a breach thereof by MannKind. For the avoidance of doubt the Loan Documents shall not contain a cross default to other indebtedness, including but not limited to the Deerfield Facility.

In the event of any event of default mentioned above relating to the failure to make payments when due; breach of the negative covenants relating to the incurrence of indebtedness or creation of liens; involuntary bankruptcy; voluntary bankruptcy; dissolution; failure to maintain the valid perfected security interest having the applicable priority purported to be granted under the security documents, the failure of any other Loan Document to be a valid binding obligation of the parties thereto enforceable in accordance with its terms or the Borrower or any guarantor shall so state in writing; or termination of the License Agreement by Sanofi as a result of a breach by MannKind of the non-compete obligations in Section 2.8(a) of the License Agreement; the Lender shall have the right but not the obligation to accelerate the amounts due under the Facility and cause the same to become immediately due and payable. In the event of any other event of default listed above, the Lender's remedy shall be to terminate the commitment to make additional loans to the Borrower but the Lender shall not have the right to accelerate the amounts outstanding under

the Facility or to otherwise cause any such obligations to become due and payable prior to the Maturity Date.

**Conditions Precedent to
Closing Date:**

The conditions set forth or referred to in Section 2 of the Commitment Letter.

Indemnity and Expenses:

The Facility will provide customary and appropriate provisions relating to indemnity and related matters in a form acceptable to the Lender. The Borrower will also pay all out-of-pocket expenses of the Lender (including the reasonable fees, disbursements and other charges of counsel) in connection with the enforcement of the Loan Documents or in any bankruptcy case or insolvency proceeding.

**Governing Law and
Jurisdiction:**

New York.

Exhibit A-4

Intercreditor Principles Agreement

Reference is made to (i) that certain Facility Agreement dated as of July 1, 2013 (as amended, restated, supplemented or otherwise modified from time to time, the "Deerfield Facility"), by and among MannKind Corporation ("MannKind") and the purchasers party thereto (the "Deerfield Lenders") and (ii) that certain Commitment Letter dated as of August 11, 2014 (the "Commitment Letter"), by and among Hoechst GmbH (the "Sanofi Lender") and MannKind.

The Deerfield Lenders and the Sanofi Lender hereby agree that (i) the Deerfield Lenders will have a first priority lien on all of the assets of MannKind and the other guarantors under the Deerfield Facility designated as collateral under the Deerfield Facility (the "Deerfield Lenders' First Lien Collateral"), (ii) (a) the Sanofi Lender will have a second priority lien on the Deerfield Lenders' First Lien Collateral (the "Sanofi Lender's Second Lien Collateral") and (b) the Sanofi Lender will have a first priority lien on (x) any insulin inventory located in the United States and (y) the real property of MannKind located in Valencia, CA (clauses (x) and (y), the "Sanofi Lender's First Lien Collateral") and (iii) the Deerfield Lenders will have no lien on the Sanofi Lender's First Lien Collateral. It is further agreed that the terms attached hereto as Exhibit A will be incorporated into an intercreditor agreement between the Deerfield Lenders and the Sanofi Lender.

This Intercreditor Principles Agreement may be executed in any number of counterparts, each of which when executed will be an original, and all of which, when taken together, will constitute one agreement. Delivery of an executed counterpart of a signature page of this Intercreditor Principles Agreement by facsimile or other electronic transmission will be effective as delivery of a manually executed counterpart hereof. This Intercreditor Principles Agreement constitutes the entire contract between the parties hereto with respect to the subject matter hereof and supersede all previous agreements and understandings, oral or written, with respect thereto. This Intercreditor Principles Agreement and the rights and obligations of the parties hereunder will be governed by and construed in accordance with the laws of the State of New York without regard to conflict of law principles that would result in the application of any law other than the law of the State of New York.

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Accepted and Agreed to as of August 11, 2014:

DEERFIELD PRIVATE DESIGN FUND II, L.P.

By: Deerfield Mgmt., L.P., its General Partner

By: J.E. Flynn Capital, LLC, its General Partner

By: _____
Name: David J. Clark
Title: Authorized Signatory

DEERFIELD PRIVATE DESIGN INTERNATIONAL II, L.P.

By: Deerfield Mgmt., L.P., its General Partner

By: J.E. Flynn Capital, LLC, its General Partner

By: _____
Name: David J. Clark
Title: Authorized Signatory

Intercreditor Principles Agreement

By: _____
Name:
Title:

By: _____
Name:
Title:

Intercreditor Principles Agreement

Exhibit A

- (i) If a default has occurred under the Deerfield Facility and the Deerfield Lenders have accelerated their indebtedness, any payment or distribution of any character by or on behalf of MannKind, whether in cash, securities or other property, that constitutes or is traceable to proceeds of the Deerfield Lender's First Lien Collateral, that is received by the Sanofi Lender before the Obligations (as defined in the Deerfield Facility) to the Deerfield Lenders shall have been paid in full in cash, shall be held in trust by the Sanofi Lender for the benefit of, and shall be paid over to the Deerfield Lenders, to the extent necessary to pay the Obligations due to them in full in cash.
- If a default has occurred under the loan provided by the Sanofi Lender to MannKind (such loan, the "Sanofi Loan") and the Sanofi Lender has accelerated its indebtedness, any payment or distribution of any character by or on behalf of MannKind, whether in cash, securities or other property, that constitutes or is traceable to proceeds of the Sanofi Lender's First Lien Collateral, that is received by the Deerfield Lenders before the obligations to the Sanofi Lender shall have been paid in full in cash, shall be held in trust by the Deerfield Lenders for the benefit of, and shall be paid over to the Sanofi Lender, to the extent necessary to pay the obligations due to the Sanofi Lender in full in cash.
- (ii) Prior to the payment in full in cash of the Obligations to the Deerfield Lenders or the obligations to the Sanofi Lender, as the case may be, the Deerfield Lenders shall have the exclusive right (as between the Deerfield Lenders and the Sanofi Lender) to manage, perform and enforce the terms of the Deerfield Facility with respect to the Deerfield Lenders' First Lien Collateral, and the Sanofi Lender shall have the exclusive right (as between the Deerfield Lenders and the Sanofi Lender) to manage, perform and enforce the terms of the loan documents related to the Sanofi Loan with respect to the Sanofi Lender's First Lien Collateral, and each party shall have the exclusive right to exercise and enforce all of their respective privileges and rights thereunder according to their sole discretion and the exercise of their sole business judgment, including the exclusive right to exercise all of their respective rights and remedies as secured lenders under the UCC with respect to assets of MannKind on which they have first liens.
- (iii) In the event of any voluntary or involuntary insolvency or bankruptcy proceedings, or any receivership, liquidation, reorganization or other similar proceedings in connection therewith relative to MannKind or to its property, then (a) the Sanofi Lender shall be paid in full in cash from the proceeds of the Sanofi Lender's First Lien Collateral in respect of all of the obligations due to it from MannKind, including without limitation, any interest due and payable thereunder whether or not such interest is an allowed claim in such proceeding before the Deerfield Lenders are entitled to receive (whether directly or indirectly), or make any demands for, any payment from the proceeds of the Sanofi Lender's First Lien Collateral; and (b) the Deerfield Lenders shall be paid in full in cash from the proceeds of the Deerfield Lenders' First Lien Collateral in respect of all of the

Obligations due to it from MannKind, including without limitation, any interest due and payable thereunder whether or not such interest is an allowed claim in such proceeding before the Sanofi Lender is entitled to receive (whether directly or indirectly), or make any demands for, any payment from the proceeds of the Deerfield Lenders' First Lien Collateral;

- (iv) The Sanofi Lender may not offer Debtor in Possession financing unless any such financing does not (a) provide for liens or claims that are senior or equal to the liens or adequate protection claims of the Deerfield Lenders with respect to the Deerfield Lenders' First Lien Collateral, (b) require a specific plan of reorganization or the sale of assets prior to a default, (c) require payment in cash upon plan confirmation the source of which, in whole or in part, is the Deerfield Lenders' First Lien Collateral unless the Obligations due to the Deerfield Lenders are first paid in full in cash or (d) have provisions that are otherwise inconsistent with terms of this term sheet.

The Deerfield Lenders may not offer Debtor in Possession financing unless any such financing does not (a) provide for liens or claims that are senior or equal to the liens or adequate protection claims of the Sanofi Lender with respect to the Sanofi Lender's First Lien Collateral, (b) require a specific plan of reorganization or the sale of assets prior to a default, (c) require payment in cash upon plan confirmation the source of which, in whole or in part, is the Sanofi Lender's First Lien Collateral unless the obligations due to the Sanofi Lender are first paid in full in cash or (d) have provisions that are otherwise inconsistent with terms of this term sheet.

- (v) The Sanofi Lender will not object to relief from stay or adequate protection requested by the Deerfield Lenders with respect to the Deerfield Lenders' First Lien Collateral so long as any such adequate protection does not provide for liens that are senior or equal to the liens or adequate protection claims of the Sanofi Lender with respect to the Sanofi Lender's First Lien Collateral;

The Deerfield Lenders will not object to relief from stay or adequate protection requested by the Sanofi Lender with respect to the Sanofi Lender's First Lien Collateral so long as any such adequate protection does not provide for liens that are senior or equal to the liens or adequate protection claims of the Deerfield Lenders with respect to the Deerfield Lenders' First Lien Collateral;

- (vi) The Sanofi Lender will not request relief from the stay with respect to their second lien on the Deerfield Lenders' First Lien Collateral;
- (vii) Following (a) acceleration of the Deerfield Facility or (b) the commencement of a proceeding under the Bankruptcy Code or any other Federal, state or foreign bankruptcy, insolvency, receivership or similar law by or against any grantor, the Sanofi Lender may request within 30 days thereof to purchase all, but not less than all, of the aggregate amount of the Deerfield Facility outstanding at the time of purchase at par; and

- (viii) The Deerfield Lenders and the Sanofi Lender will agree to additional terms as are appropriate and customary for an intercreditor agreement of this nature, including waivers of marshaling, appraisal, valuation and similar rights and waiver of any claims under Sections 506(c) and 552 of the Bankruptcy Code.

***Text Omitted and Filed Separately with
the Securities and Exchange Commission.
Confidential Treatment Requested Under
17 C.F.R. Sections 200.80(b)(4) and 240.24b-2.

EXECUTION VERSION

LICENSE AND COLLABORATION AGREEMENT

This LICENSE AND COLLABORATION AGREEMENT (the “*Agreement*”) is entered into as of August 11, 2014 (the “*Execution Date*”) between MANNKIND CORPORATION, a Delaware corporation, having a principal place of business at 28903 North Avenue Paine, Valencia, California 91355, USA (“*MannKind*”), TECHNOSPHERE INTERNATIONAL C.V., a Dutch limited partnership, having a principal place of business at 1097 JB Amsterdam, Prins Bernhardplein 200, Netherlands (“*TICV*”), MANNKIND NETHERLANDS B.V., a Dutch limited liability company, having a principal place of business at 1097 JB Amsterdam, Prins Bernhardplein 200, Netherlands (“*BV*” and together with MannKind and TICV, jointly and severally, the “*Licensors*”), and SANOFI-AVENTIS DEUTSCHLAND GMBH, a company organized and existing under the laws of Germany with a place of business at 65926 Frankfurt am Main, Germany (“*Sanofi*”).

RECITALS

WHEREAS, MannKind has developed and has obtained regulatory approval in the United States (as defined below) of Product (as defined below) for improvement of glycemic control in adult patients with diabetes and owns or controls certain patents, know-how and other intellectual property related to Product;

WHEREAS, Sanofi is engaged in the development and commercialization of pharmaceutical products; and

WHEREAS, Sanofi desires to obtain from the Licensors, and the Licensors desire to grant to Sanofi, certain exclusive rights and licenses to develop and commercialize Product in the Territory subject to the terms and conditions of this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

As used in this Agreement, the following terms shall have the meanings set out in this Article I unless otherwise specifically provided herein.

1.1 “*Adverse Ruling*” shall have the meaning set forth in Section 12.2(a).

1.2 “*Affiliate*” of a Party shall mean any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Party, as the case may be, but for only so long as such control exists. As used in this Section 1.2,

“control” shall mean: (a) direct or indirect beneficial ownership of at least 50% (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such Person; or (b) any other arrangement whereby a Person, acting alone, or a “group,” as defined in Rule 13d-3 of the Securities Exchange Act of 1934, as amended, of Third Parties (a “**Group**”), (i) controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or (ii) has the ability to cause the direction of the management or policies of a corporation or other entity. For clarity, TICV and BV are Affiliates of MannKind.

1.3 “**Alliance Manager**” shall have the meaning set forth in Section 3.2.

1.4 “**Allowable Expenses**” shall have the meaning set forth on **EXHIBIT B** hereto.

1.5 “[...***...]” shall mean [...***...]

1.6 “**Antitrust Laws**” shall mean the Clayton Act, as amended, the HSR Act, and all other applicable laws and regulations issued by a Governmental Authority, whether domestic or foreign, that are designed or intended to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade or lessening of competition.

1.7 “**Applicable Laws**” shall mean the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including Marketing Approvals) of or from any court, arbitrator, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item.

1.8 “**Audited Party**” shall have the meaning set forth in Section 7.5.

1.9 “**Auditing Party**” shall have the meaning set forth in Section 7.5.

1.10 “**Auditor**” shall have the meaning set forth in Section 7.5.

1.11 “**Bankruptcy Laws**” shall have the meaning set forth in Section 13.6.

1.12 “**Biosimilar Application**” shall have the meaning set forth in Section 9.8(a).

1.13 “**Breaching Party**” shall have the meaning set forth in Section 12.2(a).

1.14 “[...***...] **Country**” shall mean any of the following countries: [...***...].

1.15 “**Budget(s)**” shall mean the Development Budget, and the Commercialization Budget.

1.16 “**Business Day**” shall mean a day other than a Saturday or Sunday or any public holiday in the United States, France or Germany.

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1.17 “Calendar Quarter” shall mean a period of three consecutive months during a Calendar Year beginning on and including January 1st, April 1st, July 1st or October 1st.

1.18 “Calendar Year” shall mean a period of 12 consecutive months beginning on and including January 1st.

1.19 “Challenge” shall have the meaning set forth in Section 12.4.

1.20 “Change of Control” means, with respect to a Party (or in the case of Licensors and solely for purposes of this definition, any of MannKind, TICV or BV separately):

(a) (i) the acquisition by a Third Party or Group, in one transaction or a series of related transactions, of direct or indirect beneficial ownership of more than fifty percent (50%) of the outstanding voting equity securities of a Party; (ii) a merger or consolidation involving a Party, as a result of which a Third Party or a Group acquires direct or indirect beneficial ownership of more than fifty percent (50%) of the voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (iii) a sale of all or substantially all of the assets of a Party in one transaction or a series of related transactions to a Third Party or a Group; or

(b) the acquisition by a [...***...], in one transaction or a series of related transactions, of: (i) majority control of the board of directors or equivalent governing body of such Party; or (ii) direct or indirect beneficial ownership of more than [...***...] percent ([...***...]%) of the outstanding voting equity securities of a Party; or (iii) the ability to cause the direction of the management or allocation of corporate resources of such Party (provided that [...***...], shall not be deemed to be a Change of Control under this sub-clause (iii) so long as [...***...]; or (iv) all or substantially all of the assets of such Party related to the transactions contemplated by this Agreement.

1.21 “CMC” shall mean chemistry, manufacturing and controls.

1.22 “Commercialize” (including any variations such as “**Commercialization**” or “**Commercializing**”) shall mean, with respect to a Product, to promote, market, distribute, sell (and offer for sale or contract to sell), import, or otherwise commercially exploit or provide product support for such Product.

1.23 “Commercialization Budget” shall mean the budget for activities within the Commercialization Plan for conducting Commercialization activities with respect to Product in the Field in the Territory established on a Calendar Year basis by Sanofi for review and approval by the JAC.

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1.24 “**Commercialization Plan**” shall have the meaning set forth in Section 5.1(b).

1.25 “**Commercially Reasonable Efforts**” shall mean:

(a) With respect to efforts of Sanofi as measured on a country by country basis: that measure of efforts and resources consistent with Sanofi’s and its Affiliates’ own efforts and resources applied to its and their own compounds, devices and products of a similar value, stage of development, life cycle and commercial potential, taking into account all relevant factors including issues of safety and efficacy, product profile, difficulty in developing or manufacturing the applicable Product or sourcing raw materials necessary therefor, competitiveness of alternative third party products in the marketplace, regulatory approvals (including pricing approvals), pricing and reimbursement, the patent or other proprietary position of the applicable Product, the regulatory requirements involved and the potential profitability of the applicable Product for Sanofi and its Affiliates as compared to the expected profitability of other products of its then current or in development product portfolios; and

(b) With respect to efforts of the Licensors: the use of reasonable efforts and resources, in good faith, consistent with the efforts and resources that a pharmaceutical or biotechnology company of similar size and situation to the Licensors, in the exercise of prudent legal, medical, scientific and business judgment, would commonly apply to its own compounds, devices and products of a similar value, stage of development, life cycle and commercial potential to the applicable Product.

1.26 “**Commercial Strategy**” shall have the meaning set forth in Section 5.1(a).

1.27 “**Competing Product**” shall mean any product (other than Product) containing or comprising any formulation of Insulin that is or is intended to be primarily administered in or through the lungs.

1.28 “**Complaining Party**” shall have the meaning set forth in Section 12.2(a).

1.29 “**Confidential Information**” shall have the meaning set forth in Section 8.1.

1.30 “**Confidentiality Agreement**” shall mean that certain confidentiality agreement, dated May 31, 2013, between MannKind and Sanofi, as amended.

1.31 “**Control**” (including any variations such as “**Controlled**” and “**Controlling**”), in the context of intellectual property rights and Information, shall mean possession by a Party (whether by ownership or license, other than pursuant to this Agreement) of the ability to grant the applicable license under this Agreement, without violating the terms of an agreement with a Third Party.

1.32 “**Data**” shall mean any and all scientific, technical or test data pertaining to Product that is generated by or on behalf of Sanofi or its Affiliates or by or on behalf of MannKind or a MannKind Affiliate in the course of performance of studies or activities contemplated by the Development Plan or this Agreement, including research data, clinical pharmacology data, CMC data (including analytical and quality control data and stability data),

pre-clinical data, clinical data and pharmacoeconomic data, including any and all such data in publications, presentations or submissions made in association with a Regulatory Filing with respect to Product.

1.33 “Development” or “Develop” shall mean, with respect to a Product, those pre-clinical and clinical drug development activities that are necessary or useful to obtain or maintain Marketing Approval, including activities directed to label expansion after obtaining Marketing Approval that are set forth in the Development Plan, in the applicable regulatory jurisdiction, whether alone or for use together, or in combination, with another active agent or pharmaceutical product, including discovery, test method development, stability testing, toxicology (including [...***...] toxicology studies), formulation or process development, CMC development, analytical method validation, manufacturing process validation, cleaning validation, post-Marketing Approval changes, statistical analysis, development report writing, preclinical and clinical studies, regulatory filing submission and approval, all activities of the medical affairs, pharmacovigilance, regulatory, medical liaison and health outcome liaison groups with respect to the activities contemplated under this Agreement, and any other activities set forth in any Development Plan.

1.34 “Development Budget” shall mean the budget, established on a Calendar Year basis and reviewed and approved by the JAC, for activities within the Development Plan for conducting Development activities with respect to Product in the Field in the Territory, established on a Calendar Year basis by Sanofi for review and approval by the JAC.

1.35 “Development Plan” shall mean the written plan setting forth the studies and other activities to be performed by the Parties with respect to the Development of Product in the Field in the Territory, established by Sanofi and reviewed and approved by the JAC, as may be amended. A summary of the initial Development Plan has been separately delivered by letter as of the Execution Date.

1.36 “Development Term” shall mean the period during which the Parties are conducting studies and activities with respect to Product in the Field in the Territory under the Development Plan, commencing on the Effective Date and ending upon the completion of all studies and activities specified in the Development Plan or earlier termination of this Agreement.

1.37 “Device” shall mean any device through which a Formulation may be administered by inhalation, including the devices Controlled by the Licensors, such as the Dreamboat™, MedTone® and Cricket™ inhalers.

1.38 “Diabetes” shall mean diabetes mellitus, regardless of type.

1.39 “[...*...] shall mean, [...***...].**

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1.40 “**Disclosing Party**” shall have the meaning set forth in Section 8.1.

1.41 “**Effective Date**” shall have the meaning set forth in Section 15.16.

1.42 “**Export Control Laws**” shall mean all applicable laws and regulations relating to (a) sanctions and embargoes imposed by any governmental authority in the Territory or (b) the export or re-export of commodities, technologies, or services, including, but not limited to, the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 *et seq.*, the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

1.43 “**FCPA**” shall mean the U.S. Foreign Corrupt Practices Act (15 U.S.C. § 78dd-1, *et seq.*) as amended.

1.44 “**FDA**” shall mean the United States Food and Drug Administration, or any agency that is responsible for approving the sale of pharmaceutical products in the United States.

1.45 “**Field**” shall mean the prevention or treatment of diseases and other conditions in all indications in humans and animals.

1.46 “**Filings**” shall have the meaning set forth in Section 15.16.

1.47 “**First Commercial Sale**” shall mean, on a Competing Product-by-Competing Product and country-by-country basis, the first *bona fide*, arm’s length sale by, on behalf of or under the authority of Sanofi, its Affiliates or sublicensees to a Third Party, of Competing Product in a country in the Field in the Territory following receipt of Marketing Approval in such country. Sales of a Competing Product for registration samples, clinical trials, compassionate use, named patient use and inter-company transfers to Affiliates of a Party will not constitute a First Commercial Sale.

1.48 “**Formulation**” shall mean a formulation of an active pharmaceutical ingredient suitable for pulmonary administration based upon or incorporating the drug delivery technology Controlled by the Licensors that involves amorphous or crystalline diketopiperazine microparticles.

1.49 “[...***...] **Milestone**” shall mean [...***...].

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[...***...] For the avoidance of doubt, if [...***...].

1.50 “Governmental Authority” shall mean any national, international, federal, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.51 “Government Health Care Program” shall mean the Medicare Part D Coverage Gap Discount program (as defined in 42 U.S.C. 1395w-114A, as amended), the Medicaid program (Title XIX of the Social Security Act), the Department of Veterans Affairs FSS Program, TRICARE, and the Public Health Service 340B Program, and any similar federal, state, and local governmental health care plans and programs.

1.52 “Government Health Care Program Contract” shall mean, with respect to Product, any agreements that are necessary to give effect to any Government Health Care Program (whether or not such agreements constitute “government contracts” as such term is used in connection with government procurement, e.g. 340B Pharmaceutical Pricing Agreements and Medicaid Drug Rebate Agreements).

1.53 “HSR Act” shall have the meaning set forth in Section 15.16.

1.54 “HSR Filing Date” shall have the meaning set forth in Section 15.16.

1.55 “ICH” shall mean the International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use).

1.56 “IFRS” shall mean the international financial reporting standards.

1.57 “IND” shall mean an Investigational New Drug Application (including any amendments thereto) filed with the FDA pursuant to 21 C.F.R. §312 before commencement of clinical trials of a pharmaceutical product, including clinical trial applications, or any comparable filing with any Regulatory Authority in any country or jurisdiction in the Territory other than the United States.

1.58 “Indemnitee” shall have the meaning set forth in Section 11.3.

1.59 “Indemnitor” shall have the meaning set forth in Section 11.3.

1.60 “Information” shall mean all technical, scientific, marketing, financial, commercial and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs,

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apparatuses, prototypes, specifications, data, including raw data, results, customer lists, marketing materials, and other material, including: drug discovery and development technology; biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; assays and biological methodology; manufacturing and quality control procedures and data, including test procedures; and synthesis, purification and isolation techniques (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed.

1.61 “Insulin” shall mean human insulin and analogs and derivatives thereof.

1.62 “[...*...] Milestone”** shall mean [...***...].

1.63 “[...*...] Milestone”** shall mean [...***...].

1.64 “Intervening Event” shall have the meaning set forth in Section 15.1.

1.65 “Inventions” shall mean any and all inventions, discoveries, improvements, processes and techniques invented in the course of performance of studies or activities contemplated by the Development Plan or this Agreement, whether or not patentable or included in any claim of Patents and Patent applications, constituting an improvement or line extension associated with Product.

1.66 “JAC” shall have the meaning set forth in Section 3.1(a).

1.67 “Joint Inventions” shall mean any and all Inventions invented by one or more employees or contractors of Sanofi or any of its Affiliates and one or more employees or contractors of the Licensors or any MannKind Affiliate.

1.68 “Joint Patents” shall mean all Patents claiming any Joint Invention.

1.69 “Losses” shall have the meaning set forth in Section 11.1.

1.70 “MAA” shall mean a New Drug Application as defined in Title 21 of the U.S. Code of Federal Regulations, Section 314.80, et seq., or comparable filing with any Regulatory Authority in any country or jurisdiction in the Territory other than the United States, and all amendments and supplements thereto, which is filed with the FDA, including all documents,

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data, and other information concerning a pharmaceutical product which are necessary for gaining Marketing Approval in the Territory.

1.71 “**Major Market**” shall mean any of the following countries: [...***...].

1.72 “**MannKind Affiliate**” shall mean any Affiliate of the Licensors that is controlled (as such term is defined in Section 1.2) by any of the Licensors. For clarity, TICV and BV are MannKind Affiliates.

1.73 “**MannKind Indemnitees**” shall have the meaning set forth in Section 11.1.

1.74 “**MannKind Know-How**” shall mean all Information not included in the MannKind Patents Controlled by the Licensors or any MannKind Affiliate as of the Effective Date or during the Term that is necessary or useful for the Development, Manufacture, use or Commercialization of Product in the Field, including all such Information related to the design and utility of the Device and to the creation of a Formulation, and any replication or any part of such Information.

1.75 “**MannKind Patents**” shall mean all Patents Controlled by MannKind or any MannKind Affiliate as of the Effective Date or during the Term that claim or disclose Product or its components, or are necessary or useful for the Development, Manufacture, use or Commercialization of Product in the Field in the Territory, including all such Patents claiming or covering the design or utility of a Device or a Formulation, but excluding any Joint Patents. The MannKind Patents existing as of the Execution Date are listed in **EXHIBIT C**.

1.76 “**MannKind Technology**” shall mean all MannKind Know-How, MannKind Patents and MannKind’s or a MannKind Affiliate’s interest in Joint Patents and Joint Inventions.

1.77 “**MannKind Trademarks**” shall have the meaning set forth on **EXHIBIT A**.

1.78 “**Manufacture**” or “**Manufacturing**” shall mean all activities related to the manufacturing, packaging and supply of a pharmaceutical product, or any component thereof, including manufacturing product, components thereof or supplies for Development, clinical trials, and/or commercial sale; in-process and semi-finished product testing; release of product or any components thereof; quality assurance activities related to manufacturing and release of product; ongoing stability tests and regulatory activities related to any of the foregoing, and packaging of products ready for distribution and sale.

1.79 “**Marketing Approval**” shall mean all approvals, licenses, registrations or authorizations of Regulatory Authorities in a country necessary for the Manufacture, use, storage and Commercialization of Product in such country. For countries where governmental approval is required for pricing or reimbursement for Product to be reimbursed by national health insurance (or its local equivalent), “Marketing Approval” shall not be deemed to occur until such pricing or reimbursement approval is obtained.

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1.80 “Master Files” shall mean all drug master files and device master files relating to Product filed or that may be filed with any Regulatory Authority in any country or jurisdiction in the Territory.

1.81 “Materials” shall have the meaning set forth in Section 4.5.

1.82 “NDC” shall have the meaning set forth in Section 13.3(c).

1.83 “Net Sales” shall mean, with respect to a Product for any period, the gross amount billed or invoiced by Sanofi or its Affiliates for the sale of a Product to Third Parties, less the following deductions from such gross amounts, solely to the extent allocable to such Product and actually incurred, allowed or accrued (and not previously deducted in calculating the amount invoiced):

(a) normal and customary trade, quantity and prompt settlement discounts (including chargebacks and allowances) actually allowed;

(b) amounts repaid or credited by reason of rejection, return or recall of Product;

(c) rebates or bona fide retroactive price reductions;

(d) freight, postage, shipping and insurance expenses to the extent that such items are included in the gross amount invoiced;

(e) customs and excise duties and other taxes or duties related to the sales to the extent that such items are included in the gross amount invoiced;

(f) rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration, federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental program;

(g) the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to such product; and

(h) bad debts and uncollectable invoiced amounts relating to sales of Product that are actually written off in accordance with IFRS, consistently applied throughout Sanofi and its Affiliates, provided that any such amounts subsequently collected will be included in Net Sales.

For purposes of determining Net Sales, a Product shall be deemed to be sold when invoiced and a “sale” shall not include transfers or dispositions of such Product for pre-clinical or clinical purposes, compassionate use or as samples, in each case, without charge. Sanofi’s or its Affiliates’ transfer of any Product to an Affiliate or sublicensee shall not result in any Net Sales unless the transferee is an end user. In the event of any sale or other disposition of a Product for any consideration other than exclusively monetary consideration on *bona fide* arm’s-length terms, then for purposes of calculating Net Sales under this Agreement, such Product shall

be deemed to be sold exclusively for money at the weighted (by sales volume) average sale price of such Product in *bona fide* arm's-length transactions (when sold alone, and not with other products) during the applicable Calendar Quarter in the country in which such sale or other disposition occurred.

To the extent that Sanofi or its Affiliate provides to any Third Party purchaser of Product rebates, discounts or other forms of reimbursements within the permissible deductions described in clauses (a), (c) and (f) above that, in each case, are applicable both to Product and one or more other products, such rebates, discounts and reimbursements shall be allocated (for purposes of the deductions used in calculating Net Sales as above) between the Product and such other product(s) in a manner such that the reimbursements, discounts and reimbursements allocated to the Product are the lesser of: (x) a *pro rata* allocation between the Product and such other product(s) that does not unfairly or inappropriately bias the level of discounting against the Product (as compared to the other product(s)), or (y) the weighted average of rebates, discounts and reimbursements that are granted by Sanofi or its Affiliate with respect to Product (during the applicable Calendar Quarter) when Product is sold outside of any such arrangement.

All adjustments for any of clauses (a) to (h) above will be made in a manner consistent with adjustments applied to comparable products of Sanofi and its Affiliates and will not be applied disproportionately with respect to Product. In no event shall any particular amount described in clauses (a) to (h) above, be deducted more than once in calculating Net Sales (*i.e.*, no double-counting of deductions), and no such amount deducted in calculating Net Sales shall be considered an Allowable Expense.

Except as expressly set forth above in this Section 1.83, Net Sales shall be calculated in accordance with the standard internal policies and procedures of Sanofi and its Affiliates, consistently applied across all comparable products of Sanofi and its Affiliates, which must be in accordance with IFRS.

1.84 "Notice Period" shall have the meaning set forth in Section 12.2(a).

1.85 "Partial Termination" shall have the meaning set forth in Section 13.1.

1.86 "Party" shall mean the Licensors (considered together as one "**Party**") or Sanofi individually, and "**Parties**" shall mean the Licensors (considered together as one "**Party**") and Sanofi collectively.

1.87 "Patent(s)" shall mean (a) all patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications, and (b) any renewal, division, continuation (in whole or in part), or request for continued examination of any of such patents, certificates of invention and patent applications, and any all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

1.88 “Person” shall mean any individual, corporation, partnership, limited liability company, trust, governmental entity, or other legal entity of any nature whatsoever.

1.89 “PHSA” shall have the meaning set forth in Section 9.8(a).

1.90 “Platform MannKind Patent” shall mean any MannKind Patent that is not a Product-Specific MannKind Patent. The Platform MannKind Patents in existence as of the Execution Date are identified in **EXHIBIT C**. The categorization of any future MannKind Patent as a Platform MannKind Patent shall be determined in good faith by mutual agreement of the Parties.

1.91 “Product” shall mean any product in a form suitable for human applications consisting of (a) a Formulation that contains Insulin as the sole active pharmaceutical ingredient, without any other active ingredients, for use in a Device, (b) a Device, but only to the extent that it is sold (or intended to be sold) for use with such a Formulation described in clause (a), or (c) both a Device and such a Formulation described in clause (a) for use together, in each case, including all improvements thereof. For clarification, Product shall not include a Device to the extent that it is sold (or intended to be sold) for administration of a Formulation that contains an active pharmaceutical ingredient other than solely Insulin.

1.92 “Product-Specific MannKind Patent” shall mean a MannKind Patent that claims or covers no other product or product candidate in addition to Product. The Product-Specific MannKind Patents in existence as of the Execution Date are identified in **EXHIBIT C**. The categorization of any future MannKind Patent as a Product-Specific MannKind Patent shall be determined in good faith by mutual agreement of the Parties.

1.93 “Profit” shall have the meaning set forth on **EXHIBIT B** hereto.

1.94 “Public Official or Entity” shall mean (a) any officer, employee (including physician, hospital administrator, or other healthcare professional), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international organization, including, but not limited to, any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party or any official of a political party.

1.95 “Receiving Party” shall have the meaning set forth in Section 8.1.

1.96 “Regulatory Authority” shall mean any Governmental Authority whose review or approval is necessary for the Manufacture, packaging, use, storage and Commercialization of Product in a given country in the Territory. Where governmental approval is required for pricing or reimbursement for Product to be reimbursed by national health insurance (or its local equivalent), “Regulatory Authority” shall also include any Governmental Authority whose review or approval of pricing or reimbursement is required.

1.97 “Regulatory Filing” shall mean all approvals, licenses, registrations, submissions and authorizations made to or received from a Regulatory Authority necessary for the

Development, Manufacture or Commercialization of the Product, including any INDs, MAAs and Marketing Approvals, excluding Master Files.

1.98 “Responsible Party” shall mean the Party designated as responsible for conducting the applicable clinical or non-clinical studies or other activities under the Development Plan or designated by the JAC as responsible for filing and securing Marketing Approval for Product in the Field in the Territory, as applicable.

1.99 “Sanofi Indemnitees” shall have the meaning set forth in Section 11.2.

1.100 “Sanofi Know-How” shall mean all Information that (a) is Controlled by Sanofi or any of its Affiliates as of the Effective Date or during the Term and (b) is necessary or useful for the Development, Manufacture, use or Commercialization of Product in the Field, expressly excluding any Know-How pertaining to the Manufacture of Insulin.

1.101 “Sanofi Patents” shall mean all Patents Controlled by Sanofi or any of its Affiliates as of the Effective Date or during the Term that are necessary for, or useful for and actually used in, the Development, Manufacture, use or Commercialization of Product in the Field, but excluding any Joint Patents.

1.102 “Sanofi Technology” shall mean all Sanofi Know-How, Sanofi Patents and Sanofi’s or its Affiliate’s interest in Joint Patents and Joint Inventions.

1.103 “SEC” shall mean the U.S. Securities and Exchange Commission, or any successor agency.

1.104 “Service Provider” shall mean any Third Party service provider such as a contract research organization, clinical research organization, contract manufacturing organization, consultant, subcontractor or other independent contractor performing on behalf of a Party such Party’s obligations under this Agreement, but excluding any Third Party to whom a sublicense or license under any MannKind Technology, MannKind Trademarks or Sanofi Technology is granted.

1.105 “Standstill Period” shall have the meaning set forth in Section 15.12.

1.106 “Supply Agreement” shall mean that certain Supply Agreement, effective as of the Effective Date, by and between MannKind and Sanofi-Aventis Deutschland GmbH.

1.107 “Term” shall have the meaning set forth in Section 12.1.

1.108 “Terminated Country” shall have the meaning set forth in Section 13.1.

1.109 “Territory” shall mean all countries of the world, excluding any Terminated Country.

1.110 “Third Party” shall mean any Person other than the Licensors, Sanofi and their respective Affiliates.

1.111 “*Third Party Claims*” shall have the meaning set forth in Section 11.1.

1.112 “*United States*” or “*U.S.*” shall mean the United States of America, including its territories and possessions and the District of Columbia.

1.113 “*Wind-down Period*” shall mean any period after the date of termination of this Agreement during which, pursuant to Section 13.3(a), Sanofi is required to continue to perform certain activities.

1.114 “*Withdrawal Notice*” shall have the meaning set forth in Section 3.4.

ARTICLE 2

GRANT OF LICENSE

2.1 Development Licenses. Subject to the terms and conditions of this Agreement: (a) the Licensors hereby grant to Sanofi an exclusive (except as to MannKind with respect to Development activities to be performed by MannKind pursuant to the Development Plan and subject to the rights reserved by the Licensors pursuant to Section 2.5), worldwide, royalty-free license, with the right to grant sublicenses as provided in Section 2.4, under the MannKind Technology to Develop Product in the Field in accordance with this Agreement; and (b) Sanofi hereby grants to the Licensors a non-exclusive, worldwide, royalty-free license under the Sanofi Technology as is necessary solely for the Licensors to Develop Product in the Field in accordance with this Agreement.

2.2 Commercialization License. Subject to the terms and conditions of this Agreement, the Licensors hereby grant to Sanofi an exclusive, payment-bearing license, with the right to grant sublicenses as provided in Section 2.4, under the MannKind Technology to (a) Manufacture and have Manufactured Product in the Field in the Territory, subject to the terms of and as permitted by the Supply Agreement, and (b) use, Commercialize and have Commercialized Product in the Field in the Territory. The license granted in this Section 2.2 shall be exclusive even as to the Licensors, subject to the rights reserved by the Licensors pursuant to Section 2.5.

2.3 License to MannKind Trademarks. Subject to the terms and conditions of this Agreement, MannKind grants Sanofi the license to the MannKind Trademarks on the terms set forth in **EXHIBIT A**.

2.4 Sublicenses. Sanofi shall have the right to grant sublicenses of the rights granted to it under this Article 2 to any of its Affiliates or Third Parties for the purposes of Development, regulatory, Manufacture and Commercialization activities with respect to Product in the Field in the Territory; *provided, however*, that (a) the prior written consent of MannKind shall be required for sublicenses to any Third Party that include a right of Commercialization in any or all of the Major Markets, such consent not to be unreasonably withheld, conditioned or delayed, and (b) the prior approval of the JAC shall be required for sublicenses to any Third Party that include a right of Commercialization outside the Major Markets. Any sublicense shall be in writing and

on substantially the same (or narrower) license terms as those contained in this Agreement (except that such sublicensee shall not have the right to further sublicense). Sanofi shall be responsible for the acts or omissions of its sublicensees in exercising rights under the sublicense which would constitute a breach hereunder.

2.5 Reserved Rights; No Implied Licenses. Except for the rights and licenses expressly granted in this Agreement, the Licensors retain all rights under their respective intellectual property, including the MannKind Technology and MannKind Trademarks, and Sanofi retains all rights under its intellectual property, including the Sanofi Technology, and no rights shall be deemed granted by one Party to the other Party by implication, estoppel or otherwise. Without limiting the foregoing, the Licensors reserve and retain the right under the MannKind Technology, subject to the terms and conditions of this Agreement (i) to perform Development under the Development Plan pursuant to Article 4, (ii) to Manufacture, have Manufactured and supply Product to Sanofi pursuant to Section 5.2 and the Supply Agreement and (iii) to submit, obtain and maintain Master Files.

2.6 Sanofi Acknowledgment and Negative Covenant.

(a) Sanofi hereby acknowledges that the licenses granted by the Licensors to Sanofi under the MannKind Technology pursuant to this Agreement are expressly limited to the Development, Manufacture and Commercialization of Product in the Field in the Territory.

(b) Sanofi hereby covenants, on behalf of itself and its Affiliates, that neither Sanofi nor any of its Affiliates will: (i) either during or after the Term, infringe any MannKind Patents; (ii) either during, or within the first ten (10) years after the end of, the Term, use any MannKind Know-How (other than MannKind Know-How that is or becomes generally available to the public or otherwise part of the public domain other than through any act or omission of Sanofi or any of its Affiliates in breach of this Agreement) outside the scope of the licenses granted hereunder; or (iii) license or authorize any Third Party to engage in any of the actions described in the preceding clauses (i) and (ii) of this Section 2.6(b).

2.7 [...*...] Product.**

(a) During the Term, if any of the Licensors or any MannKind Affiliate proposes to grant any Third Party (which, solely for purposes of this Section 2.7, shall mean any Person other than a MannKind Affiliate), a license or other rights to develop or commercially exploit any product [...***...] (each, a “[...***...] **Product**”), then, prior to granting any such license or other rights, MannKind shall so notify Sanofi in writing and shall promptly establish and provide Sanofi with access to an electronic data room containing any study results and data generated by or on behalf of the Licensors or MannKind Affiliates with respect to such [...***...] Product (the “**Data Room**”). Subject to the terms and conditions of this Agreement, MannKind hereby grants to Sanofi, during the [...***...] -day period beginning on the date the Data Room is first accessible by Sanofi (the “**Initial Election Period**”), the first right to negotiate with the Licensors for the grant to Sanofi or any of its Affiliates of a license under all intellectual property of the Licensors or the MannKind

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Affiliates pertaining to such [...] Product (a “**Transaction**”), and the Licensors agree not to grant and cause the MannKind Affiliates not to grant any Third Party access to the Data Room, or a license or other rights to develop or commercially exploit such [...] Product during the Initial Election Period.

(b) If Sanofi or any of its Affiliates is interested in negotiating a Transaction with the Licensors, then Sanofi shall so notify the Licensors in writing prior to expiration of the Initial Election Period (such notice, an “**Indication of Interest**”). If Sanofi delivers an Indication of Interest to the Licensors prior to expiration of the Initial Election Period, then Sanofi shall have an additional [...] days from expiration of the Initial Election Period (the “**Due Diligence Period**”) in which to complete due diligence regarding the [...] Product and, if Sanofi or any of its Affiliates in good faith wishes to negotiate with the Licensors regarding a Transaction, to deliver to the Licensors a written non-binding offer letter setting forth the principal terms and conditions upon which Sanofi or its Affiliate would be willing to enter into such Transaction (an “**NBO**”). If Sanofi delivers an NBO to the Licensors prior to expiration of the Due Diligence Period, then the Parties shall negotiate in good faith a definitive agreement regarding the Transaction for up to an additional [...] days from expiration of the Due Diligence Period (the “**Negotiation Period**”); *provided, however*, that the Licensors shall have no obligation to enter into a Transaction with Sanofi or its Affiliates.

(c) If Sanofi (whether on its own behalf or on behalf of its Affiliate) (i) fails to deliver an Indication of Interest to the Licensors prior to expiration of the Initial Election Period, or (ii) delivers an Indication of Interest prior to expiration of the Initial Election Period but fails to deliver an NBO to the Licensors prior to expiration of the Due Diligence Period, or (iii) delivers an Indication of Interest prior to expiration of the Initial Election Period and an NBO prior to expiration of the Due Diligence Period, but the Parties have not entered into a definitive agreement for a Transaction prior to expiration of the Negotiation Period, then, in each case, upon the expiration of the Initial Election Period, Due Diligence Period or Negotiation Period, respectively, the Licensors shall be free to grant one or more Third Parties a license or other right to develop or commercially exploit a [...] Product, without further obligation to Sanofi (or any of its Affiliates), provided that, for a period of [...] months following the expiration of the Initial Election Period, the Due Diligence Period or the Negotiation Period, as applicable, the Licensors shall not grant any such license or other right to any Third Party on terms that are materially less favorable, taken as a whole, to the Licensors than the terms last offered by Sanofi to the Licensors during the Parties’ negotiations. If the Licensors have not entered into a definitive agreement with a Third Party granting a license or other right to develop or commercially exploit a [...] Product within such [...] month period pursuant to the foregoing sentence, Sanofi’s rights under this Section 2.7 and all applicable time periods for exercise of such rights shall reset, provided that the Negotiation Period shall be an additional [...] days from expiration of the Due Diligence Period.

(d) For the avoidance of doubt, nothing in this Section 2.7 shall be construed to give Sanofi or any of its Affiliates any rights whatsoever with respect to any proposed sale of all or substantially all of the business or assets of the Licensors, or of a substantial portion of the business or assets of the Licensors that relates to two or more *bona fide* development programs

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or products of the Licensors, including [...***...] Products, in each case, whether by merger, sale of stock, sale of assets or otherwise.

2.8 Covenants.

(a) MannKind Non-Compete. During the Term, the Licensors covenant to Sanofi that the Licensors and MannKind Affiliates shall not either themselves or with, for the benefit of, or sponsored by any Third Party, (i) conduct any activity directed to the Development (*mutatis mutandis*) or registration of a Competing Product in the Territory, (ii) Manufacture a Competing Product that is intended for sale in the Territory, (iii) Commercialize (*mutatis mutandis*) a Competing Product in the Territory, or (iv) license or authorize, under any MannKind Technology, MannKind Trademarks or Data, any entity other than a MannKind Affiliate to engage in any of the activities described in the preceding clauses (i), (ii) and (iii).

(b) Sanofi Non-Compete. During the Term, Sanofi covenants to the Licensors that Sanofi and its Affiliates shall not either themselves or with, for the benefit of, or sponsored by any Third Party, (i) conduct any activity directed to the Development (*mutatis mutandis*) or registration of a Competing Product in the Territory, (ii) Manufacture a Competing Product that is intended for sale in the Territory, (iii) Commercialize (*mutatis mutandis*) a Competing Product in the Territory, or (iv) license, sublicense or authorize, under any MannKind Technology, MannKind Trademarks, Sanofi Technology or Data, any Third Party to engage in any of the activities described in the preceding clauses (i), (ii) and (iii). Notwithstanding the foregoing:

(i) Starting on the fifth (5th) anniversary of the Effective Date, Sanofi may, at its sole cost and expense, Develop (*mutatis mutandis*) internally at Sanofi or one of its Affiliates a Competing Product generated solely from Sanofi's or its Affiliate's internal research efforts; *provided, however*, that Sanofi and its Affiliates shall not use any MannKind Technology in connection therewith. For the avoidance of doubt, Sanofi shall bear all costs and expenses of Development (*mutatis mutandis*) of such Competing Product and such costs and expenses shall not be Allowable Expenses and shall not otherwise be subject to **EXHIBIT B**, except to the extent incurred after the First Commercial Sale of such Competing Product pursuant to approval by the JAC in accordance with the immediately succeeding sentence. The Commercialization (*mutatis mutandis*) of any such Competing Product during the Term shall require the prior written approval of the JAC. Upon approval by the JAC of such Commercialization, (A) subject to **EXHIBIT B**, Sanofi shall bear all Commercialization costs and expenses with respect to any such Competing Product, (B) except as expressly set forth below, such Competing Product shall be deemed a "Product" for purposes of Section 6.3 and **EXHIBIT B**, and (C) payment of Allowable Expenses and calculation and sharing of Profit and Loss with respect to such Competing Product shall be subject to **EXHIBIT B**; *provided, however*, that no Development Costs (*mutatis mutandis*) incurred prior to the First Commercial Sale of such Competing Product shall be included in Allowable Expenses or in the calculation of Profit or Loss.

(ii) Starting on the tenth (10th) anniversary of the Effective Date, Sanofi may in-license or acquire a Competing Product from a Third Party and the Development (*mutatis mutandis*) and Commercialization (*mutatis mutandis*) of such in-licensed or acquired

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Competing Product shall not be governed by the terms of this Agreement. For clarity, Sanofi shall be exclusively responsible for any and all costs and expenses with respect to such Development (*mutatis mutandis*) and Commercialization (*mutatis mutandis*) and all costs and expenses with respect to such Development (*mutatis mutandis*) and Commercialization (*mutatis mutandis*) and, as between the Parties, shall be entitled to all revenues with respect to such Competing Product.

(c) Acknowledgment. The Parties acknowledge (i) that this Section 2.8 has been negotiated by the Parties, (ii) the geographical and time limitations on activities contained in this Section 2.8 are reasonable, valid and necessary for the adequate protection of the Product business, and (iii) that the Parties would not have entered into this Agreement without the protection afforded by this Section 2.8. Notwithstanding the foregoing, if a court of competent jurisdiction determines that the restrictions set forth in this Section 2.8 are too broad or are otherwise unreasonable under Applicable Law, including with respect to duration, geographic scope, or field, the court is hereby requested and authorized by the Parties to revise the foregoing restrictions to include the maximum restrictions allowable under Applicable Law.

(d) Acquiring Party Business Combination. Neither Party shall be in breach of the provisions of Section 2.8 by reason of its acquisition of a Third Party or its assets or by a Third Party if: (a) within sixty (60) days following the closing of such acquisition, the acquiring Party (or acquiring Third Party) commits in writing to the other Party that such acquirer will promptly divest itself of the Competing Product of such Third Party (whether through sale of business or assets or discontinuation of all activities with respect to the Competing Product); and (b) such divestiture is completed within twelve (12) months after the closing of such acquisition.

ARTICLE 3

GOVERNANCE

3.1 Joint Afrezza Committee.

(a) Establishment. Within 30 days following the Effective Date, MannKind and Sanofi shall establish a Joint Afrezza Committee (the “JAC”) to oversee, review and coordinate the activities of the Parties under this Agreement with regard to the Development, regulatory and other activities relating to Product in the Field in the Territory.

(b) Membership. Subject to Section 3.4, the JAC shall be composed of eight members (or such other even number agreed to in writing by the Parties so long as each Party has an equal number of members on the JAC). One-half of the total number of members on the JAC shall be nominated by MannKind and one-half of the total number of members on the JAC shall be nominated by Sanofi, which members shall be employees of the applicable Party with the requisite experience and seniority to make decisions on behalf of the Parties with respect to responsibilities within the jurisdiction of the JAC. Each Party will notify the other Party of its initial JAC members within 30 days after the Effective Date. Each Party shall designate one of its representatives on the JAC as the co-chair of the JAC, whose roles shall be to convene and

preside at meetings of the JAC, but the co-chairs shall not be entitled to prevent items from being discussed or, subject to Section 3.1(f), to cast any tie-breaking vote. Each Party may change its JAC members at any time by written notice to the other Party. Any member of the JAC may designate a substitute to attend and perform the functions of that member at any meeting of the JAC.

(c) Meetings. The JAC will hold meetings at such frequency as determined by the JAC members, but no less than once per Calendar Quarter. Such meetings may be conducted by videoconference, teleconference or in person, as agreed by the Parties; provided, that at least one JAC meeting per year shall be held in person and the location of such in-person meeting shall alternate between MannKind's and Sanofi's offices, unless the Parties otherwise agree. Each Party may invite a reasonable number of non-member, non-voting representatives of such Party to attend meetings of the JAC. Minutes will be kept of all JAC meetings and will reflect material decisions made at such meetings. The responsibility to prepare minutes of JAC meetings will be Sanofi's. Meeting minutes will be sent to each member of the JAC for review and approval promptly following each meeting. Minutes will be deemed approved unless a member of the JAC objects to the accuracy of such minutes within 15 days of receipt. Any costs and expenses incurred by a Party related to a JAC meeting, including, if applicable, travel and/or telecommunication expenses, shall be borne by such Party.

(d) JAC Responsibilities. The JAC shall have the following responsibilities:

(i) providing a forum for the Parties to exchange information and coordinate their respective activities with respect to Development, regulatory and Manufacturing matters pertaining to Product in the Territory;

(ii) reviewing and approving the Development Plan and material changes to the Development Plan, including any Development Budget (which Budget shall be reviewed and approved on an annual basis);

(iii) reviewing and approving the regulatory strategy for Product in the Territory;

(iv) reviewing and approving Commercialization Plan(s), Commercialization Budget(s), and updates and amendments thereto;

(v) reviewing and approving revisions to the Paid Price set forth in the Supply Agreement;

(vi) providing a forum for discussion as to whether the content of a Commercialization Plan (or any such plan as proposed to be updated or amended) is sufficient to satisfy Sanofi's obligations to use Commercially Reasonable Efforts in accordance with Section 5.1(c);

(vii) receiving periodic updates on material Development and regulatory activities conducted or proposed to be conducted with respect to Product in the Territory, including the submission and prosecution of applications for Marketing Approval;

(viii) reviewing safety and compliance reports for Product in the Territory;

(ix) overseeing the activities managed by the Manufacturing working group of the JAC as described in Section 3.1(e);

(x) providing a forum for coordinating the Parties' activities in response to crises with respect to Product, including unexpected disruptions to the supply of Product, safety issues, and recalls or withdrawals of Product;

(xi) establishing and overseeing working groups of the JAC as necessary to implement the responsibilities delegated to the JAC pursuant to this Agreement or by written agreement of the Parties;

(xii) reviewing and approving potential sublicensees outside the Major Markets;

(xiii) reviewing and approving the filing of an IND for Product using an amorphous Formulation; and

(xiv) making such other decisions as may be delegated to the JAC pursuant to this Agreement or the Supply Agreement or by written agreement of the Parties.

(e) Working Groups of the JAC. From time to time, the JAC may establish working groups to oversee particular projects or activities within the scope of authority of the JAC, as it deems necessary or advisable. Each working group shall consist of such number of representatives of each Party as the JAC determines is appropriate from time to time and shall meet with such frequency as the JAC shall determine. All decisions of each working group shall be made by unanimous vote or written consent, with the MannKind members of the working group collectively having one vote and the Sanofi members of the working group collectively having one vote in all decisions of the working group. If, with respect to a matter that is subject to a working group's decision-making authority, the working group cannot reach agreement, the matter shall be referred to the JAC, which shall resolve such matter in accordance with Section 3.1(f). The Manufacturing working group of the JAC shall be responsible for (i) overseeing the forecasting, Manufacture and supply of Product, and any regulatory activities with respect thereto, and (ii) discussing and overseeing the Parties' efforts to reduce Cost of Goods and approving in advance any costs to be incurred by MannKind for such efforts.

(f) JAC Decision-Making. All decisions within the authority of the JAC shall be made by unanimous vote or written consent, with the MannKind members of the JAC collectively having one vote and the Sanofi members of the JAC collectively having one vote in all decisions of the JAC. The members of the JAC shall use reasonable efforts to reach agreement on all matters. If, despite such efforts, agreement on a particular matter cannot be reached by the JAC within 15 days after the JAC first considers such matter (or such shorter or longer time as may be agreed by the Parties), then either Party may, by written notice to the other Party, have such matter referred to, on behalf of MannKind, the President of MannKind and, on

behalf of Sanofi, the Senior Vice President – Global Diabetes of Sanofi. Such executives shall use reasonable efforts to resolve the matter referred to them within 10 days after such referral. If, despite such efforts, such executives are unable to resolve such matter within 10 days after such referral (or such shorter or longer time as may be agreed by the Parties), then the Sanofi co-chair on the JAC shall have the right to make the final decision with regard to the disputed matter following good faith consideration of MannKind's comments, subject to Section 3.4 and provided that the Sanofi co-chair on the JAC shall not have power to resolve a dispute: (i) in a manner that would require MannKind to perform activities (A) for which Sanofi will not reimburse MannKind's costs (except as expressly set forth in this Agreement or the Supply Agreement) or (B) which MannKind has not agreed to perform as set forth in this Agreement or otherwise in writing; (ii) in a manner that would conflict with the terms of this Agreement or the Supply Agreement, including all Exhibits and Schedules hereto and thereto; (iii) by unilaterally determining that it has fulfilled any diligence obligations hereunder; (iv) in a manner that would modify or increase MannKind's responsibilities under the Development Plan; or (v) regarding changes to any Budget, except as may be required to reflect activities required by a Regulatory Authority or Applicable Laws. For all purposes under this Agreement, any decision made pursuant to this Section 3.1(f) shall be deemed to be the decision of the JAC.

3.2 Alliance Managers. Promptly after the Effective Date, each Party shall appoint an individual to act as the alliance manager for such Party (the "**Alliance Manager**"). Each Alliance Manager shall be permitted to attend meetings of the JAC. The Alliance Managers shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party.

3.3 Scope of Governance. Notwithstanding the creation of the JAC, each Party shall retain the rights, powers and discretion granted to it hereunder, and the JAC shall not be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly agree in writing. The JAC shall not have the power to amend or modify this Agreement, and no decision of the JAC shall be in contravention of any terms and conditions of this Agreement. It is understood and agreed that issues to be formally decided by the JAC are only those specific issues that are expressly provided in this Agreement to be decided by the JAC. Any dispute regarding the interpretation of this Agreement or any alleged breach of this Agreement will be resolved in accordance with the terms of Article 14.

3.4 Withdrawal from the JAC. At any time during the Term and for any reason, MannKind shall have the right to withdraw from the JAC upon written notice to Sanofi, which notice shall be effective immediately upon receipt ("**Withdrawal Notice**"). Following the issuance of a Withdrawal Notice and subject to this Section 3.4, the JAC shall be suspended and Sanofi shall have the right to make the final decision on all matters within the scope of authority of the JAC. If, at any time, following the issuance of a Withdrawal Notice, MannKind wishes to resume participation in the JAC, MannKind shall notify Sanofi in writing and, thereafter, MannKind's representatives to the JAC, shall be entitled to attend any subsequent meeting of the

JAC, and to participate in the activities of, and decision-making by the JAC as provided in this Article 3 as if a Withdrawal Notice had not been issued by MannKind.

ARTICLE 4

DEVELOPMENT AND REGULATORY ACTIVITIES

4.1 Development Activities.

(a) Development Responsibility. Sanofi shall have the exclusive right and responsibility to Develop Product in the Field in the Territory during the Term (other than the Development activities assigned to MannKind by the JAC in the Development Plan), subject to the terms and conditions of this Agreement and in accordance with a Development Plan established by Sanofi and approved by the JAC, which shall specify the Development activities to be performed by or on behalf of the Parties, and shall set forth a proposed Development Budget for such activities. Subject to **EXHIBIT B**, each Party shall be responsible for bearing the costs and expenses of the Development activities assigned to such Party in the Development Plan; *provided, however*, that prior to the filing of an IND in respect of an amorphous Formulation, MannKind shall be solely responsible for the expenses associated with the Development of such Formulation and such expenses shall not be considered Allowable Expenses for purposes of **EXHIBIT B**, but all expenses associated with the Development of an amorphous Formulation incurred after the filing of such IND shall be considered Allowable Expenses for purposes of **EXHIBIT B**. The Development Plan shall be subject to the terms and conditions of this Agreement, in addition to the specific details set forth in the Development Plan. To the extent any terms or provisions of a Development Plan conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement shall control. Any changes to the Development Plan shall be in writing and approved by the JAC.

(b) Development Budget. Each Development Budget shall set forth the budget associated with the various Development activities to be performed under the Development Plan. Each Party shall, on an annual basis during the fourth Calendar Quarter of each Calendar Year during the Development Term, prepare and submit to the JAC for review, discussion and approval a draft Development Budget for activities planned to be performed by such Party under the Development Plan during the forthcoming Calendar Year. Subject to Section 3.1(f), the JAC shall have the right to amend each annual Development Budget from time to time. In the event that any Regulatory Authority requires a modification to any Development Plan, the JAC may not limit or prevent any corresponding revision to a Development Budget as necessary to accommodate and comply with such Regulatory Authority requirements. The Development Budget for the initial Development Plan shall be submitted to the JAC concurrently therewith.

(c) Conduct of Development Activities. All Development activities in support of Product in the Field in the Territory will be conducted by or on behalf of the Parties in accordance with the Development Plan and the other provisions of this Agreement. Each Party shall conduct those activities for which it is the Responsible Party under the Development Plan in compliance in all material respects with all Applicable Laws and in accordance with good

scientific and clinical practices, applicable under the Applicable Laws of the country in which such activities are conducted.

(d) Information Regarding Development Activities. Each Party shall maintain records, in sufficient detail and in good scientific manner appropriate for Patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of such Party in the performance of its Development activities under this Agreement. Each Party shall keep the JAC appropriately informed of the status of studies and other activities with respect to Product in the Field in the Territory conducted under the Development Plan. Upon request by the JAC, without limiting the foregoing, each Party shall promptly provide the JAC with summaries in reasonable detail of all Data and results generated or obtained in the course of such Party's performance of studies and activities under the Development Plan.

4.2 Regulatory Activities.

(a) Regulatory Strategy. Sanofi shall be solely responsible for developing the regulatory strategy for Product in the Field in the Territory for review and approval by the JAC. Such strategy shall include the strategy with respect to any data, market or other regulatory exclusivity periods that may be applicable to Product in the Field in the Territory, including with respect to any such periods listed in the FDA's Orange Book.

(b) Regulatory Responsibilities. Within 30 days after the Effective Date, MannKind will transfer to Sanofi the MAA and, at Sanofi's option, the IND for Product in the Field in the United States to enable Sanofi to manage the Commercialization and any additional Development of Product in the Field in the United States and Sanofi shall thereafter be responsible with respect to filing for, obtaining and maintaining Marketing Approval for Product in the Field in the United States with oversight by the JAC. Sanofi shall be responsible with respect to filing for, obtaining and maintaining Marketing Approval for Product in the Field in all other countries in the Territory with oversight by the JAC. Subject to **EXHIBIT B**, Sanofi shall be responsible for bearing the costs and expenses associated with performing the activities contemplated by this Section 4.2(b).

(c) Conduct of Regulatory Activities. All regulatory activities with respect to Product in the Field in the Territory will be conducted by or on behalf of Sanofi in accordance with the provisions of this Agreement and the regulatory strategy developed by Sanofi and approved by the JAC; *provided, however*, that MannKind reserves the exclusive right, as manufacturer of Product, to submit, obtain and maintain Master Files in MannKind's name in the Territory, *provided, further*, that, solely to the extent and for so long as the licenses granted by the Licensors to Sanofi under Sections 2.1 and 2.2 remain in full force and effect, Sanofi shall have the irrevocable right to refer to the Master Files with respect to the Product in the Territory solely for the purposes of (i) Developing Product in the Field in accordance with this Agreement, (ii) Manufacturing and having Manufactured Product in the Field in the Territory, subject to the terms of and as permitted by the Supply Agreement, and (iii) using, Commercializing and having Commercialized Product in the Field in the Territory. For the avoidance of doubt, and notwithstanding the foregoing or any other provision of this Agreement to the contrary, Sanofi

shall have no right to refer to the Master Files with respect to the Product in the Territory for the purpose of developing, manufacturing, having manufactured, using, commercializing or having commercialized any Competing Product. Sanofi shall conduct those regulatory activities in compliance in all material respects with all Applicable Laws. Sanofi shall use Commercially Reasonable Efforts to file for, obtain and maintain Marketing Approvals for Product in the Field in all Major Markets and all [...] Countries, it being understood that the application of Commercially Reasonable Efforts may include a consideration of [...] and may result in Sanofi deciding not to pursue or maintain Marketing Approval in a particular Major Market or [...] Country. From time to time after the [...] anniversary of the Effective Date, at MannKind's request, Sanofi shall present an analysis to the JAC of the commercial viability of Product in countries in the Territory that are not Major Markets or [...] Countries and where Sanofi has not at such time filed for or obtained Marketing Approvals for Product in order to assess the opportunities for sublicensing or otherwise Commercializing Product in such countries, it being understood that MannKind can request such analysis for no more than one such country per Calendar Quarter. MannKind acknowledges and agrees that, irrespective of the results of such analysis, Sanofi shall have no obligation to take any efforts to file for, obtain or maintain Marketing Approvals for Product in the Field in any such country. For the avoidance of doubt, all expenses associated with any such analysis requested by MannKind shall be considered Allowable Expenses for purposes of **EXHIBIT B**.

(d) Data. All Data generated by or on behalf of a Party or the Parties shall be owned jointly by MannKind and Sanofi. MannKind shall have the right to use, make reference to and incorporate the Data in regulatory filings with regulatory authorities for products (other than Product and Competing Products) outside of the field of Diabetes without Sanofi's consent and without obligation to Sanofi. Should MannKind wish to use, make reference to or incorporate the Data in regulatory filings with regulatory authorities for products (other than Product) in the field of Diabetes, MannKind shall obtain the prior written consent of Sanofi prior to such use, reference to or incorporation of the Data, which Sanofi may grant or withhold in its sole discretion. Sanofi shall have the right to use, make reference to and incorporate the Data in regulatory filings with regulatory authorities for products in the Field without MannKind's consent and without obligation to MannKind.

(e) Regulatory Reporting. During the Term, Sanofi will keep MannKind updated regarding all Regulatory Filings and, upon request, shall (i) provide MannKind with copies of all submissions to Regulatory Authorities related to the Manufacture or Commercialization of Product (other than ministerial submissions which do not involve safety or efficacy issues), and (ii) promptly disclose to MannKind all Regulatory Filings, and any Data included or referenced therein, made by or on behalf of Sanofi, with respect to Product in the Field in the Territory. During the Term, MannKind will keep Sanofi updated regarding any submission with respect to the Master Files related to the Product and, upon request, shall (i) provide Sanofi with copies of all submissions to Regulatory Authorities related to such Master Files, and (ii) promptly disclose to Sanofi all such Master Files, and any Data included or referenced therein. Each Party will notify the other Party promptly (and in any event within two Business Days) of its receipt of information from any Governmental or Regulatory Authority, that: (A) raises any material concerns regarding the safety or efficacy of Product or would affect

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Product labeling, (B) indicates a potential material liability for either Party arising in connection with Product, or (C) is reasonably likely to lead to a recall or market withdrawal of Product.

(f) Device Vigilance; Pharmacovigilance. Representatives from competent departments of each Party shall, within three (3) months following the Effective Date, negotiate and implement detailed device vigilance and/or pharmacovigilance agreement(s) or safety data exchange procedures defining the respective responsibilities of the Parties to ensure worldwide safety surveillance of Product and to comply with all applicable device and safety reporting obligations as amended from time to time. Such agreement(s) shall be on terms no less stringent than those required by ICH guidelines, including: (i) providing detailed procedures regarding the maintenance of core safety information and the exchange of safety data relating to Product worldwide within appropriate timeframes and in an appropriate format to enable each Party to meet both expedited and periodic regulatory reporting requirements; and (ii) ensuring compliance with the reporting requirements of all applicable Regulatory Authorities on a worldwide basis for the reporting of safety data in accordance with standards stipulated in the ICH guidelines, and all applicable regulatory and legal requirements regarding the management of safety data. Notwithstanding the foregoing, the Licensors shall reasonably assist Sanofi during the term of this Agreement to answer any query of Sanofi or any Regulatory Authority in the Territory.

(g) Cooperation. Sanofi shall, at MannKind's request, reasonably cooperate with MannKind by (i) updating MannKind on a regular basis regarding Sanofi's regulatory activities in the Territory and (ii) providing MannKind with summaries of its communications and correspondence with Regulatory Authorities with respect to Product in the Territory.

4.3 Transfer of Know-How. Promptly following the Effective Date, the Licensors will make available to Sanofi, at no additional cost or expense to Sanofi, the MannKind Know-How that exists as of the Effective Date. Subject to the Supply Agreement, MannKind shall cooperate with Sanofi to provide such reasonable technical assistance as may be necessary in connection with the transfer to Sanofi of the Development and Manufacture of the Product. MannKind shall furnish, at Sanofi's request and expense, a representative to attend regulatory meetings with the FDA regarding Product and/or participate in activities related to such regulatory meetings. During the Term, the Licensors shall provide to Sanofi, at no additional cost or expense to Sanofi, all MannKind Know-How that has not previously been provided hereunder promptly upon such MannKind Know-How being obtained or generated by MannKind. During the Term, Sanofi shall provide to MannKind, at no additional cost or expense to MannKind, all Sanofi Know-How that is necessary for MannKind to perform its obligations hereunder and has not previously been provided hereunder promptly upon such Sanofi Know-How being obtained or generated by Sanofi. For the avoidance of doubt, nothing in this Agreement or the Supply Agreement shall oblige Sanofi to disclose proprietary information about its Insulin manufacturing process.

4.4 Use of Subcontractors. Sanofi may perform some of its Development or regulatory activities under this Agreement through one or more Service Providers, provided that the Service Provider undertakes in writing obligations of confidentiality and non-use regarding Confidential Information which are substantially the same as those undertaken by the

Parties pursuant to Article 8. In the event Sanofi performs any of its Development or regulatory activities hereunder through a Service Provider, then Sanofi will at all times be fully responsible for the performance and payment of such Service Provider.

4.5 Materials Transfer. In order to facilitate the Development or regulatory activities contemplated by this Agreement, either Party may provide to the other Party certain biological materials or chemical compounds Controlled by the supplying Party (collectively, “*Materials*”) for use by the other Party in furtherance of such Development activities. Except as otherwise provided for under this Agreement, all such Materials delivered to the other Party will remain the sole property of the supplying Party, will be used only in furtherance of the Development activities conducted in accordance with this Agreement, will not be used or delivered to or for the benefit of any Third Party, except for Service Providers pursuant to Section 4.4 or, in the case of Sanofi only, sublicensees, without the prior written consent of the supplying Party, and will be used in compliance with all Applicable Laws. The Materials supplied under this Agreement must be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT OR THE SUPPLY AGREEMENT, THE MATERIALS ARE PROVIDED “AS IS” AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

ARTICLE 5

COMMERCIALIZATION; MANUFACTURE AND SUPPLY

5.1 Commercialization of Product.

(a) Sanofi Responsibilities. Sanofi shall have the exclusive right to Commercialize Product in the Field in the Territory during the Term, subject to the terms and conditions of this Agreement. Without limiting the foregoing, during the Term, Sanofi will have the exclusive right and responsibility, at Sanofi’s sole expense (but subject to **EXHIBIT B**), for the following with respect to Product in the Field in the Territory:

- (i) establish the Commercialization and marketing strategy and tactics (the “*Commercial Strategy*”);
- (ii) establishing pricing and reimbursement, including payment of applicable rebates and chargebacks;
- (iii) managed care and government contracting (including contracting for the Product to be available under the Government Health Care Programs);
- (iv) receiving, accepting and filling orders;
- (v) distribution to customers;

(vi) controlling invoicing, order processing and collecting accounts receivable for sales;

(vii) recording sales in its books of account for sales; and

(viii) tracking and reporting transfers of value in connection with Product under applicable state and federal “aggregate spend”/“sunshine” reporting laws (except to the extent legally the responsibility of the Licensors).

(b) Commercialization Plan. Within a reasonable time prior to anticipated launch of Product in any Major Market and [...***...] Country, Sanofi shall prepare and submit to the JAC a three-year, non-binding plan for the marketing, promotion and pricing of Product in such Major Market or [...***...] Country, which plan shall be reasonable in scope and detail and may be amended by Sanofi (each, a “**Commercialization Plan**”). In addition, Sanofi shall prepare and submit to the JAC for approval an initial Commercialization Budget to be included in each Commercialization Plan that specifies amounts to be spent on Product launch, detailing, meetings, symposiums, Congressional support, clinical support, brand support and other items during the first year of such Commercialization Plan. Thereafter, in the fourth Calendar Quarter of each Calendar Year during the Term, Sanofi shall prepare and submit to the JAC for review, discussion and approval an initial draft of the Commercialization Budget for planned activities to be performed under such Commercialization Plan during the forthcoming Calendar Year. The JAC shall have the right to amend each annual Commercialization Budget from time to time. Sanofi shall promptly provide any material amendments to a Commercialization Plan to the JAC.

(c) Diligence. Sanofi shall use Commercially Reasonable Efforts to market, promote and Commercialize Product in the Field in countries in the Territory where regulatory approval has been received, it being understood that the application of Commercially Reasonable Efforts may result in Sanofi deciding not to market, promote or Commercialize Product in any particular country or countries.

5.2 Manufacture and Supply of Product.

(a) Generally. MannKind shall Manufacture and supply or have Manufactured and supplied to Sanofi and its Affiliates or sublicensees their requirements of Product pursuant to the Supply Agreement or any other written agreement between the Parties for such purpose.

(b) [...***...]. Promptly after the Effective Date, MannKind shall commence and diligently pursue [...***...].

(c) Investments. Subject to the Supply Agreement, MannKind shall be responsible for making, during the Term, the capital investments required in order to expand the capacity of the MannKind Facility (as defined in the Supply Agreement) so as to ensure the uninterrupted supply of Sanofi’s potential requirements of up to [...***...] cartridges of Product annually.

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(d) Capacity Expansion. The Manufacturing working group of the JAC will discuss planning for Manufacturing capacity expansion, which may include the establishment and qualification of Sanofi or any of its Affiliates as a secondary source of supply of Product in accordance with the Supply Agreement.

(e) Launch Conditions. Recognizing that Sanofi’s obligations to launch Product are ultimately determined by application of a standard of Commercially Reasonable Efforts, the Licensors acknowledge that Sanofi does not intend to launch the Product before and until achievement or completion of the [...***...] Milestone.

ARTICLE 6

CONSIDERATION

6.1 Initial Payment. In partial consideration for the licenses and rights granted to Sanofi hereunder, Sanofi shall pay to MannKind a non-refundable, non-creditable payment in the amount of one hundred fifty million U.S. dollars (\$150,000,000) within ten (10) days from the Effective Date.

6.2 Milestone Payments. In partial consideration for the licenses and rights granted to Sanofi hereunder, Sanofi shall pay to the Licensors, as specified below, the non-refundable, non-creditable milestone payments set out below following the first (1st) achievement of the corresponding milestone. Such payment shall be made within forty-five (45) days of (a) Sanofi’s receipt of written notice from MannKind of the achievement of the applicable milestone by MannKind or (b) Sanofi notifying MannKind in writing of the achievement of the applicable milestone event by Sanofi, or any of its Affiliates, as applicable, which notice must be delivered to MannKind within ten (10) days following the achievement of the applicable milestone event.

<u>Milestone Event</u>	<u>Milestone Payment</u>
1. Manufacturing Milestones	
(a) [...***...] Milestone	\$ [...***...]
(b) [...***...] Milestone†	\$ [...***...]
(b) [...***...] Milestone†	up to \$ [...***...]*
2. Regulatory Milestones	
(a) [...***...]	\$ [...***...]
(b) [...***...]	\$ [...***...]

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3. Sales Milestones	
(a) Annual Net Sales of Product in the Territory first exceed \$[...***...]	\$[...***...]
(b) Annual Net Sales of Product in the Territory first exceed \$[...***...]	\$[...***...]
(c) Annual Net Sales of Product in the Territory first exceed \$[...***...]	\$[...***...]
(d) Annual Net Sales of Product in the Territory first exceed \$[...***...]	\$[...***...]
(e) Annual Net Sales of Product in the Territory first exceed \$[...***...]	\$[...***...]
(f) Annual Net Sales of Product in the Territory first exceed \$[...***...]	\$[...***...]
4. [...***...]	\$[...***...]

* If the [...***...] Milestone is achieved and MannKind has [...***...] of up to [...***...] Sanofi shall pay an amount equal to the product of: (i) [...***...] U.S. Dollars (\$[...***...]) multiplied by (ii) the quotient of the (A) [...***...] divided by (B) [...***...].

† If for any reason (e.g., [...***...], etc.) the JAC determines that MannKind should not [...***...], as contemplated by Sections 1.62 and 1.63, [...***...] despite the fact that MannKind has demonstrated the ability to [...***...], (i) MannKind shall have no obligation to [...***...], (ii) MannKind will be deemed to have achieved both the [...***...] Milestone (if not previously achieved) and the [...***...] Milestone and (iii) Sanofi shall pay in full to Licensors the corresponding milestone payments (to the extent not previously paid) in accordance with this Section 6.2.

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Any milestone payment payable by Sanofi pursuant to Section 6.2 shall be made no more than once with respect to the achievement of each such milestone event, upon the first achievement of such milestone event. "Annual Net Sales" as described above shall be measured on a Calendar Year basis. For clarity, if annual Net Sales in a Calendar Year satisfies more than one milestone event set forth above, then payment shall be made for each such milestone event that is satisfied. Sales of Product by sublicensees of Sanofi that would be considered Net Sales if made by Sanofi shall be included in the computation of "Annual Net Sales" for purposes of this Section 6.2.

All payments in respect of the Manufacturing Milestones and the [...***...] milestone above shall be made to MannKind. All payments in respect of the Regulatory Milestones above shall be made to TICV (or one or more permitted assignees designated by TICV). All payments in respect of the Sales Milestones above shall be made to MannKind and TICV (or one or more permitted assignees designated by the foregoing) in proportion to Net Sales of Product in the United States, and outside the United States, respectively, for the applicable Calendar Year. Notwithstanding the foregoing, MannKind may, upon five (5) Business Days written notice to Sanofi, change the payee of the foregoing payments as between MannKind, TICV and BV such that the allocation of payments reflects the utilization of assets owned by or exclusively licensed to each such entity in the relevant territory or territories to which the payments relate.

6.3 Payment of Expenses; Sharing of Profit and Loss. EXHIBIT B sets forth the terms regarding responsibility for payment of Allowable Expenses and calculation and sharing of Profit and Loss. For any countries outside the United States, the Parties may include as an Allowable Expense in the calculation of Profit the expenses of recordkeeping and compliance with EXHIBIT B; as such, and for other reasons, the Parties may agree that in such other countries it may be preferable to have the Licensors' remuneration computed as a royalty on Net Sales (any such country, a "**Royalty Country**"). All payments of worldwide Profit shall be paid to MannKind and TICV (or one or more permitted assignees designated by the foregoing) on the basis that (a) MannKind shall be paid the Profit determined for the United States only in U.S. Dollars, and (b) TICV shall be paid the remaining amount of the worldwide Profit after deducting the amount paid to MannKind pursuant to (a) above; provided that if there is Profit in only one of the United States and the Territory outside the United States and a loss in the other territory, the entirety of the worldwide Profit shall be paid to either MannKind (in the case of Profit only in the United States) or TICV (in the case of Profit only in the Territory outside the United States) and no balancing payment shall be due for other jurisdiction. All payments of royalties on Net Sales in Royalty Countries shall be paid to TICV (or one or more permitted assignees designated by TICV).

ARTICLE 7

PAYMENTS, BOOKS AND RECORDS

7.1 Payment Method. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account in the name of MannKind or TICV (or one or more permitted assignees designated by the foregoing), as applicable, designated in

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writing by the Licensors. Payments hereunder will be considered to be made as of the day on which they are received by the receiving Party's designated bank.

7.2 Payment Currency. Unless otherwise expressly stated in this Agreement, all amounts specified to be payable under this Agreement are in Euros. Net Sales, Allowable Expenses and other elements of Profit invoiced in currency other than Euros, as appropriate, shall be translated to Euros shall be performed in a manner consistent with Sanofi's normal practices used to prepare its audited financial statements for external reporting purposes, which uses a widely accepted source of published exchange rates, as disclosed to MannKind.

7.3 Taxes.

(a) Cooperation and Coordination. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use their reasonable efforts to cooperate and coordinate with each other to achieve such objective.

(b) Payment of Tax.

(i) Subject to the provisions of this Section 7.3(b), each Party shall pay or economically bear (in the case of withholding taxes) all taxes imposed upon such Party. If Applicable Laws require that taxes be deducted and withheld from a payment, the remitting Party shall (i) deduct those taxes from the payment; (ii) pay the taxes to the proper taxing authority; (iii) send evidence of the obligation together with proof of payment to such taxing authority to the other Party within 30 days following that payment; and (iv) cooperate with the other Party in any way reasonably required to obtain available reductions, credits or refunds of such taxes. The cooperation referred to in clause (iv) of the foregoing sentence shall include that MannKind, TICV and BV shall provide Sanofi with a written confirmation from the competent tax authority that MannKind has its residence in the United States, and TICV and BV have their respective residences in the Netherlands, together with a copy of the necessary German exemption certificate(s) to benefit from the zero percent withholding tax rate set forth in Article 12 of the Double Taxation Convention existing between Germany and the United States and the double tax treaty between Netherlands and Germany.

(ii) All remuneration amounts payable by Sanofi to the Licensors are net amounts. It is the common understanding of the Parties that the transactions under this Agreement are subject to the reverse-charge-mechanism under the German VAT Code. Sanofi shall be responsible for all Value Added Taxes ("VAT" – *Umsatzsteuer*) attributable to transactions contemplated by this Agreement without any offset or reimbursement from the Licensors. The Licensors will refer to the reverse-charge-mechanism in its invoices and will not add VAT to the net amounts in the invoices. Sanofi will pay this VAT according to the German VAT Code. The Licensors shall cooperate with Sanofi in any way reasonably requested by Sanofi to obtain available reductions, credits or refunds of any VAT amounts attributable to transactions contemplated by this Agreement. In the event that the reverse-charge-mechanism should not be applicable, VAT shall be added to the net amounts and be paid by Sanofi to the

Licensors. In this case, Sanofi is entitled to receive a proper tax invoice where any VAT amount is shown separately.

(iii) Notwithstanding the foregoing, if Sanofi takes any action, including any assignment or transfer of some or all of its rights and obligations to any Person and if, as a result of such action, the withholding or deduction of tax is required by (or is increased under) Applicable Law with respect to payments under this Agreement then any amount payable under this Agreement shall be increased to take into account such withheld taxes as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts) the recipient payee receives an amount equal to the sum they would have received had no such withholding been made.

7.4 Records. Each Party shall keep, and require its Affiliates to keep, complete, true and accurate books of accounts and records for the purpose of determining the amounts payable pursuant to this Agreement. Such books and records shall be kept for such period of time required by law, but no less than three years following the end of the Calendar Quarter to which they pertain. Such records shall be subject to inspection in accordance with Section 7.5.

7.5 Audits. Upon not less than 60 days' prior written notice, the Licensors, in the case of Allowable Expenses incurred by the Licensors or Sanofi, in the case of Allowable Expenses incurred by Sanofi and determination of Profit or Loss according to **EXHIBIT B** (as applicable, the "**Audited Party**") shall permit an independent, certified public accountant selected by the other Party (the "**Auditing Party**") and reasonably acceptable to the Audited Party, which acceptance will not be unreasonably withheld or delayed (for the purposes of this Section 7.5, the "**Auditor**"), to audit or inspect those books or records of the Audited Party and its Affiliates that relate to Allowable Expenses and Profit or Loss (including the items included in the calculation of Profit or Loss) for the sole purpose of verifying the amounts payable hereunder. The Auditor will disclose to the Auditing Party only the amount and accuracy of payments reported and actually paid or otherwise payable under this Agreement. The Auditor will send a copy of the report to the Audited Party at the same time it is sent to the Auditing Party. Such inspections may be made no more than once each Calendar Year and during normal business hours, and shall not be permitted at any time after the three (3) year period immediately following the applicable Calendar Year. No such inspection shall be made more than once for each applicable period. Such records for any particular Calendar Quarter shall be subject to no more than one inspection. Inspections conducted under this Section 7.5 shall be at the expense of the Auditing Party, unless a variation or error producing an underpayment in amounts payable exceeding 5% of the amount paid for a period covered by the inspection is established, in which case all reasonable costs relating to the inspection for such period and any unpaid amounts that are discovered shall be paid by the Audited Party. The Parties will endeavor in such inspection to minimize disruption of the Audited Party's normal business activities to the extent reasonably practicable.

7.6 Late Payments. In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest from the date due at a rate per annum equal to 1% above the U.S. Prime Rate (as set forth in the Wall Street Journal, Eastern Edition) for the date on which payment was due, calculated daily on the basis of a 365-day year, or similar reputable data source; provided that, in no event shall such rate exceed the maximum legal

annual interest rate. The payment of such interest shall not limit the Party entitled to receive such payment from exercising any other rights it may have as a consequence of the lateness of any payment.

ARTICLE 8

CONFIDENTIALITY

8.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by MannKind and Sanofi, the Parties agree that the receiving Party (the "**Receiving Party**"), shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement or any other written agreement between the Parties or between the Licensors and Sanofi any confidential or proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which is disclosed or made available to it by or on behalf of the other Party (the "**Disclosing Party**") including all information concerning Product and any other technical or business information of whatever nature (collectively, "**Confidential Information**"). For clarification, all MannKind Technology shall be Confidential Information of MannKind and, as applicable, TICV and BV, and all Sanofi Technology shall be Confidential Information of Sanofi. The Receiving Party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information.

8.2 Exceptions. Notwithstanding Section 8.1, the obligations of confidentiality and non-use shall not apply to Confidential Information that, in each case as demonstrated by competent evidence:

- (a) was already known to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality, at the time of disclosure;
- (b) was generally available to the public or was 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 to the Receiving Party and other than through any act or omission of the Receiving Party or any of its Affiliates in breach of this Agreement;
- (d) was subsequently lawfully disclosed to the Receiving Party or any of its Affiliates by a Person other than the Disclosing Party, and who, to the best knowledge of the Receiving Party, did not directly or indirectly receive such information directly or indirectly from the Disclosing Party under an obligation of confidence; or

(e) was developed by the Receiving Party or its Affiliate without use of or reference to any information or materials disclosed by the Disclosing Party.

8.3 Permitted Disclosures. Notwithstanding Section 8.1, the Receiving Party may disclose Confidential Information of the Disclosing Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing or prosecuting Patents as permitted by this Agreement;
- (b) prosecuting or defending litigation as permitted by this Agreement;
- (c) complying with applicable court orders or governmental regulations;

(d) disclosure to Affiliates, sublicensees, contractors, employees and consultants who need to know such information in connection with Development, Manufacturing, regulatory and Commercialization activities with respect to Product as contemplated by this Agreement, on the condition that any such Persons are subject to confidentiality and non-use obligations consistent in scope with those set forth in this Article 8; and

(e) disclosure to Third Parties in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by similar terms of confidentiality and non-use consistent in scope with those set forth in this Article 8.

In the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to Section 8.3(b) or (c), it will, except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as the Receiving Party would use to protect its own confidential information, but in no event less than reasonable efforts; provided, that any Confidential Information so disclosed shall remain subject to the restrictions on use set forth in this Article 8. In any event, the Receiving Party agrees to take all reasonable action to avoid disclosure of Confidential Information hereunder.

8.4 Confidentiality of this Agreement and its Terms. Except as otherwise provided in this Article 8, each Party agrees not to disclose to any Third Party the terms of this Agreement without the prior written consent of the other Party hereto, except that each Party may disclose the terms of this Agreement, which are not otherwise made public as contemplated by Section 8.5, as permitted under Section 8.3.

8.5 Public Announcements.

(a) **Press Releases.** As soon as practicable following the execution of this Agreement, the Parties will issue a joint press release announcing the existence of this Agreement. Except as required by Applicable Laws, including disclosure requirements of the

SEC, the NASDAQ stock exchange or any other stock exchange on which securities issued by a Party or its Affiliates are traded, neither Party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed; provided, that it shall not be unreasonable for a Party to withhold consent with respect to any public announcement containing any of such Party's Confidential Information. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text.

(b) Filing of Agreement. The Parties will coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC, the NASDAQ stock exchange or any other stock exchange or governmental agency on which securities issued by a Party or its Affiliate are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided, that each Party will ultimately retain control over what information to disclose to the SEC, the NASDAQ stock exchange or any other stock exchange or governmental agency, as the case may be, and provided further that the Parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) will be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC, the NASDAQ stock exchange or any other stock exchange or governmental agency.

8.6 Publication of the Product Information. During the Term, Sanofi shall be entitled to issue scientific publications with respect to Product or its testing, in accordance with Sanofi's internal guidelines; *provided, however*, that Sanofi shall adhere to academic attribution standards in any such publications; *provided further*, that at least thirty (30) days prior to publishing, publicly presenting and/or submitting for written or oral publication a manuscript, abstract or the like that includes Information relating to any Product that has not been previously published, Sanofi shall provide to MannKind a draft copy thereof for its review (unless Sanofi is required by Applicable Laws to publish such Information sooner, in which case Sanofi shall provide such draft copy to MannKind as much in advance of such publication as possible). Sanofi shall consider in good faith any comments provided by MannKind during such thirty (30)-day period. In addition, Sanofi shall, at MannKind's reasonable request, remove therefrom any Confidential Information of MannKind. MannKind shall not publish or present regarding Product or its testing without Sanofi's prior consent (except as MannKind may determine is appropriate in connection with the filing, prosecution and maintenance of the MannKind Patents or Joint Patents and/or is required to comply with Applicable Law).

8.7 Prior Non-Disclosure Agreements. As of the Effective Date, the terms of this Article 8 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement, including the Confidentiality Agreement. Any information disclosed under such prior agreements shall be deemed disclosed under this Agreement.

8.8 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a party would suffer upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the parties agree that monetary damages would not be a sufficient remedy for any breach of this Article 8. In addition to all other remedies, a party shall be entitled to specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 8.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 Ownership of Intellectual Property.

(a) MannKind Know-How, MannKind Patents. MannKind has, and shall retain all right, title and interest in and to, the MannKind Know-How and the MannKind Patents.

(b) Inventions. For purposes of determining questions of inventorship for Inventions, the Parties shall apply the laws of the United States. A Party shall have and retain all right, title and interest in all Inventions which are invented solely by one or more employees or contractors of such Party or its Affiliates, and (ii) the Parties shall jointly own all right, title and interest in all Joint Inventions and Joint Patents. Subject to the rights and licenses granted under this Agreement, each Party shall have the right to use, and grant licenses to use, any Joint Invention and Joint Patent without the other Party's consent and shall have no duty to account to the other Party for such use or license, and each Party hereby waives any right it may have under the laws of any country to require any such consent or accounting.

9.2 Patent Prosecution and Maintenance.

(a) MannKind Patents.

(i) Initial Responsibility. MannKind shall be responsible, in its discretion, for the preparation, filing, prosecution and maintenance of all MannKind Patents (including the right to conduct any interferences or oppositions (subject to Section 9.2(d)) thereon and to request any reissues or patent term extensions thereof), at MannKind's sole expense. With respect to MannKind Patents, MannKind shall provide in-house patent counsel designated by Sanofi:

(A) with a copy of the final draft of any proposed application at least 30 days prior to filing the same in any patent office in the Territory, unless otherwise agreed by patent counsel for both parties. Sanofi shall have the right to provide suggestions and recommendations regarding the content of the proposed application by no later than 15 days prior to its filing. MannKind shall give reasonable consideration to and will not unreasonably refuse to accept any suggestions or recommendations Sanofi provides;

(B) with a copy of all Patent applications as filed, together with a notice of its filing date and serial number;

(C) with a copy of any action, communication, letter, or other correspondence issued by the relevant patent office within at least 10 days of receipt thereof;

(D) with a copy of any response, amendment, paper, or other correspondence to be filed with the relevant patent office no more than 30 days prior to filing the same in any patent office in the Territory, unless otherwise agreed by patent counsel for both Parties. Sanofi shall have the right to provide suggestions and recommendations regarding the content of the response, amendment, paper, or other correspondence by no later than 15 days prior to its filing. MannKind shall give reasonable consideration to and will not unreasonably refuse to accept any suggestions or recommendations Sanofi provides;

(E) with a copy of any response, amendment, paper, or other correspondence as filed with the relevant patent office no more than 10 days after MannKind receives confirmation from the relevant patent office that the response, amendment, paper, or other correspondence has indeed been filed; and

(F) with notification of the allowance, grant, or issuance of any MannKind Patent.

(ii) Option of Sanofi to Maintain. In the event that MannKind desires to abandon or cease maintenance of any issued MannKind Patent in the Territory under which Sanofi then has a license under this Agreement, MannKind shall provide reasonable prior written notice to in-house patent counsel designated by Sanofi of such intention to abandon (which notice shall, to the extent possible, be given no later than 90 days prior to the next deadline for any action that must be taken with respect to any such issued MannKind Patent in the relevant patent office). Sanofi shall then have the right, but not obligation, to assume responsibility for the maintenance of such issued MannKind Patent in Sanofi's name and at Sanofi's own expense, upon providing written notice to MannKind of its assumption of this responsibility. In such case, MannKind shall assign all of its right, title and interest in such issued MannKind Patent to Sanofi, and shall perform all acts that Sanofi reasonably requests to permit and assist Sanofi, at Sanofi's expense, in obtaining, perfecting and enforcing the full benefits, enjoyment, rights and title in such issued MannKind Patent in the Territory. Any issued MannKind Patent so assigned to Sanofi shall no longer be considered a MannKind Patent and shall be considered a Sanofi Patent.

(b) Sanofi Patents. Sanofi shall be responsible, in its discretion, for the preparation, filing, prosecution and maintenance of Sanofi Patents (including the right to conduct any interferences, oppositions, or reexaminations (subject to Section 9.2(d)) thereon and to request any reissues or patent term extensions thereof), at Sanofi's sole expense. Sanofi shall keep MannKind informed in a timely manner, but not less frequently than quarterly, with regard to the preparation, filing, prosecution and maintenance of Sanofi Patents. Sanofi will consider in good faith the requests and suggestions of MannKind with respect to strategies for filing and prosecuting Sanofi Patents.

(c) Joint Patents.

(i) Initial Responsibility. MannKind shall be responsible, in its discretion, for the preparation, filing, prosecution and maintenance of Joint Patents in the Territory (including the right to conduct any interferences or oppositions (subject to Section 9.2(d)) thereon and to request any reissues or patent term extensions thereof), subject to this Section 9.2(c) and at MannKind's sole expense.

(ii) Cooperation. For any Joint Patents, MannKind shall keep Sanofi fully informed of progress with regard to the preparation, filing, prosecution and maintenance of the Joint Patents in the Territory. With respect to Joint Patents, MannKind shall provide in-house patent counsel designated by Sanofi:

(A) with a copy of the final draft of any proposed application at least 30 days prior to filing the same in any patent office in the Territory, unless otherwise agreed by patent counsel for both parties. Sanofi shall have the right to provide suggestions and recommendations regarding the content of the proposed application by no later than 15 days prior to its filing. MannKind shall accept any suggestions or recommendations Sanofi provides;

(B) with a copy of all Patent applications as filed, together with a notice of its filing date and serial number;

(C) with a copy of any action, communication, letter, or other correspondence issued by the relevant patent office within at least 10 days of receipt thereof;

(D) with a copy of any response, amendment, paper, or other correspondence to be filed with the relevant patent office no more than 30 days prior to filing the same in any patent office in the Territory, unless otherwise agreed by patent counsel for both parties. Sanofi shall have the right to provide suggestions and recommendations regarding the content of the response, amendment, paper, or other correspondence by no later than 15 days prior to its filing. MannKind shall accept any suggestions or recommendations Sanofi provides;

(E) with a copy of any response, amendment, paper, or other correspondence as filed with the relevant patent office no more than 10 days after MannKind receives confirmation from relevant patent office that the response, amendment, paper, or other correspondence has indeed been filed; and

(F) with notification of the allowance, grant, or issuance of such Joint Patent.

(iii) Option of Sanofi to Prosecute and Maintain. In the event that MannKind desires to abandon or cease prosecution or maintenance of any Joint Patent, MannKind shall provide reasonable prior written notice to Sanofi of such intention to abandon (which notice shall, to the extent possible, be given no later than 90 days prior to the next deadline for any action that must be taken with respect to such Joint Patent in the relevant patent office). In such case, at Sanofi's sole discretion, upon written notice from Sanofi, Sanofi may elect to continue prosecution and maintenance of any such Joint Patent at its own expense, and

MannKind shall execute such documents and perform such acts, at MannKind's expense, as may be reasonably necessary to effect an assignment of MannKind's entire right, title, and interest in and to such Joint Patent to Sanofi. Any such assignment shall be completed in a timely manner to allow Sanofi to continue prosecution and maintenance of any such Joint Patent. Any Patents so assigned shall no longer be considered Joint Patents and shall be considered Sanofi Patents.

(d) Post Grant Proceedings.

(i) By Third Party for Product-Specific MannKind Patents or Joint Patents. In the event that MannKind becomes aware that a Third Party has filed a post grant proceeding with respect to any Product-Specific MannKind Patent or Joint Patent, MannKind will notify Sanofi in writing to that effect within 10 days of becoming aware of such filing. Once such a post grant proceeding has commenced, MannKind shall provide in-house patent counsel designated by Sanofi:

(A) with a copy of any action, communication, letter, or other correspondence issued by the relevant patent office or the third party within at least 10 days of receipt thereof;

(B) with a copy of any response, amendment, paper, or other correspondence to be filed with the relevant patent office no more than 30 days prior to filing the same in any patent office worldwide, unless otherwise agreed by patent counsel for both parties. Sanofi shall have the right to provide suggestions and recommendations regarding the content of the response, amendment, paper, or other correspondence by no later than 15 days prior to its filing. MannKind shall accept any suggestions or recommendations Sanofi provides;

(C) with a copy of any response, amendment, paper, or other correspondence as filed with the relevant patent office no more than 10 days after MannKind receives confirmation from the relevant patent office that the response, amendment, paper, or other correspondence has indeed been filed; and

(D) MannKind shall not settle any post grant proceeding a Third Party files without the prior written approval of Sanofi, not to be unreasonably withheld or delayed.

(ii) By Third Party for Platform MannKind Patents. In the event that MannKind becomes aware that a third Party has filed a post grant proceeding with respect to any Platform MannKind Patent, MannKind shall provide in-house patent counsel designated by Sanofi:

(A) with any copy of any action, communication, letter, or other correspondence issued by the relevant patent office or the third party within at least 10 days of receipt thereof;

(B) with a copy of any response, amendment, paper or other correspondence to be filed with the relevant patent office no more than 30 days prior to filing the same in any patent office worldwide, unless otherwise agreed by patent counsel for both parties.

Sanofi shall have the right to provide suggestions and recommendations regarding the content of the response, amendment, paper or other correspondence by no later than 15 days prior to its filing. MannKind shall give reasonable consideration to and will not unreasonably refuse to accept any suggestions or recommendations Sanofi provides;

(C) with a copy of any response, amendment, paper, or other correspondence as filed with the relevant patent office no more than 10 days after MannKind receives confirmation from the relevant patent office that the response, amendment, paper or other correspondence has indeed been filed; and

(D) MannKind shall not settle any post grant proceeding a Third Party files without the prior written approval of Sanofi, not to be unreasonably withheld or delayed.

(iii) By Party for Product-Specific MannKind Patents or Joint Patents. Should a Party desire to file a post grant proceeding with respect to a Product-Specific MannKind Patent or a Joint Patent, including but not limited to an ex parte reexamination or a supplemental examination, such Party shall so notify the other Party. The Parties shall then consult with each other and consider each other's input with respect to whether such a post grant proceeding should be filed; *provided, however*, Sanofi shall have final decision authority with respect to the filing of such a proceeding. Should such a proceeding be filed, MannKind shall provide in-house patent counsel designated by Sanofi:

(A) with a copy of any action, communication, letter, or other correspondence issued by the relevant patent office within at least 10 days of receipt thereof;

(B) with a copy of any response, amendment, paper, or other correspondence to be filed with the relevant patent office no more than 30 days prior to filing the same in any patent office worldwide, unless otherwise agreed by patent counsel for both parties. Sanofi shall have the right to provide suggestions and recommendations regarding the content of the response, amendment, paper, or other correspondence by no later than 15 days prior to its filing. MannKind shall accept any suggestions or recommendations Sanofi provides;

(C) with a copy of any response, amendment, paper, or other correspondence as filed with the relevant patent office no more than 10 days after MannKind receives confirmation from the relevant patent office that the response, amendment, paper, or other correspondence has indeed been filed; and

(D) MannKind shall not settle such a post grant proceeding without the prior written approval of Sanofi, not to be unreasonably withheld or delayed.

(iv) By Party for Platform MannKind Patent. Should a Party desire to file a post grant proceeding with respect to a Platform MannKind Patent, including but not limited to an ex parte reexamination or a supplemental examination, such Party shall so notify the other Party. The Parties shall then consult with each other and consider each other's input with respect to whether such a post grant proceeding should be filed; *provided, however*,

MannKind shall have final decision authority with respect to the filing of such a proceeding. Should such a proceeding be filed, MannKind shall provide in-house patent counsel designated by Sanofi:

(A) with a copy of any action, communication, letter, or other correspondence issued by the relevant patent office within at least 10 days of receipt thereof;

(B) with a copy of any response, amendment, paper, or other correspondence to be filed with the relevant patent office no more than 30 days prior to filing the same in any patent office worldwide, unless otherwise agreed by patent counsel for both parties. Sanofi shall have the right to provide suggestions and recommendations regarding the content of the response, amendment, paper, or other correspondence by no later than 15 days prior to its filing. MannKind shall give reasonable consideration to and not unreasonably refuse to accept any suggestions or recommendations Sanofi provides;

(C) with a copy of any response, amendment, paper, or other correspondence as filed with the relevant patent office no more than 10 days after MannKind receives confirmation from the relevant patent office that the response, amendment, paper, or other correspondence has indeed been filed; and

(D) MannKind shall not settle such a post grant proceeding without the prior written approval of Sanofi, not to be unreasonably withheld or delayed.

9.3 Infringement by Third Parties.

(a) **Notice.** In the event that either MannKind or Sanofi becomes aware of any infringement or threatened infringement by a Third Party of any Patents that are subject to the prosecution, maintenance or enforcement rights of the other Party under this Agreement, it will notify the other Party in writing to that effect within 10 days of receipt of such notice. Any such notice shall include evidence to support an allegation of infringement or threatened infringement by such Third Party.

(b) MannKind Patents.

(i) **Product-Specific MannKind Patents.** Subject to this Section 9.3(b), Sanofi shall have the first right (but not the obligation), as between MannKind and Sanofi, to bring and control any action or proceeding with respect to infringement of any Product-Specific MannKind Patent, at its own expense and by counsel of its own choice. MannKind shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and Sanofi and its counsel will reasonably cooperate with MannKind and its counsel in strategizing, preparing and presenting any such action or proceeding. Sanofi though shall have the final word regarding litigation strategy. If Sanofi fails to bring an action or proceeding with respect to infringement of any Product-Specific MannKind Patent described in the preceding sentence within (i) 90 days following the notice of alleged infringement or (ii) 10 days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, MannKind shall have the right (but not the obligation) to

bring and control any such action at its own expense and by counsel of its own choice, and Sanofi shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. MannKind and its counsel will reasonably cooperate with Sanofi and its counsel in strategizing, preparing and presenting any such action or proceeding. Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding, and (A) any remaining compensatory damages relating to Product (including lost sales or lost profits with respect to the Product) shall be deemed Net Sales for purposes of calculation of Profit or Loss, and (B) any punitive damages shall be shared by the Parties according to the ratio set forth in Section 3 of **EXHIBIT B**.

(ii) Platform MannKind Patents. Subject to this Section 9.3(b), the Controlling Party shall have the first right (but not the obligation), as between MannKind and Sanofi, to bring and control any action or proceeding with respect to Competitive Infringement of any Platform MannKind Patent, at its own expense and by counsel of its own choice, and the other Party shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and the Controlling Party and its counsel will reasonably cooperate with the other Party and its counsel in strategizing, preparing and presenting any such action or proceeding. If the Controlling Party fails to bring an action or proceeding with respect to an alleged Competitive Infringement of any such Platform MannKind Patent within (i) 90 days following the notice of alleged Competitive Infringement or (ii) 10 days before the time limit, if any, set forth in the appropriate laws and regulations for filing such actions, whichever comes first, the other Party shall have the right (but not the obligation) to bring and control any such Competitive Infringement action or proceeding by counsel of its own choice, thereby becoming the Controlling Party and subject to the obligation to reasonably cooperate with the other Party and its counsel in strategizing, preparing and presenting any such action or proceeding. Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such Competitive Infringement action or proceeding shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to the infringement action or proceeding, and (A) any remaining compensatory damages relating to Product (including lost sales or lost profits with respect to the Product) shall be deemed Net Sales for purposes of calculation of Profit or Loss, and (B) any punitive damages shall be shared by the Parties according to the ratio set forth in Section 3 of **EXHIBIT B**. For purposes of this Section 9.3(b)(ii), "**Controlling Party**" shall mean Sanofi for actions commenced during such time that Sanofi is the sole licensee of such Platform MannKind Patent, and shall mean MannKind for all other actions, and "**Competitive Infringement**" shall mean (i) any allegedly infringing activity in the Field in the Territory for the Product, which activity is reasonably expected to reduce Net Sales of Product then being sold by Sanofi and its Affiliates and sublicensees in the Territory, or (ii) the making, using, selling, offering for sale or importing Product in the Territory.

(c) Sanofi Patents. Subject to this Section 9.3(c), Sanofi shall have the sole right (but not the obligation), as between MannKind and Sanofi, to bring and control any action or proceeding with respect to infringement of any Sanofi Patent worldwide, at its own expense and by counsel of its own choice and any recovery or damages realized as a result of such action

or proceeding shall be used first to reimburse Sanofi's documented out-of-pocket legal expenses relating to the action or proceeding, and (A) any remaining compensatory damages relating to Product (including lost sales or lost profits with respect to Product) shall be deemed Net Sales for purposes of calculation of Profit or Loss and (B) any punitive damages relating to Product shall be shared by the Parties according to the ratio set forth in Section 3 of **EXHIBIT B**.

(d) Joint Patents. Subject to this Section 9.3(d), Sanofi shall have the first right (but not the obligation) to bring and control any action or proceeding with respect to infringement of any Joint Patent worldwide, at its own expense and by counsel of its own choice. MannKind shall cooperate in such action in the manner described in Section 9.3(e) and shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Sanofi though shall have the final word regarding litigation strategy. If Sanofi fails to bring an action or proceeding within (i) 90 days following the notice of alleged infringement or (ii) 10 days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, MannKind shall have the right (but not the obligation) to bring and control any such action at its own expense and by counsel of its own choice, and Sanofi shall cooperate in such an action as defined in Section 9.3(e) and shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any recovery or damages from an action or proceeding relating to Joint Patents shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding, and (A) any remaining compensatory damages relating to Product (including lost sales or lost profits with respect to Product) shall be deemed Net Sales for purposes of calculation of Profit or Loss, and (B) any punitive damages shall be shared by the Parties according to the ratio set forth in Section 3 of **EXHIBIT B**.

(e) Cooperation. In the event a Party brings an infringement action in accordance with this Section 9.3, the other Party shall cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or being joined as a party to such action.

9.4 TICV. MannKind warrants that TICV does not have legal title to any of the MannKind Patents or rights to maintain, prosecute or enforce such patents. If, notwithstanding the foregoing, TICV's action is required to give effect to the provisions of this Article 9, MannKind shall cause TICV to take such action.

9.5 Infringement of Third Party Rights.

(a) Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of either of the Parties pursuant to this Agreement or the Supply Agreement infringes or may infringe the intellectual property rights of such Third Party.

(b) MannKind shall have the sole right (but not the obligation), as between MannKind, TICV and BV, on the one hand, and Sanofi, on the other hand, to bring and control any defense of any such claim involving alleged infringement of Third Party rights by MannKind's, TICV's or BV's activities pursuant to this Agreement or the Supply Agreement at its own expense and by counsel of its own choice; *provided, however*, that such expenses shall be

considered Allowable Expenses for the purposes of **EXHIBIT B**. Sanofi shall have the right, at its own expense, to be represented in any such defense by counsel of its own choice. MannKind shall solely bear all of its costs related to the defense of such an infringement action as well as any and all damages awarded to the Third Party. Should MannKind conclude it is necessary to obtain a license in the intellectual property rights of the Third Party for MannKind, TICV or BV to conduct activities for which it is reasonable as contemplated by this Agreement or the Supply Agreement, MannKind shall pay all costs and royalties necessary to obtain such license and maintain such license, at its own expense, during the Term.

(c) Sanofi shall have the sole right (but not the obligation), as between Sanofi, on the one hand, and MannKind, TICV and BV, on the other hand, to bring and control any defense of any such claim involving alleged infringement of Third Party rights by Sanofi's and its Affiliates' and sublicensees' activities pursuant to this Agreement or the Supply Agreement at its own expense and by counsel of its own choice. MannKind shall have the right to be represented in any such defense by counsel of its own choice at its own expense; *provided, however*, that such expenses shall be considered Allowable Expenses for purposes of **EXHIBIT B**. Sanofi shall bear all of its costs related to the defense of such an infringement action as well as any and all damages awarded to the Third Party; *provided, however*, that such costs and damages (but excluding any such damages for willful infringement or willful misconduct by Sanofi or its Affiliates or sublicensees and any litigation sanctions awarded against Sanofi or its Affiliates (collectively, "**Special Damages**")) shall be considered Allowable Expenses for purposes of **EXHIBIT B**. Should Sanofi conclude it is necessary to obtain a license in the intellectual property rights of the Third Party for Sanofi or its Affiliates or sublicensees to conduct activities for which it is responsible as contemplated by this Agreement or the Supply Agreement, Sanofi shall pay all costs and royalties necessary to obtain such license and maintain such license, as an Allowable Expense, during the Term.

9.6 Consent for Settlement. Neither Party shall enter into any settlement or compromise of any action or proceeding under this Article 9 which would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party.

9.7 Paragraph IV Notice. If either Party receives a notice under 21 U.S.C. §355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) (or any foreign equivalent) concerning any MannKind Patent, Joint Patent or Sanofi Patent, then it shall provide a copy of such notice to the other Party within two Business Days after its receipt thereof. Patent infringement litigation based on such a notice concerning a MannKind Patent, Joint Patent or Sanofi Patent shall be brought and controlled as provided in Section 9.3(b), 9.3(c) or 9.3(d), as applicable.

9.8 Biosimilar Applications.

(a) If either Party receives a copy of an application submitted to the FDA under subsection (k) of Section 351 of the Public Health Service Act ("**PHSA**") or comparable provisions of Applicable Laws in any other jurisdiction (a "**Biosimilar Application**") naming a Product as a reference product or otherwise becomes aware that such a Biosimilar Application has been filed (such as in an instance described in Section 351(1)(9)(C) of the PHSA) or any

equivalent or similar certification or notice in any other jurisdiction, such Party shall, within 10 Business Days, notify the other Party. Sanofi will then seek permission to view the application and related confidential information from the filer of the Biosimilar Application under Section 351(l)(1)(B)(iii) of the PHSA. Regardless of the Party that is the “reference product sponsor” for purposes of such Biosimilar Application, Sanofi shall have the sole right:

(i) to designate pursuant to Section 351(l)(1)(B)(ii) of the PHSA or comparable provisions of Applicable Laws in any other jurisdiction the outside counsel and in-house counsel who shall receive confidential access to the Biosimilar Application;

(ii) to list any Patents, including MannKind Patents, Sanofi Patents and Joint Patents, insofar as they claim or cover the applicable Product as required pursuant to Section 351(l)(3)(A), Section 351(l)(5)(b)(i)(II), or Section 351(l)(7) of the PHSA or comparable provisions of Applicable Laws in any other jurisdiction;

(iii) to respond to any communications with respect to such lists from the filer of the Biosimilar Application;

(iv) to negotiate with the filer of the Biosimilar Application as to whether to utilize a different mechanism for information exchange other than that specified in Section 351(l) of the PHSA or comparable provisions of Applicable Laws in any other jurisdiction; and

(v) to identify Patents or respond to communications under any equivalent or similar listing in any other jurisdiction with respect to the applicable Product.

(b) If required pursuant to Applicable Law, MannKind shall prepare such list and make such response at Sanofi’s direction. MannKind will provide to Sanofi, within 15 days of Sanofi’s request, all information, including a correct and complete list of MannKind and Joint Patents that is necessary or reasonably useful to enable Sanofi to make such lists of Patents that cover the Product, and cooperate with Sanofi’s reasonable requests in connection therewith, including meeting any submission deadlines, in each case, to the extent required or permitted by Applicable Law. Sanofi shall reasonably consult with MannKind prior to identifying any MannKind Patents to a Third Party as contemplated by this Section 9.8. Sanofi shall consider in good faith advice and suggestions with respect thereto received from MannKind, and notify MannKind of any such lists or communications promptly after they are made. If Sanofi does not proceed under this Section 9.8, then thereafter MannKind shall have the right to proceed in place of Sanofi under this Section 9.8 with the roles of the Parties reversed. For clarity, the subsequent enforcement of Patents against a filer of a Biosimilar Application shall be in accordance with Section 9.3.

9.9 Orange Book Listings. The Parties shall consult with each other and consider input from each other as applicable with respect to the listing of MannKind Patents, Joint Patents and Sanofi Patents with the applicable Regulatory Authorities; *provided, however*, that Sanofi shall have the final decision authority with respect to which Patents are to be listed. Sanofi shall have the sole authority and discretion to maintain with the applicable Regulatory Authorities

during the Term listings of applicable Sanofi Patents for Product then being Commercialized by Sanofi in the Territory, including all Orange Book listings required under the Hatch-Waxman Act (and all foreign equivalents). With respect to MannKind Patents and Joint Patents, Sanofi shall instruct MannKind which Patents are to be listed, and MannKind shall promptly perform all acts necessary to maintain with all the applicable Regulatory Authorities during the Term listings of the MannKind and Joint Patents Sanofi instructs MannKind to list, including the completion and filing of Form FDA 3542 as required for all Orange Book Listings under the Hatch-Waxman Act.

ARTICLE 10

REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 Mutual Representations, Warranties and Covenants. Each Party hereby represents and warrants to the other Party, as of the Effective Date, as follows:

(a) Duly Organized. Such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent such Party from performing its obligations under this Agreement.

(b) Due Authorization; Binding Agreement. The execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary corporate action. This Agreement is a legal and valid obligation binding on such Party and enforceable in accordance with its terms and does not: (i) to such Party's knowledge and belief, violate any law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over such Party; nor (ii) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which such Party is a party or by which it is bound.

(c) Consents. Such Party has obtained, or is not required to obtain, the consent, approval, order or authorization of any Third Party, or has completed, or is not required to complete any registration, qualification, designation, declaration, or filing with, any Regulatory Authority or Governmental Authority, in connection with the execution and delivery of this Agreement and the performance by such Party of its obligations under this Agreement, except as contemplated by Section 15.16.

(d) No Conflicting Grant of Rights. Such Party has the right to grant the licenses and rights as contemplated under this Agreement and has not, and will not during the Term, grant any right to any Third Party which would conflict with the licenses and rights granted to the other Party hereunder.

(e) Employee/Contractor Agreements. All of such Party's and its Affiliates' employees or contractors acting on its behalf pursuant to this Agreement are and will be obligated under a binding written agreement to assign to such Party or its designee all

Inventions and to comply with obligations of confidentiality and non-use consistent in scope with those set forth in Article 8.

(f) Debarment. Such Party is not debarred under the United States Federal Food, Drug and Cosmetic Act, excluded from a federal health care program, or debarred from federal contracting, and such Party does not, and will not during the Term, employ or use the services of any Person who is so debarred or excluded, or who has been convicted of or pled nolo contendere to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug or device products or fraud, or convicted of any other crime for which an entity or person could be so debarred or excluded (including by the FDA under 21 U.S.C. § 335a (or subject to a similar sanction of any other Governmental Authority)), in connection with the Development, Manufacture or Commercialization of the Products. In the event that either Party becomes aware of the debarment. Exclusion, or threatened debarment or exclusion of any Person providing services to such Party, including the Party itself and its Affiliates, which directly or indirectly relate to activities under this Agreement, the other Party shall be immediately notified in writing, and at the other Party's option this Agreement shall terminate automatically as of the first date of such noncompliance.

10.2 Representations and Warranties of the Licensors. The Licensors represent and warrant to Sanofi that, as of the Effective Date:

(a) Patents. MannKind has delivered to Sanofi a list of MannKind Patents as of the Effective Date under separate cover, which (i) is a true and complete list of all Patents Controlled by Licensors or their Affiliates as of the Effective Date that that claim or disclose Product or its components, or are necessary for the Development, Manufacture, use or Commercialization of Product in the Field in the Territory, including all such Patents claiming or covering the design or utility of a Device or a Formulation, and (ii) indicates the current status, date and country of filing and issuance. All official fees, maintenance fees and annuities for the MannKind Patents have been paid through the Effective Date.

(b) Patent and Technology Status. As of the Effective Date, (i) all issued MannKind Patents are in full force and effect and subsisting, and inventorship of each Patent is properly identified on such Patents; (ii) none of the MannKind Patents is currently involved in any interference, reissue, reexamination, or opposition proceeding; (iii) neither MannKind nor any of its Affiliates has received any written notice from any Person, or has knowledge, of such actual or threatened proceeding; (iv) to the knowledge of the Licensors, all issued MannKind Patents and registered MannKind Trademarks are valid; (v) the Licensors have taken reasonable security measures consistent with industry standard practices, including measures against unauthorized disclosure, to protect the secrecy and confidentiality of trade secrets within MannKind Technology; (vi) the Licensors are in compliance with and have complied with all duties of candor required by applicable governing bodies or jurisdictions in the course of the Licensors' prosecution of any rights in any of the MannKind Technology licensed to Sanofi under this Agreement; (vii) the Licensors have obtained valid and enforceable assignments of interests to any rights in any of the MannKind Technology licensed to Sanofi under this Agreement from any inventors who contributed to the discovery, creation, development or reduction to practice of any such MannKind Technology; (viii) to the knowledge of the

Licensors, the MannKind Technology licensed to Sanofi under this Agreement comprises all of the intellectual property rights necessary and sufficient to develop and distribute Product and no intellectual property rights owned by any Third Party are necessary to develop and distribute Product; and (ix) the Licensors are not subject to any inventor remuneration obligations related to the MannKind Technology.

(c) Transfers of Undertakings Directive. Licensors do not employ any personnel in the European Union.

(d) Non-Infringement by Third Parties. As of the Effective Date, to the Licensors' knowledge, there are no activities by Third Parties that would constitute infringement of the MannKind Patents or misappropriation of the MannKind Know-How.

(e) Non-Infringement of Third Party Rights. Neither the Licensors nor any of their Affiliates have received any written notice from any Person, or have knowledge of, any actual or threatened claim or assertion that the use or practice of the MannKind Patents, or MannKind Know-How infringes or misappropriates the intellectual property rights of a Third Party.

(f) No Action or Claim. As of the Effective Date, there are no actual, pending, or alleged or threatened in writing, adverse actions, suits, claims, interferences or formal governmental investigations by or against the Licensors or any of their Affiliates in or before any court, Governmental Authority involving any MannKind Know-How, MannKind Patents or Product, including in connection with the conduct of any clinical trials or Manufacturing activities. As of the Effective Date, there are no material unsatisfied judgments or outstanding orders, injunctions, decrees, stipulations or awards (whether rendered by a court, an administrative agency or by an arbitrator) against the Licensors with respect to any MannKind Know-How, MannKind Patents or Product. The issued MannKind Patents have not been used or enforced in a manner that would result in the abandonment, cancellation or unenforceability of any such issued MannKind Patent.

(g) No Governmental Funding. As of the Effective Date, none of the MannKind Patents has been developed with the use of any funding from any Governmental Authority.

(h) Compliance. As of the Effective Date, the Licensors and their Affiliates and, to the Licensors' knowledge, any contract research organization to which the Licensors or their Affiliates have subcontracted activities in connection with Product have complied in all material respects with all Applicable Laws, including all good clinical practices, good laboratory practices and good manufacturing practices, permits, governmental licenses, registrations, approvals, authorizations, orders, injunctions and decrees, in the research, Development, Manufacture and use of Product, and neither the Licensors nor any of their Affiliates nor, to the Licensors' knowledge, any contract research organization to which the Licensors or their Affiliates have subcontracted activities in connection with Product, has received any written notice from any Governmental Authority claiming that any such activities as conducted by them are not in such compliance.

(i) No Injunction. No Governmental Authority (including the FDA) has commenced or, to the Licensors' knowledge, threatened to initiate any action to enjoin production of Product at any facility, nor have the Licensors or any of their Affiliates or, to the Licensors' knowledge, any of their subcontractors involved in production of Product, received any notice to such effect since January 1, 2000.

(j) Clinical, Safety and Regulatory Information. The Licensors have made available to Sanofi a true and correct copy, which is complete in all material respects, of (i) all MAA submissions associated with Product, (ii) all Data from clinical studies conducted under any IND for Product, (iii) all material correspondence with the FDA regarding Product, and (iv) all minutes of meetings and telephone conferences with the FDA with respect to the MAA for Product. The Licensors have disclosed or otherwise provided Sanofi with all material information in the Licensors' possession as of the Effective Date relating to (A) the MannKind Know-How or MannKind Patents, (B) the safety or efficacy of Product, or (C) the Manufacture of Product.

(k) MannKind Trademarks. MannKind hereby represents and warrants to Sanofi as of the Effective Date that:

(i) Licensors have all right, title, and interest in and to the MannKind Trademarks;

(ii) to the best knowledge of MannKind, there is no Third Party using or infringing any of the MannKind Trademarks in the Territory in derogation of the rights granted to Sanofi in this Agreement;

(iii) MannKind has not received notice of any opposition, cancellation action or pending litigation or any communication which expressly threatens an opposition or cancellation action, or other litigation, before any trademark office, court or any other governmental entity in the Territory with respect to any of the MannKind Trademarks;

(iv) the MannKind Trademarks are the only trademarks owned, held, Controlled, licensed or otherwise used (or intended to be used) by MannKind or its Affiliates with respect to the Product in the Territory (other than MannKind's corporate name and/or logo);

(v) MannKind has all rights to use the MannKind Trademarks with respect to the Product in the Territory and to license the MannKind Trademarks to Sanofi hereunder; and

(vi) to the best knowledge of MannKind, MannKind has not infringed, misappropriated, diluted or otherwise violated any trademark of any Third Party by registering or using the MannKind Trademarks in the Territory; and

(vii) to the knowledge of MannKind, no claims or proceedings, asserting that the MannKind Trademarks infringe the right of any Third Party, are pending or threatened.

10.3 Representations and Warranties of Sanofi. Sanofi represents and warrants to the Licensors that there is no action, suit, proceeding or investigation pending or, to its knowledge, threatened before any court or administrative agency against Sanofi or its Affiliates which could, directly or indirectly, reasonably be expected to materially affect its ability to perform its obligations hereunder or the Commercialization by Sanofi of the Product.

10.4 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, OR ANY OTHER AGREEMENT CONTEMPLATED HEREUNDER, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT, VALIDITY AND ENFORCEABILITY OF PATENTS, OR THE PROSPECTS OR LIKELIHOOD OF DEVELOPMENT OR COMMERCIAL SUCCESS OF PRODUCT.

ARTICLE 11

INDEMNIFICATION AND INSURANCE

11.1 Indemnification of MannKind. Sanofi shall indemnify and hold harmless each of Licensors and their Affiliates and the directors, officers, shareholders and employees of such entities and the successors and assigns of any of the foregoing (the “*MannKind Indemnitees*”), from and against any and all losses, liabilities, damages, penalties, fines, costs and expenses (including, reasonable attorneys’ fees and other expenses of litigation) (“*Losses*”) from any claims, actions, suits or proceedings brought by a Third Party (a “*Third Party Claims*”) incurred by any MannKind Indemnitee, arising from, or occurring as a result of any material breach of any representations, warranties or covenants by Sanofi under this Agreement; except to the extent such Third Party Claims fall within the scope of the indemnification obligations of MannKind set forth in Section 11.2 of this Agreement or in Section 11.2 of the Supply Agreement. In addition, Sanofi shall indemnify and hold harmless the MannKind Indemnitees from and against any and all Special Damages (as such term is defined in Section 9.5(c)).

11.2 Indemnification of Sanofi. The Licensors shall indemnify and hold harmless each of Sanofi and its Affiliates and the directors, officers and employees of such entities, and the successors and assigns of any of the foregoing (the “*Sanofi Indemnitees*”), from and against any and all Losses from any Third Party Claims incurred by any Sanofi Indemnitee, arising from, or occurring as a result of: (a) the Manufacturing, Development and regulatory activities relating to Product conducted by or on behalf of the Licensors or their Affiliates before the Effective Date; and (b) any material breach of any representations, warranties or covenants by the Licensors under this Agreement, except to the extent such Third Party Claims falls within the scope of the indemnification obligations of Sanofi set forth in Section 11.1 of this Agreement or in Section 11.1 of the Supply Agreement.

11.3 Procedure. A party that intends to claim indemnification under this Article 11 (the “*Indemnitee*”) shall promptly notify the indemnifying Party (the “*Indemnitor*”) in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such

indemnification, and the Indemnitor shall have sole control of the defense and/or settlement thereof. The indemnity arrangement in this Article 11 shall not apply to amounts paid in settlement of any action with respect to a Third Party Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 11 if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by this indemnification.

11.4 Insurance. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with industry standards during the Term and shall name the other Party as an additional insured with respect to such insurance. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.

ARTICLE 12

CONDITIONS PRECEDENT, TERM AND TERMINATION

12.1 Term. This Agreement shall commence on the Effective Date, and unless terminated earlier as provided in this Article 12, shall continue in full force and effect until terminated pursuant to Section 12.2, 12.3 or 12.4 (the “**Term**”).

12.2 Termination by the Parties.

(a) Termination for Material Breach. In the event that either Party shall be in material breach in the performance of any of its obligations under this Agreement (the “**Breaching Party**”), in addition to any other right and remedy the other Party (the “**Complaining Party**”) may have, the Complaining Party may terminate this Agreement by giving notice in writing specifying the breach and its claim of right to terminate; *provided, however*, that if the breach is remediable, the Breaching Party shall have ninety (90) days (or forty-five (45) days for any payment breach) (the “**Notice Period**”) to rectify the breach and termination shall become effective at the end of the Notice Period only if the Breaching Party fails to cure the breach complained about during (i) the Notice Period or, (ii) if such breach (other than any payment breach) has not been cured within such 90-day period, if the Breaching Party has commenced actions to cure such breach within the Notice Period and thereafter uses reasonable efforts to cure such breach, such longer period as is reasonably required to cure such breach, but in any event, not to exceed ninety (90) days following expiration of the Notice Period; *provided further*, that, if Sanofi is the Breaching Party and the breach is with respect to Sanofi’s failure to comply with its obligation to use Commercially Reasonable Efforts with respect to (x) the United States, MannKind may terminate this Agreement in its entirety, and (y) any Major Market (other than the United States) or [...***...] Country, MannKind may terminate this Agreement only with respect to such Major Market or [...***...] Country (as applicable) and not in its entirety. If the Breaching Party disputes in good faith that it has materially breached one of

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its obligations under this Agreement, termination shall not take effect pending resolution of such dispute pursuant to Article 14. If, as a result of the application of such dispute resolution procedures, the Breaching Party is determined to be in material breach of one or more of its obligations under this Agreement (an “**Adverse Ruling**”), then if the Breaching Party fails to complete the actions specified by the Adverse Ruling to cure such breach within ninety (90) days (or forty five (45) days for any payment breach) after such Adverse Ruling, then the Complaining Party may terminate this Agreement upon written notice to the Breaching Party.

(b) Termination Upon Insolvency. Either Party will be entitled to terminate this Agreement with immediate effect by notice in writing if the other Party files for protection under bankruptcy or insolvency laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver, administrator, manager, trustee or like official over its property that is not discharged within 90 days, proposes a written agreement of composition or extension of its debts, is a party to any dissolution, winding-up or liquidation or has any such petition filed against it which involuntary petition is not discharged within 60 days of the filing thereof.

12.3 Additional Sanofi Termination Rights.

(a) If, at any time on or after January 1, 2016, Sanofi determines in good faith that Commercialization of Product is no longer economically viable in the United States, then Sanofi may terminate this Agreement in its entirety upon delivery of at least ninety (90) days’ prior written notice to MannKind. In addition, at any time on or after January 1, 2016, upon delivery of at least six (6) months’ prior written notice to MannKind, Sanofi shall have the right to terminate this Agreement for any reason (a) in its entirety, or (b) on a country-by-country basis other than with respect to the United States; *provided, however*, that if Sanofi terminates this Agreement under this Section 12.3(a) in each of [...***...], then Sanofi shall terminate this Agreement with respect to all countries of the European Union. For purposes of clarity, Sanofi shall have no right to terminate this Agreement with respect to only the United States under this Section 12.3(a).

(b) Termination for Safety or Regulatory Reasons. On a country-by-country basis, Sanofi shall have the right in its sole discretion to terminate this Agreement in such country immediately upon thirty (30) days’ written notice to MannKind in the event:

(i) of withdrawal or indefinite suspension of any MAA for a Product in such country; or

(ii) that Sanofi determines in good faith that pursuing the Development or Commercialization of a Product in the Territory or any part thereof poses an unacceptable medical risk to patients.

12.4 Additional MannKind Termination Right. MannKind shall have the right to terminate this Agreement immediately upon written notice to Sanofi if Sanofi or any of its Affiliates or sublicensees directly, or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of,

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or opposes any extension of or the grant of a supplementary protection certificate with respect to, any MannKind Patent; provided that MannKind shall not have such right to terminate this Agreement for a proceeding, challenge or opposition of the type described above (in each case, a “**Challenge**”) by a sublicensee if (a) the sublicense agreement with such sublicensee includes a right of the applicable sublicensor (Sanofi, its Affiliate or another sublicensee, as applicable) to terminate the sublicense following written notice to such sublicensee and, if applicable, a cure period not to exceed sixty (60) days if such sublicensee directly, or indirectly through any Third Party, institutes a Challenge of any MannKind Patent and (b) either (i) the applicable sublicensor diligently enforces its rights to cause the sublicensee to withdraw or dismiss such Challenge including, if applicable, exercise of such termination right promptly following the expiration of any applicable cure period or (ii) such Challenge is withdrawn or dismissed within thirty (30) days after a request by the applicable sublicensor or by MannKind to do.

12.5 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein. Notwithstanding the foregoing, termination of this Agreement in the applicable [...***...] Country in accordance with Section 12.2(a) shall be MannKind’s sole remedy for Sanofi’s failure to comply with its obligations under Section 4.2(c) to use Commercially Reasonable Efforts to file for, obtain or maintain Marketing Approvals for Product in the Field in any [...***...] Country.

ARTICLE 13

EFFECT OF TERMINATION

13.1 Partial Termination. In case of termination of this Agreement, not in its entirety, but with respect to only a particular country (other than the United States) by MannKind pursuant to clause (y) of Section 12.2(a) or with respect to only a particular country or region by Sanofi pursuant to Section 12.3(a) (a “**Partial Termination**” and each country or region in which such Partial Termination occurs, a “**Terminated Country**”), then the effects of termination described under this Article 13 shall only apply to the Terminated Country, and this Agreement shall remain in full force and effect in accordance with its terms in all countries of the Territory other than the Terminated Country.

13.2 Accrued Obligations. The expiration or termination of this Agreement, in whole or part, for any reason shall not release either Party from any liability or deprive either Party of any right which, at the time of such expiration or termination, has already accrued to such Party or which is attributable to a period prior to such expiration or termination, nor will any expiration or termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement.

13.3 Rights on Termination Other than Termination By Sanofi for Cause. This Section 13.3 shall apply and shall only apply upon the termination of this Agreement by MannKind pursuant to Section 12.2 or Section 12.4, or by Sanofi pursuant to Section 12.3(a):

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(a) Wind-down Period.

(i) Development. In the event there are any on-going clinical trials of Product in the Field in the Territory, Sanofi shall, to the extent so requested by MannKind, promptly transition, at MannKind's expense, to MannKind or its designee such clinical trials then being conducted by Sanofi, or portions thereof, for MannKind or its designee to complete at their expense.

(ii) Commercialization. Sanofi and its Affiliates and sublicensees shall continue, to the extent that Sanofi and its Affiliates and sublicensees continue to have stocks of usable Product, to fulfill orders received from customers for Product in the Field in the Territory until up to 180 days after the later of (A) the date on which MannKind notifies Sanofi in writing that MannKind intends to Commercialize such Product or has secured an alternative distributor or licensee for the Product and (B) Sanofi has initiated transition of the MAAs and Marketing Approvals for Product in the Field in the Territory to MannKind or such distributor or licensee, but in no event for more for than 12 months after the date of notice of termination. For Product sold by Sanofi after the effective date of a termination (i.e., after the expiration of the applicable termination notice period), the profit-or-loss provisions in Section 6.3 shall continue to apply. Notwithstanding the foregoing, Sanofi and its Affiliates and sublicensees shall cease such activities in the Territory upon 60 days written notice given by MannKind at any time after the effective date of a termination requesting that such activities (or portion thereof) cease. In the case of a termination of this Agreement in its entirety, within 30 days after MannKind has given notice to Sanofi requesting the cessation of activities pursuant to the provision of this Section, Sanofi shall notify MannKind of an estimate of the quantity of Product and its shelf life remaining in Sanofi's inventory and MannKind shall have the right to purchase any such quantities of Product from Sanofi at a price mutually agreed by the Parties. To the extent MannKind does not purchase such quantities, Sanofi may sell such quantities during the 180 days after the effective date of such termination within the shelf life remaining for Product.

(b) Assignment of Filings and Marketing Approvals. At MannKind's option, which shall be exercised by written notice to Sanofi, to the extent permitted under Applicable Laws, Sanofi shall assign or cause to be assigned to MannKind or its designee (or to the extent not so assignable, Sanofi shall take all reasonable actions to make available to MannKind or its designee the benefits of) all regulatory filings and registrations (including INDs, MAAs and Marketing Approvals) for Product in the Territory, including any such regulatory filings and registrations made or owned by its Affiliates. MannKind shall notify Sanofi before the effective date of termination, whether the regulatory filings and registrations should be assigned to MannKind or its designee, and if the latter, identify the designee, and provide Sanofi with all necessary details to enable Sanofi to effect the assignment (or availability). If MannKind fails to provide such notification prior to the effective date of termination, Sanofi shall assign the regulatory filings and registrations to MannKind.

(c) Transition. The Parties shall negotiate in good faith a written transition agreement pursuant to which the Parties would effectuate this Section 13.3 to coordinate the transition of relevant obligations and rights to MannKind as necessary to Develop and Commercialize Product in the Field in the Territory to ensure no interruption of therapy or

coverage for patients, including promptly submitting all necessary filings with Governmental Authorities. Sanofi shall use diligent efforts to cooperate with MannKind or its designee to effect a smooth and orderly transition in the Development and Commercialization of Product in the Territory during the notice and the Wind-down Period. Without limiting the foregoing, Sanofi shall use diligent efforts to conduct, in an expeditious manner, any activities to be conducted under this Section 13.3. MannKind shall use diligent efforts to identify and finalize an agreement or other arrangement with a Third Party in relation to Product or, to the extent MannKind is able to take over such activities under Applicable Laws, take over, directly or through an Affiliate, all activities related to Product in the Territory, and in particular Development activities on-going at the time of the effective date of the termination and the transfer of the regulatory filings and registrations (including INDs, MAAs and Marketing Approvals) into the name of MannKind or MannKind's designee so that the Wind-down Period will be as limited as possible. On terms to be further clarified in the written transition agreement, Sanofi shall use commercially reasonable efforts to maintain its Government Health Care Program Contracts for the Product bearing the Sanofi National Drug Codes ("*NDCs*") during the Wind-down Period. Reasonably in advance of the date upon which MannKind or its designee begins Commercialization of the Product, the Parties shall coordinate to permit MannKind to establish such agreements, and Sanofi shall provide to MannKind (or its designee) all information reasonably necessary to allow MannKind to report government pricing and comply with Applicable Laws. During the Wind-down Period, Sanofi shall work with MannKind and the applicable Government Health Care Programs to transition the Product from Sanofi's Government Health Care Program Contracts for the Product bearing the Sanofi NDC to MannKind's Government Health Care Program Contracts for the Product bearing the MannKind NDC (or the NDC of MannKind's designee) as necessary. The transition agreement shall further clarify the Parties' respective financial obligations as to allocation of any rebates or chargebacks accrued with respect to Product sold or dispensed during the Wind-down Period (*provided, however*, that Sanofi shall remain solely liable for such payments as may be accrued, but not yet paid, as of the effective date of termination of this Agreement).

(d) Rights Become Non-Exclusive. Notwithstanding any other provision of this Agreement, following the effective date of termination and during the Wind-down Period, Sanofi's and its Affiliates' rights with respect to Product in the Field in the Territory shall be non-exclusive, and, without limiting the foregoing, MannKind shall have the right to engage one or more other distributors and/or licensees of Product in the Field in the Territory.

(e) Continuing Payment Obligations. Any Product sold or disposed of by Sanofi and its Affiliates and sublicensees, in accordance with this Section 13.3 and any Allowable Expenses associated therewith shall be subject to the applicable payment obligations under Article 6.

(f) Licenses. Sanofi hereby grants to MannKind, effective upon termination of this Agreement, a non-exclusive, worldwide (or in the event of a Partial Termination, in the applicable Terminated Region), royalty-free, fully-paid license (with rights to sublicense) to use all Sanofi Technology and any Information and Regulatory Filings generated by Sanofi or its Affiliates with respect to Product, then Controlled by Sanofi or any of its Affiliates as of the effective date of termination, to Develop, Manufacture, have Manufactured, use, Commercialize

and have Commercialized Product in its form as of the effective date of termination (but excluding any improvements thereafter).

(g) Insulin Supply. In the case of termination of this Agreement in its entirety or in a particular country, Sanofi shall, for up to [...] months following the effective date of such termination, supply to MannKind and MannKind shall have the right to use, Insulin supplied by Sanofi to MannKind for Product Developed, used, Manufactured and Commercialized in countries in the Territory where Product has been launched and where such Insulin has been approved for use in Product by the applicable Regulatory Authorities, at a price equal to Sanofi's cost for such Insulin plus [...] percent ([...]%). Upon such termination, Sanofi and MannKind shall agree on the maximum quantity of Insulin to be supplied, with the understanding that such maximum quantity shall not exceed [...] months' requirements, as determined by the good faith estimate of the Parties, taking into account previously approved Budgets for Insulin and current sales trends.

(h) Competing Product. In the event that, prior to such termination, Sanofi Develops (*mutatis mutandis*) or Commercializes (*mutatis mutandis*) an internally developed Competing Product in accordance with Section 2.8(b)(i), the payment of Allowable Expenses and calculation and sharing of Profit and Loss with respect to each such Competing Product shall survive such termination for a period of [...] years from the date of the First Commercial Sale of such Competing Product.

13.4 Rights on Termination By Sanofi for Breach or Insolvency of MannKind. Upon the termination of this Agreement by Sanofi pursuant to Section 12.2(a) for MannKind's uncured material breach of this Agreement (other than a breach of Section 5.2 or a material uncured breach of MannKind's obligations under the Supply Agreement) or pursuant to Section 12.2(b), Sanofi shall have the option to either (a) return the rights granted hereunder with respect to Product to MannKind, in which case Section 13.4(b) below will apply, or (b) retain its rights to Product hereunder and discontinue MannKind's participation in the Development, Manufacturing and Commercialization of Product hereunder, in which case Section 13.4(b) below will apply. In the event of a termination of this Agreement pursuant to Section 12.2(a) for MannKind's uncured material breach of Section 5.2 or a material uncured breach of MannKind's obligations under the Supply Agreement, Sanofi shall not be able to elect to retain its rights granted hereunder and Section 13.4(a) below will apply. For clarity, in the event of a termination of the Supply Agreement for a material uncured breach of MannKind's obligations under the Supply Agreement, Sanofi shall have no obligation to terminate this Agreement.

(a) Return of Rights. If Sanofi elects, pursuant to this Section 13.4, to return the rights to the Product to MannKind:

(i) Winding-Down of Development Activities. In the event there are any on-going clinical trials of Product in the Field in the Territory:

(A) The Parties shall work together in good faith to adopt, and Sanofi shall have the final decision-making authority with respect to, a plan to wind-down the Development activities in an orderly fashion, with due regard for patient safety and the rights of

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any subjects that are participants in any clinical trials of Product and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all Applicable Laws. Sanofi shall provide to MannKind (or its designee) all information reasonably necessary to allow MannKind to report government pricing and comply with Applicable Law. During the wind-down period, Sanofi shall work with MannKind and the applicable Government Health Care Programs to transition the Product from Sanofi's Government Health Care Program Contracts for the Product bearing the Sanofi NDC to MannKind's Government Health Care Program Contracts for the Product bearing the MannKind NDC (or the NDC of MannKind's designee) as necessary. The wind-down plan shall further clarify the Parties' respective financial obligations as to allocation of any rebates or chargebacks accrued with respect to Product sold or dispensed during the Wind-down Period (*provided, however*, that Sanofi shall remain solely liable for such payments as may be accrued, but not yet paid, as of the effective date of termination of this Agreement); and

(B) All costs and expenses incurred from the effective date of the termination in winding-down the Development activities with respect to the applicable Product and otherwise carrying out the plan described in Section 13.4(a)(i)(A) shall be borne solely by MannKind unless the Parties agree otherwise in writing.

(ii) Termination of Licenses. Any and all licenses granted by the Licensors to Sanofi under this Agreement shall terminate, except as otherwise expressly provided herein.

(iii) Sanofi Regulatory Filings (including Marketing Approval). Upon Sanofi's request and to the extent permitted by Applicable Laws, MannKind may purchase all Regulatory Filings (including Marketing Approval) that are owned by Sanofi or any of its Affiliates for Product, and Sanofi shall assign or cause to be assigned to MannKind or its designees (or to the extent not so assignable, Sanofi shall take all reasonable actions to make available to MannKind or its designee the benefits of) such Regulatory Filings (including INDs, MAAs and Marketing Approval) for Product in the Territory that are so purchased, including any such Regulatory Filings made or owned by its Affiliates, at an amount equal to 100% of the costs incurred by Sanofi and its Affiliates and sublicensees in obtaining such Regulatory Filings.

(iv) Termination Assistance. Sanofi and its Affiliates and sublicensees may continue to sell its inventory of Product in the Territory for up to [...***...] months after the effective date of the termination or offer MannKind to purchase the inventories of Product at a price mutually agreed by the Parties. MannKind may to the extent permitted by the applicable Third Party, assume such supply or distribution agreement. MannKind shall provide such other assistance, at no cost to Sanofi, as may be reasonably necessary or useful for Sanofi to terminate the Development or Commercialization of the applicable Product in the applicable countries of the Territory.

(v) Continuing Payment Obligations. Any Product sold or disposed of by Sanofi or its Affiliates, in accordance with this Section 13.4 shall be subject to the applicable payment obligations under Article 6.

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(b) Retention of Rights. If Sanofi elects, pursuant to Section 13.4, to retain the rights to Product:

(i) the JAC shall be disbanded, all approval rights of the JAC shall become approval rights of Sanofi, and MannKind shall no longer have the right to receive any Development or Commercialization reports or other information from Sanofi;

(ii) a Trigger Event (as defined in the Supply Agreement) under the Supply Agreement shall be deemed to have occurred;

(iii) Sanofi shall have the option to cause all Development activities being conducted by MannKind to be taken over by Sanofi;

(iv) Sanofi's and Licensors' payment obligations under the Agreement shall remain in full force and effect; and

(v) Section 4.2(d) shall no longer apply.

13.5 Rights on Termination By Sanofi for Safety or Regulatory Reasons. Upon termination of this Agreement under Section 12.3(b), any and all licenses granted by the Licensors to Sanofi under this Agreement shall terminate, except as otherwise expressly provided herein. Following such termination, Sanofi shall have no further obligations with respect to Product.

13.6 Rights Upon Bankruptcy. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction in the Territory or where a Party is situated (collectively, the "**Bankruptcy Laws**"), licenses of rights to "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall provide to the other Party copies of all Information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.

13.7 Return of Confidential Information. Upon termination or expiration of this Agreement, except to the extent that a Party retains a license from the other Party as contemplated by this Article 13, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only subject to a continuing confidentiality obligations.

13.8 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any rights or obligation accruing prior to such expiration or termination. In addition, upon expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall terminate, except those described in the following Articles and Sections: Sections 2.6(b), 7.4, 7.5, 7.6, 8.1, 8.2, 8.3, 8.4, 8.8, 9.1, 10.4, 11.1, 11.2, 11.3 and 12.5, and Articles 1, 13, 14 and 15 (excluding Sections 15.10 and 15.17), which Articles and Sections will survive in accordance with their terms.

ARTICLE 14

DISPUTE RESOLUTION AND GOVERNING LAW

14.1 Disputes. In the event of any dispute arising out of or relating to this Agreement or either Party's rights or obligations hereunder, except as otherwise provided in this Agreement, the Party wishing to invoke dispute resolution proceedings shall send to the other Party, in accordance with the notice provisions set forth in Section 15.8, a written notice of dispute indicating that such notifying Party wishes to invoke such negotiations pursuant to this Section 14.1 and that sets out in reasonable detail the claims asserted, the nature of the dispute, any facts that are or are not in dispute, and the intended treatment and effect of such pending dispute ("**Notice of Dispute**"). The Parties shall, through their respective executive officers, first meet and attempt to resolve the dispute in face-to-face negotiations. Unless otherwise agreed in writing by the Parties, this meeting shall occur within fifteen (15) days after either Party provides such notice of dispute to the other Party. If the Parties are unable to resolve such dispute through such negotiations within the earlier of (x) sixty (60) days after the meeting referenced in this Section 14.1 or (y) sixty (60) days after receipt of the Notice of Dispute (or such longer period agreed in writing by the Parties) ("**Arbitration Deadline**"), then, except in the case of a dispute, controversy or claim that concerns (a) the validity or infringement of a patent, trademark or copyright, or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory, the dispute shall be resolved by binding arbitration in accordance with Section 14.2.

14.2 Arbitration. Any disputes to be resolved by binding arbitration pursuant to Section 14.1 shall be resolved in accordance with the rules of conciliation and arbitration of the International Chamber of Commerce of Paris by a panel of three (3) independent and neutral experienced arbitrators, one (1) chosen by MannKind, one (1) chosen by Sanofi, and the third (3rd) chosen by the foregoing two (2) arbitrators (with such third acting as the chairperson of the panel). The place of arbitration shall be New York, New York. Any arbitration shall be conducted in the English language and the arbitrators shall use the governing law provided for in Section 14.4. The arbitration panel shall issue its decision and award by reasoned, written decision within one (1) year after appointment of the chairperson of the arbitration panel. The

arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Except to the extent necessary to confirm or enforce an award or as may be required by law, neither a Party nor any arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both MannKind and Sanofi. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations. Each Party shall bear its own attorneys' fees, costs and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; *provided, however*, that the arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for the fees and costs of the arbitrators. Each Party agrees to fully perform and satisfy any arbitration award made against it within fifteen (15) days of the service of the award. The taking of evidence in the arbitration shall be guided by the International Bar Association's 2010 Rules on the Taking of Evidence in International Commercial Arbitration ("**IBA Guidelines on Evidence**"); *provided, however*, that the arbitrators shall permit such pre-hearing discovery and such presentation of evidence at any Evidentiary Hearing (as defined in the IBA Guidelines on Evidence) as, in each case, is reasonably necessary for a full and fair understanding and resolution of any legitimate issue raised in the arbitration. The arbitration panel shall ensure that document disclosures are conducted on a timely basis. By agreeing to this binding arbitration provision, the Parties understand that they are waiving certain rights and protections which may otherwise be available if a dispute between the Parties were determined by litigation in court, including the right to seek or obtain certain types of damages precluded by this provision, the right to a jury trial, certain rights of appeal and a right to invoke formal rules of procedure and evidence. For the sake of clarity, any disputes that arise under both this Agreement and the Supply Agreement may be consolidated in a single arbitration. Any settlement discussions or arbitration proceedings occurring under this Agreement shall be conducted in strict confidence. Except as necessary to enforce an award or as required by law, no information or documents produced, generated or exchanged in connection with settlement discussions or arbitration proceedings (including any award(s) that might be rendered by the arbitration panel) shall be disclosed to any person other than counsel without the prior written consent of all Parties to the settlement or arbitration proceedings. This restriction shall not apply to public records or other documents obtained by the Parties in the normal course of business independent of any settlement discussions or arbitration proceedings.

14.3 Court Actions. Nothing contained in this Agreement shall deny either Party the right to seek, upon good cause, injunctive or other equitable relief from a court of competent jurisdiction in the context of an emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing dispute resolution discussions or arbitration proceedings.

14.4 Governing Law. This Agreement, and all questions regarding the existence, validity, interpretation, breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law. The United Nations Conventions on Contracts for the International Sale of Goods shall not be applicable to this Agreement.

ARTICLE 15

GENERAL PROVISIONS

15.1 Intervening Events. If the performance of any part of this Agreement by either Party (other than making payment when due) is prevented, restricted, interfered with or delayed by any reason or cause beyond the reasonable control of such Party (including: fire, flood, embargo, power shortage or failure, acts of war, insurrection, riot, terrorism, strike, lockout or other labor disturbance (save where such strike, lockout, or other labor disturbance is initiated by the employees of the Party which seeks to rely on this clause), acts of God or any acts, omissions or delays in acting of the other Party) (an “*Intervening Event*”), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such Intervening Event, provided that the affected Party shall use its substantial efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. If either Party becomes aware that such an Intervening Event has occurred, is imminent or likely, it will immediately notify the other Party. The Party which is subject to such Intervening Event shall exert all reasonable efforts to overcome it. Such Party will keep the other informed as to the progress of overcoming such Intervening Event.

15.2 Waiver of Breach. The failure of either Party at any time or times to require performance of any provision of this Agreement shall in no manner affect its rights at a later time to enforce such rights. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

15.3 Performance by Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligation. Either Party may use one or more of its Affiliates to perform its obligation hereunder, provided that the Parties will remain liable hereunder for the prompt payment and performance of all their respective obligations hereunder.

15.4 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in a prior writing signed by all of MannKind and Sanofi. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by the Parties hereto.

15.5 Severability. In the event any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate, in good faith and enter into a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties. All other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

15.6 Entire Agreement. This Agreement (including the Exhibits attached hereto and any letter delivering information referenced herein) and the Supply Agreement, including the Exhibits attached thereto, constitute the entire agreement between the Parties relating to the subject matter hereof and thereof and supersede and cancel all previous express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof and thereof. Each of the Parties acknowledges and agrees that in entering into this Agreement, and the documents referred to in it, it does not rely on, and shall have no remedy in respect of, any statement, representation, warranty or understanding (whether negligently or innocently made) of any Person (whether party to this Agreement or not) other than as expressly set out in this Agreement or the Supply Agreement. Nothing in this clause shall, however, operate to limit or exclude any liability for fraud.

15.7 Language. The language of this Agreement and all activities to be pursued under this Agreement is English. Any and all documents proffered by one Party to the other in fulfillment of any provision of this Agreement shall only be in compliance if in English. Any translation of this Agreement in another language shall be deemed for convenience only and shall never prevail over the original English version. This Agreement is established in the English language.

15.8 Notices. Any notice or communication required or permitted under this Agreement shall be in writing in the English language, delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by internationally-recognized courier or sent by registered or certified mail, postage prepaid to the following addresses of the Parties (or such other address for a Party as may be at any time thereafter specified by like notice):

To the Licensors:

MannKind Corporation
28903 North Avenue Paine
Valencia, California 91355
Telephone: (661) 775-5300
Facsimile: (661) 775-2086
Attention: General Counsel

To Sanofi:

Sanofi
c/o Genzyme
500 Kendall Street
Cambridge, MA 02142
Telephone: +1 617 768 6527
Facsimile: +1 617 252 7600.
Attention: Vice President, Corporate
Business Development

with a copy to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
Telephone: (858) 550-6000
Facsimile: (858) 550-6420
Attention: L. Kay Chandler, Esq.

with a copy to:

Sanofi
54 Rue La Boétie, 75008
Paris, France
Telephone: +33 1 53 77 90 24
Facsimile: +33 1 53 77 43 03
Attention: General Counsel

Any such notice shall be deemed to have been given: (a) when delivered if personally delivered; (b) on the next Business Day after dispatch if sent by confirmed facsimile or by internationally-recognized overnight courier; and/or (c) on the third Business Day following the date of mailing if sent by mail or nationally recognized courier. Notices hereunder will not be deemed sufficient if provided only between or among each Party's representatives on the JAC.

15.9 Assignment. This Agreement shall not be assignable, pledged or otherwise transferred, nor may any right or obligations hereunder be assigned, pledged or transferred, by either Party to any Third Party without the prior written consent of the other Party, which consent, in the event of a financing transaction by the Party asking for consent, shall not be unreasonably withheld, conditioned or delayed by the other Party; except either Party may assign or otherwise transfer this Agreement without the consent of the other Party to an entity that acquires all or substantially all of the business or assets of the assigning Party relating to the subject matter of this Agreement, whether by merger, acquisition or otherwise; provided that intellectual property rights that are owned or held by the acquiring Person to such transaction (if other than one of the Parties to this Agreement) shall not be included in the technology licensed hereunder. In addition, either Party shall have the right to assign or otherwise transfer this Agreement to an Affiliate upon written notice to the non-assigning Party; *provided, however*, the assigning or transferring Party shall continue to remain liable for the performance of this Agreement by such Affiliate and, prior to the Effective Date, Sanofi may assign this Agreement to any Affiliate. Nothing herein shall be deemed to prohibit MannKind or any of its Affiliates from granting a security interest in this Agreement and any rights hereunder to any Third Party in connection with any financing transaction to the extent provided under (and subject to the restrictions on the rights of secured parties contained in) Sections 9-406 and 9-408 of the New York Uniform Commercial Code. In addition, MannKind or any Affiliate of MannKind shall have the right to sell, assign, pledge or otherwise transfer any accounts and payment intangibles (each as defined under the New York Uniform Commercial Code but including, for the avoidance of doubt, rights to payment of MannKind pursuant to Sections 6.2 and 6.3) in connection with any financing transaction. Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns. Any assignment of this Agreement in contravention of this Section 15.9 shall be null and void.

15.10 Change of Control of MannKind.

(a) If MannKind's Board of Directors determines to pursue a Change of Control of MannKind (whether such determination is made in response to an offer or term sheet submitted by a Third Party or such determination is made by the Board of Directors independently of any such Third Party offer or term sheet), MannKind shall provide written notice to Sanofi of such determination no later than the date MannKind or its representatives first notifies any potential Third Party acquirer of such determination, so that Sanofi may, at its discretion, participate in the sale process and negotiate with MannKind for the potential acquisition of MannKind by Sanofi. MannKind shall not enter into a Change of Control transaction with a Third Party within the thirty (30) day period following delivery of such notice to Sanofi. MannKind shall ensure that during the Term of this Agreement that neither TICV nor BV undergoes a Change of Control other than a transaction in which MannKind undergoes the same Change of Control.

(b) In the case MannKind, BV or TICV undergoes a Change of Control involving [...***...], Sanofi may by written notice delivered to MannKind within thirty (30) days after the first public announcement of such Change in Control, elect to retain its rights to Product hereunder and discontinue MannKind's participation in the Development, Manufacture, and Commercialization of Product hereunder, in which case Section 13.4(b) shall apply.

15.11 No Partnership or Joint Venture. Nothing in this Agreement or any action which may be taken pursuant to its terms is intended, or shall be deemed, to establish a joint venture or partnership between Sanofi and the Licensors. Neither Party to this Agreement shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

15.12 Standstill Agreement. Until the date that is five years after the Effective Date (the "*Standstill Period*"), none of Sanofi, Sanofi's Affiliates, nor any of their respective directors, officers, employees, agents or representatives (provided such person is acting on behalf of Sanofi) will, in any manner, directly or indirectly, without the prior express written consent of MannKind:

(a) make, effect, initiate, directly participate in or cause (i) any acquisition of beneficial ownership of any securities of MannKind or any securities of any subsidiary or other Affiliate of MannKind, if, after such acquisition, Sanofi would beneficially own more than 5% of the outstanding common stock of MannKind, (ii) any acquisition of any assets of MannKind or any assets of any subsidiary or other Affiliate of MannKind, (iii) any tender offer, exchange offer, merger, business combination, recapitalization, restructuring, liquidation, dissolution or extraordinary transaction involving MannKind or any subsidiary or other Affiliate of MannKind, or involving any securities or assets of MannKind or any securities or assets of any subsidiary or other affiliate of MannKind or (iv) any "solicitation" of "proxies" (as those terms are used in the proxy rules of the SEC) or consents with respect to any securities of MannKind; provided that nothing in this Section 15.12 shall preclude any activities of Sanofi or its Representatives with

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respect to the grant by MannKind or any Affiliate of MannKind of any license in each case to Sanofi or any of its Affiliates as contemplated by this Agreement;

(b) form, join or participate in a group (within the meaning of Section 13(d)(3) of the Securities Exchange Act of 1934, as amended) with respect to the beneficial ownership of any securities of MannKind;

(c) act, alone or in concert with others, to seek to control the management, board of directors or policies of MannKind;

(d) take any action that would reasonably be expected to require MannKind to make a public announcement regarding any of the types of matters set forth in Section 15.12(a);

(e) agree or offer to take, or encourage or propose (publicly or otherwise) the taking of, any action referred to in Section 15.12(a), (b), (c) or (d);

(f) assist, induce or encourage any Third Party to take any action of the type referred to in Section 15.12(a), (b), (c), (d) or (e); or

(g) enter into any discussions, negotiations, arrangement or agreement with any Third Party relating to any of the foregoing.

For purposes of this Agreement, a Party's "Representatives" will be deemed to include each person or entity that is or becomes (i) an Affiliate of such Party, or (ii) an officer, director, employee, partner, attorney, advisor, accountant, agent or representative of such Party or of any of such Party's Affiliates, providing such person is acting on behalf of such Party.

Notwithstanding the foregoing, Section 15.12 shall no longer apply (i) during a period commencing with MannKind's announcement in a filing with the SEC or a press release that (a) it is seeking a purchaser for itself or (b) is otherwise exploring strategic options in this regard, and ending with MannKind's announcement in a filing with the SEC or a press release that is terminating such search or exploration; (ii) during the period beginning with the commencement by a Third Party of a publicly-announced tender or exchange offer for more than 50% of voting power of the outstanding voting securities of MannKind, and ending with the termination by such Third Party of such tender or exchange offer; or (iii) if MannKind announces in a filing with the SEC or a press release a transaction, or an intention to effect any transaction, which would result in (a) the sale by MannKind or one or more Affiliate(s) of assets representing 50% or more of the consolidated assets of MannKind; or (b) the common shareholders of MannKind immediately prior to such transaction owning less than 50% of the outstanding common stock of the acquiring entity or, in case of a merger transaction, the surviving corporation (or, if the surviving corporation is an Affiliate of a parent company, the parent company); provided that, in the case of clause (ii) Sanofi has not directly or indirectly taken any action prohibited under this Section 15.12.

The expiration of the Standstill Period will not terminate or otherwise affect any of the other provisions of this Agreement.

15.13 Interpretation. The captions to the several Articles and Sections of this Agreement are not a part of this Agreement but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression; (b) the word “or” means “and/or” unless the context dictates otherwise because the subject of the conjunction are mutually exclusive; (c) the words “herein,” “hereof” and “hereunder” and other words of similar import refer to this Agreement as a whole and not to any particular Article or Section or other subdivision; (d) references in this Agreement to “days” shall mean calendar days; (e) the singular shall include the plural and vice versa; and (f) masculine, feminine and neuter pronouns and expressions shall be interchangeable. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under IFRS, or if not defined by IFRS, the meaning applied to it by Sanofi in preparing its publicly reported financial statements, in each case, consistently applied, but only to the extent consistent with its usage and the other definitions in this Agreement.

15.14 Counterparts; Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

15.15 Limitation of Liability. EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 8, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE OR RIGHT GRANTED HEREUNDER; *provided, however*, that this Section 15.15 shall not be construed to limit either Party’s indemnification obligations with respect to Third Party Claims under Article 11.

15.16 Antitrust Filings/Agreement Effectiveness. Each of MannKind and Sanofi shall use its reasonable best efforts to file, as soon as practicable after the date of this Agreement, all notices, reports and other documents required to be filed by such Party, pursuant to the Antitrust Laws, with any Governmental Authority (the “*Filings*”) with respect to this Agreement and the transactions contemplated hereby, and to submit promptly any additional information requested by any such Governmental Authority. Without limiting the generality of the foregoing, each of MannKind and Sanofi agrees to prepare and make appropriate filings under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder (the “*HSR Act*”) relating to this Agreement and the transactions contemplated hereby as soon as reasonably practicable, but in any event within ten (10) Business Days after the Execution Date (the “*HSR Filing Date*”). The Parties agree to cooperate and consult with each other in connection with the making of all Filings. Sanofi will pay all fees, payable to any Governmental Authority, associated with Filings. Other than the provisions of this Section 15.16, the rights and obligations of the Parties under this Agreement shall not become effective until the earliest date on which all of the following have occurred: (i) the waiting period provided by the HSR Act, and those associated with any other of the Filings which the Parties reasonably conclude must be obtained prior to making the rights and

obligations of this Agreement effective, shall have terminated or expired; and (ii) either (A) MannKind and Hoechst GmbH (or its permitted assignee) have entered into the "Loan Documents" as defined and described in the Commitment Letter between MannKind and Hoechst GmbH dated of even date herewith (the "Commitment Letter") or (B) MannKind, in its sole discretion, has terminated the Commitment Letter and waived in writing the condition set forth in the preceding subclause (A) of this clause (ii) (such date, the "**Effective Date**" of this Agreement), provided that, pursuant to Section 15.9 hereof, Sanofi shall be permitted to assign this Agreement to any Affiliate at any time between the Execution Date and the Effective Date. Upon the occurrence of the Effective Date, all provisions of this Agreement shall become effective automatically without the need for further action by the Parties. In the event that (I) any such clearance associated with the Filings is not obtained, or (II) the Loan Documents are not executed within 120 days after the Execution Date (or such later date as agreed in writing by the Parties), this Agreement may be terminated by either Party; provided that a Party shall not have the right to terminate under clause (II) of this sentence if the Loan Documents have not been executed as a result of a breach by such Party (or, in the case of Sanofi, by Hoechst GmbH or its permitted assignee) of the Commitment Letter (for so long as such Party is in breach) or if MannKind has terminated the Commitment Letter.

15.17 Restrictions on Sale of Profit Share. None of the Licensors shall enter into any transaction or arrangement pursuant to which (i) it receives a fixed (single or recurring) sum in exchange for any portion of its share of Profits (other than in connection with a permitted assignment of this Agreement pursuant to Section 15.9); or (ii) borrows any sums against its share of Profits on a non-recourse basis; in each case without the prior written consent of Sanofi, not to be unreasonably withheld, conditioned or delayed.

ARTICLE 16

COMPLIANCE WITH LAW

16.1 Export Laws. Notwithstanding anything to the contrary contained herein, all obligations of MannKind and Sanofi are subject to prior compliance with export and import regulations and such other laws and regulations in effect in such jurisdictions or any other relevant country as may be applicable, and to obtaining all necessary approvals required by the applicable agencies of the governments of any relevant countries. The Licensors and Sanofi shall cooperate with each other and shall provide assistance to the other as reasonably necessary to obtain any required approvals.

16.2 Securities Laws. Each of the Parties acknowledges that it is aware that the securities laws of the United States and the securities laws of other countries prohibit any person who has material non-public information about a publicly listed company from purchasing or selling securities of such company or from communicating such information to any person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell such securities. Each Party agrees to comply with such securities laws make its Affiliates, employees and agents aware of the existence of such securities laws and their need to comply with such laws.

16.3 Conduct of Activities. As to all matters contained in this Agreement, each Party shall conduct the activities allocated to it in compliance in all material respects with all Applicable Laws and in accordance with good scientific, clinical and manufacturing practices and applicable industry ethical codes, applicable under the laws and regulations of the country in which such activities are conducted. Each Party represents, warrants and covenants to the other Party as of the Effective Date that:

(a) it is familiar with the provisions and restrictions contained in the OECD Convention and FCPA and it has adopted and maintains an FCPA policy;

(b) In the performance of its obligations under this Agreement, it shall comply and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws, and shall obtain and maintain all licenses, permits, approvals and other authorizations applicable to it in order to enable it to perform its respective obligations hereunder.

(c) its and its Affiliates' employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a Public Official or Entity or other Person for purpose of obtaining or retaining business for or with, or directing business to, any Person, including either Party (it being understood that such Party, and to its knowledge, its and its Affiliates' employees and contractors, has not directly or indirectly promised, offered or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a Public Official or Entity or any other person in connection with the performance of such Party's obligations under this Agreement, and shall not, directly or indirectly, engage in any of the foregoing).

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have executed this License and Collaboration Agreement as of the Execution Date.

SANOFI-AVENTIS DEUTSCHLAND GMBH

By: /s/ Emmanuel Siregar
Name: Emmanuel Siregar
Title: VP HR Sanofi Germany

By: /s/ ppa. Bergmann
Name: Bergmann
Title: Head of Finance

[SIGNATURE PAGE TO LICENSE AND COLLABORATION AGREEMENT]

IN WITNESS WHEREOF, the Parties have executed this License and Collaboration Agreement as of the Execution Date.

MANKIND CORPORATION

By: /s/ Alfred E. Mann
Name: Alfred E. Mann
Title: Chairman & CEO

[SIGNATURE PAGE TO LICENSE AND COLLABORATION AGREEMENT]

IN WITNESS WHEREOF, the Parties have executed this License and Collaboration Agreement as of the Execution Date.

TECHNOSPHERE INTERNATIONAL C.V.

By: MannKind Corporation, its General Partner

By: /s/ Matthew J. Pfeffer

Name: Matthew J. Pfeffer

Title: Corporate Vice President and Chief Financial Officer

[SIGNATURE PAGE TO LICENSE AND COLLABORATION AGREEMENT]

IN WITNESS WHEREOF, the Parties have executed this License and Collaboration Agreement as of the Execution Date.

MANKIND NETHERLANDS B.V.

By: /s/ Matthew J. Pfeffer

Name: Matthew J. Pfeffer

Title: Managing Director

[SIGNATURE PAGE TO LICENSE AND COLLABORATION AGREEMENT]

EXHIBIT A

MANNKIND TRADEMARK LICENSE

This Exhibit sets forth the terms of the license granted with respect to the trademark(s) and/or trade name(s) owned by the Licensors that are set forth on **EXHIBIT A-1** (the “*MannKind Trademarks*”). All capitalized terms used and not otherwise defined in this Exhibit will have the meaning given such terms in this Agreement. References in this **EXHIBIT A** to MannKind shall refer to TICV or BV as applicable outside the United States.

1. License to MannKind Trademarks. Subject to the terms and conditions of this Agreement, including this **EXHIBIT A**, the Licensors hereby grant to Sanofi during the Term a non-exclusive license, with the right to grant limited sublicenses pursuant to Section 2.4 of this Agreement, to use the MannKind Trademarks, solely in connection with Developing, obtaining Marketing Approval of, Manufacturing, having Manufactured, using and Commercializing Product in the Field in the Territory.

2. Quality Control. All uses by Sanofi and its Affiliates and sublicensees of the MannKind Trademarks shall be in compliance with all Applicable Laws and shall be in accordance with such commercially reasonable quality standards as have been used by Sanofi in the past for comparable products. In all packaging, labeling, advertising, promotional and other material of Sanofi and its Affiliates and sublicensees referencing the MannKind Trademarks, Sanofi and its Affiliates and sublicensees shall not: (a) vary the spelling, add or delete hyphens, abbreviate, make one word two, or use a possessive or plural form of the MannKind Trademarks; (b) modify the design, add or delete any elements or words, change any colors or proportion of the MannKind Trademarks; (c) use the MannKind Trademarks in a manner which disparages MannKind or any of its products or services; or (d) use the MannKind Trademarks in a manner that interferes with or adversely affects MannKind’s use of the MannKind Trademarks; in each case except to the extent required by Applicable Laws, provided that Sanofi will review and discuss with MannKind any such exceptions required by Applicable Laws before using the MannKind Trademarks pursuant to such exception. At the request of MannKind, Sanofi will provide from time to time copies of packaging, labeling, advertising, promotional and other material of Sanofi or its Affiliates referencing the MannKind Trademarks to allow MannKind to confirm compliance with the foregoing.

3. Ownership Rights, as Between Parties. MannKind shall own and shall retain the ownership of the entire right, title and interest in and to the MannKind Trademarks. Sanofi acknowledges, as between the Parties, the exclusive right, title and interest of MannKind in and to the MannKind Trademarks and will not do or cause to be done any act or thing contesting or, in any way, impairing any part of said right, title and interest for the Term and after its expiration. Sanofi will not, and will require that its Affiliates not, make any representations or take any actions, which may be taken to indicate that it has any right title or interest in or to the ownership or use of the MannKind Trademarks except under the terms of this Agreement, including this **EXHIBIT A**, and acknowledges that nothing contained in this Agreement, including this **EXHIBIT A**, shall give Sanofi or any of its Affiliates any right, title or interest in or to the MannKind Trademarks except the license rights granted under Section 1 of this **EXHIBIT A**.

4. Registration of the MannKind Trademarks. MannKind shall, at its own cost and expense, and in its sole discretion, file within the Territory and endeavor in good faith to obtain the registration of the MannKind Trademarks in the Territory, and when registered, thereafter maintain the applicable MannKind Trademark in the Territory at its own expense.

5. Enforcement. Sanofi shall, as soon as practicable after receiving notice of any potential infringement of a MannKind Trademark in the Territory, inform MannKind of any such potential infringement. MannKind shall have the first right and discretion to bring infringement or unfair competition proceedings involving the MannKind Trademark in the Territory and MannKind shall bear all costs in connection with any such proceedings. Sanofi shall cooperate with MannKind in any such proceedings at its own expense including by giving testimony and producing documents and materials supporting the MannKind Trademark, and shall endeavour to cause the employees of Sanofi, as appropriate, to cooperate with MannKind, all at MannKind' expense. Any recoveries obtained as a result of any infringement litigation undertaken by MannKind alone or in settlement of such infringement shall be retained by MannKind. Sanofi shall have the right, but shall not be obliged, to participate with MannKind as a party plaintiff in any infringement or unfair competition action undertaken by MannKind hereunder in the Territory, at Sanofi's costs and expense, and any recovery obtained shall be shared between MannKind and Sanofi in proportion to incurred expenses, except that any recovery with respect to unfair competition claims in the Territory shall be retained solely by Sanofi. Should MannKind fail to institute infringement proceedings in the Territory, Sanofi, if it deems necessary, shall have the right but shall not be obligated, to bring suit for such infringement under its name and at its own costs and expenses. MannKind shall cooperate with Sanofi in any such proceedings at its own expense including giving testimony and producing document and material supporting the MannKind Trademark and shall endeavour to cause the employees of MannKind, as appropriate, to cooperate with Sanofi, all at Sanofi's expense. Any recoveries obtained in suit for trademark infringement litigation or in settlement of such infringement undertaken without MannKind' involvement shall be retained by Sanofi.

6. Infringement of Third Party rights by the MannKind Trademarks. MannKind shall: (i) defend, through counsel of its choosing, at its own cost and expense, any claim from a Third Party that claims that the MannKind Trademarks infringe such Third Party's intellectual Property in the Territory; (ii) consult with Sanofi, take into consideration Sanofi's comments, incorporate and act on such comments to the extent reasonable in defending against any such claim; and (iii) release and hold Sanofi, its Affiliates and sublicensees harmless from any liabilities arising from or connected with any such claim.

7. Goodwill. Any accretion of goodwill derived by Sanofi or any of its Affiliates to the extent attributed to the MannKind Trademarks shall accrue to MannKind and MannKind may call for, and Sanofi will provide, and require its Affiliates to provide, a confirmatory assignment thereof.

8. Registered User. Where reasonably required to carry out the purpose of the Agreement, MannKind shall make applications to the applicable Governmental Authority for the registration of Sanofi or any of its Affiliates as a registered user of the MannKind Trademarks, and Sanofi

and its Affiliates and sublicensees shall cooperate with MannKind in making such applications. Sanofi and its Affiliates and sublicensees shall take reasonable actions requested by MannKind at MannKind's expense which may be necessary or desirable for registering and maintaining registration of Sanofi and its Affiliates and sublicensees as registered users of the MannKind Trademarks.

9. Reasonable Assistance. Sanofi shall, and shall require its Affiliates to, reasonably cooperate, upon request, with MannKind or its authorized representative to provide information as to its use of the MannKind Trademarks which MannKind may require and will render any assistance reasonably required by MannKind in securing and maintaining the registration(s) of the MannKind Trademark in the Territory.

10. Further Acts. MannKind shall execute, acknowledge and deliver such instruments and do all such other acts as may be necessary or appropriate in order to have this Agreement recorded by any authority operating as a trademark office in the Territory or in order to ascertain or confirm Sanofi's right to use the MannKind Trademarks.

EXHIBIT A-1

MANKIND TRADEMARKS

Attached.

A-4.

Trademarks

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

<u>Mark</u>	<u>Country</u>	<u>Status</u>	<u>Applic. No./ File Date</u>	<u>Reg. No./ Reg. Date</u>	<u>Class/Goods/Services</u>
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

***Confidential Treatment Requested

EXHIBIT B

PAYMENT OF EXPENSES; SHARING OF PROFIT

Attached.

B-1.

EXHIBIT B

PAYMENT OF EXPENSES; SHARING OF PROFIT

This EXHIBIT B to the License and Collaboration Agreement (the “*Agreement*”), dated as of August 11, 2014, between MANNKIND CORPORATION (“*MannKind*”), TECHNOSPHERE INTERNATIONAL C.V. (“*TICV*”), MANNKIND NETHERLANDS BV (“*BV*” and together with MannKind and TICV, the “*Licensors*”) and SANOFI-AVENTIS DEUTSCHLAND GMBH (“*Sanofi*”), addresses the accounting policies and procedures to be followed with respect to Allowable Expenses and determination and sharing of Profit (where applicable) separately for the United States on the one hand and all other countries in the Territory, cumulatively, on the other hand. Capitalized terms used and not otherwise defined in this EXHIBIT B shall have the meanings set forth for such terms in the Agreement.

1. General Principles. The Parties acknowledge and agree that the accounting policies and procedures to be followed with respect to computation of Allowable Expenses and computation and sharing of Profit (including the computation of the individual components thereof) is intended to be consistent with the accounting policies and procedures used by Sanofi in generating its publicly-reported financial statements in accordance with International Financial Reporting Standards (“*IFRS*”). Each Party shall prepare and provide all reports and calculations required hereunder in accordance with such accounting policies and procedures. Notwithstanding the foregoing, (a) if a specific category of Allowable Expense described below is also one accounted for in Sanofi’s books and records, then the amounts recorded in Sanofi’s books and records shall control provided that they are consistent with IFRS and Sanofi’s publicly-reported financial statements; and (b) if IFRS changes after the Effective Date in any manner that would affect computations hereunder, the Parties shall implement such change in a manner consistent with Sanofi’s implementation of such change in Sanofi’s publicly-reported financial statements.

2. Reporting of Allowable Expenses. Within 15 days after the end of each Calendar Quarter beginning with the first full Calendar Quarter after the Execution Date, MannKind will provide Sanofi with a written report (each, a “*Quarterly Report*”) setting forth the Allowable Expenses incurred by MannKind or its Affiliates for such Calendar Quarter (including, in the first such report, the Allowable Expenses incurred from the Effective Date until the beginning of the first full Calendar Quarter) in reasonable detail sufficient to enable Sanofi’s calculations of Profit as set forth in Section 3. Neither Party shall be entitled to include Allowable Expenses in such Profit calculations that exceed the Budget for such Allowable Expenses by more than ten percent (10%) unless otherwise approved by the JAC; *provided* that the JAC shall in good faith consider adjustments to the Budgets for any Allowable Expenses to accommodate unexpected circumstances that arise following the determination of the applicable Budget.

3. Sharing of Profit and Loss. “*Profit*” shall equal the positive amount of (a) Net Sales of Product in the Territory plus any additional net revenue received from sublicensees of the Product (collectively, “*Net Receipts*”) less (b) Allowable Expenses. “*Loss*” shall equal the positive amount of Allowable Expenses less Net Receipts. Subject to the terms of this EXHIBIT B, the Parties shall share Profit and Loss on the basis of thirty-five percent (35%) to MannKind and sixty-five (65%) to Sanofi (the “*Sharing Percentages*”).

3.1 Periodic Calculations. Sanofi shall be responsible for the calculation of Profit and Loss and the determination of the cash payment to or from the Licensors for each Calendar Quarter of the Term so that following such payment each Party has borne the Sharing Percentage of Profit or Loss.

3.2 Calculation of Profit. All calculations of Profit and Loss will be made using, and all defined and undefined terms will be construed in accordance with the principles set forth in Section 1 of this **EXHIBIT B**. Without limiting the foregoing, no cost item will be included more than once in calculating any Allowable Expenses or Profit. For the sake of example only, a sample demonstration of the Profit sharing calculations are set forth as **SCHEDULE B-2** to this **EXHIBIT B**.

4. Profit/Loss Reporting and Payment.

4.1 Profit/Loss Statement.

(a) The reporting and determination of Profit and Loss shall be governed by a statement of Profit and Loss for the applicable Calendar Quarter (the "**Profit/Loss Statement**"). Sanofi will provide to MannKind, by the submission dates set forth in Section 4.1(b), a Profit/Loss Statement (i) showing the results for the applicable Calendar Quarter (including the Calendar Year-to-date) in a similar form to that attached hereto as **SCHEDULE B-1**, (ii) comparing the applicable Calendar Quarter (including the Calendar Year-to-date) results to the Budgets, (iii) calculating Profit or Loss for the applicable Calendar Quarter and (iv) determining the cash payment to or from the Licensors for the applicable Calendar Quarter. To the extent any Calendar Year-end adjustments are determined in good faith by Sanofi to be appropriate, an appropriate adjustment to Profit or Loss for the applicable Calendar Year will be made and an appropriate payment will be made by the applicable Party within thirty (30) days following receipt of the Profit/Loss Statement describing such adjustment; *provided, however*, that in the event of a dispute between the Parties with respect to whether any such adjustment is appropriate, such dispute will be referred to the JAC for resolution pursuant to Section 3.1 of the Agreement. Any such adjustment payment will be without interest if such amount is less than ten percent (10%) of Profit or Loss for such Calendar Year and will bear interest at the rate set forth in Section 7.6 of the Agreement if the absolute value of such amount is greater than or equal to ten percent (10)% of Profit or Loss for such Calendar Year.

(b) Reporting of Profit and Loss will be performed as follows:

<u>Reporting Event</u>	<u>Frequency</u>	<u>Timing of Submission</u>
Actuals	Each Calendar Quarter	The earlier of (i) the day that Sanofi reports its earnings or (ii) 30 days following the end of each Calendar Quarter
Adjustment	Each Calendar Year	The earlier of (i) the day that Sanofi reports its earnings or (ii) 45 days following the end of each Calendar Year

4.2 Payment of Profit. For each Calendar Quarter, Sanofi or Licensors, as applicable, shall make any payment of Profit or Loss as determined pursuant to Section 1 no later than fifteen (15) days following Sanofi's delivery of the Profit/Loss Statement for such Calendar Quarter (the "**Payment Date**"). The Licensors shall be jointly and severally liable for payment of any such Loss. Payments of Profit or reimbursements of Loss made by one Party to the other after the Payment Date shall accrue interest from the applicable Payment Date at a rate per quarter of two point zero six percent (2.06%) (equivalent to eight point five percent (8.5%) annually) until such outstanding amounts are paid to the applicable Party. If MannKind disputes an amount provided in the Profit/Loss Statement, then such disputed amount shall be reviewed by the JAC and any payment owed with respect to the undisputed amounts in the Profit/Loss Statement shall be paid within fifteen (15) days following Sanofi's delivery of such Profit/Loss Statement.

4.3 Foreign Exchange. The functional currency for accounting for Profit will be Euros, except for Profit within the United States, which shall be in U.S. Dollars. The Profit/Loss Statement will be translated into Euros using Sanofi's standard exchange rate conversion methodology.

5. Definitions. As used in this EXHIBIT B and as a supplement to the definitions set forth in Article 1 of the Agreement, the following terms shall have the meanings set forth in this Section 5 unless otherwise specifically provided herein.

5.1 "Allocable Overhead" means (for any particular cost item) a Party's internal allocation (determined in accordance with the last two (2) sentences of this Section 5.1), based on direct project headcount or other generally accepted activity-based accounting methods, of indirect overhead costs incurred by a Party or any of its operating units to support and carry out the activities of the specific business function, such as Development, obtaining or maintaining Regulatory Filings, Manufacturing (which, for the avoidance of doubt, shall be included solely as Cost of Goods under the Supply Agreement) and Commercialization, with respect to Product for the Territory, which indirect costs may include but are not limited to: indirect labor costs;

occupancy costs; repair and maintenance costs; office supplies and service costs; equipment costs; insurance costs; outside professional and other service costs; and excise taxes and other taxes including those related to the U.S. Affordable Care Act. Such overhead will exclude any indirect costs associated with any excess or unused capacity. Except as provided herein, overhead costs of a Party or operating units that are not engaged in the Development, obtaining or maintaining Regulatory Filings, Manufacturing or Commercialization of Product in the Territory, including, by way of example only, executive management, investor relations, business development, legal affairs, human resources and finance, will not be recoverable as Allocable Overhead or otherwise. The Parties acknowledge and agree that each Party's Allocable Overhead for all applicable cost items shall be determined by mutual agreement of the Parties on an annual basis prior to each Calendar Year and such agreed-upon annual Allocable Overhead amount shall be the amount used for such Calendar Year for all calculations of Allowable Expenses hereunder. For the sake of clarity, neither Party shall be entitled to any reimbursement for Allocable Overhead that exceed such mutually agreed-upon annual Allocable Overhead amount.

5.2 "Allowable Expenses" means those costs and expenses incurred by the Parties or for their account that are specifically attributable or related to the Development, JAC-approved Product- and process-improvements (but not to the extent included in Cost of Goods), obtaining or maintaining Regulatory Filings, Manufacturing or Commercializing of Product in the Territory, and consisting of: (i) Paid Price, as trued-up to Cumulative COGS in accordance with Section 4.1(c) of the Supply Agreement, with respect to Product manufactured by or for MannKind; (ii) Cost of Goods for Product manufactured by or for Sanofi; (iii) Development Expenses; (iv) Commercial Expenses; (v) Replacement Supply Costs; and (vi) costs arising under or relating to sublicense agreements for Product.

5.3 "Commercial Expenses" shall mean, with respect to the applicable Calendar Quarter, the sum of the following costs and expenses (each of which is specified below) incurred by the Parties and their Affiliates after the Execution Date, in each case to the extent directly attributable to the Commercialization of Product in the Field in the Territory in such Calendar Quarter in accordance with the Commercialization Plan and the Commercialization Budget, excluding the Cost of Goods for Product used in conducting or performing such activities, calculated on a fully burdened basis (*i.e.*, Commercial Expenses shall include Allocable Overhead specifically attributable thereto):

- (a) Advertising;
- (b) Distribution;
- (c) Education;
- (d) Legal and Litigation;
- (e) Marketing Management;
- (f) Market Research;
- (g) Promotion;

(h) Selling Expenses; and

(i) any other expenses included in the Commercialization Budget approved by the JAC.

The costs of activities that promote a Party's business as a whole without being product specific (such as corporate image advertising) are specifically excluded from Commercial Expenses. To the extent multiple products are involved and some of such products are not the Product, then such allowances will be allocated on a *pro rata* basis consistent with Sanofi's standard internal allocation methodology. Commercial Expenses shall not include any costs or expenses that have been included in Cost of Goods, Development Expenses or any time spent traveling to or attending any meeting of the JAC, or any subcommittee or working group of the foregoing.

"Advertising" shall mean all media costs associated with Product advertising in the Territory including, but not limited to production expense/artwork including set up; design and art work for an advertisement; consumer and professional internet and digital media spending; social media spending; the cost of securing print space, air time, etc. in newspapers, magazines, trade journals, television, radio, billboards, etc.

"Distribution" shall mean the sales commissions payable to distributors and the portion of distribution costs relating to moving Product in the Territory from the manufacturing point to a warehouse to the customer as follows: landing costs and duties (in-house or subcontracted), handling and transportation to fulfill orders including export/import taxes, insurance and transit running costs, etc. (excluding such costs, if any, treated as a deduction in the definition of Net Sales); customer services, including order entry, billing and adjustments, inquiry and credit, collection, and litigation with customers concerning orders/deliveries; order administration; and departments coordinating sales forecasts and supply management; physical distribution centers and other direct cost of storage and distribution of the Products, including distribution and storage subcontracted to third parties; distribution services between physical distribution centers and commercial activities; local supply chain department; transportation packaging modifications as a result of marketing decisions or regulatory requirements; and the costs of the traffic department where there is a separate department that has responsibility for administration of freight costs. "Distribution" at the local country level shall be deemed to apply at a rate equal to two percent (2%) of Net Sales in the United States and five percent (5%) of Net Sales in all countries of the Territory other than the United States, as applicable, in such Calendar Quarter.

"Education" shall mean expenses associated with professional education with respect to Product in the Territory through any means, including, but not limited to, articles appearing in journals, newspapers, magazines or other media; seminars, and scientific exhibits; symposia, advisory boards and opinion leader development activities; peer-to-peer activities; speakers programs, including training of such speakers; transporting, housing and maintaining sales representatives for training and the costs of all training materials used for such purpose; medical management and support; the coordination of medical information requests and field based medical scientific liaisons with respect to Product, including activities of medical scientific liaisons and the provision of medical information services.

“Legal and Litigation” shall mean the expenses associated with general, worldwide administrative legal and litigation expenses for Product including Losses from any Third Party Claims relating to the Manufacturing or Commercializing of the Product and costs associated with recall or withdrawal of Product other than, in each case, expenses, Losses and costs subject to indemnification under Section 11.1 or 11.2 of the Supply Agreement or under Section 11.1 or 11.2 of this Agreement, or relating to or arising from a Party’s gross negligence or willful misconduct; and real losses on receivables (other than Net Sales) that have become irrecoverable; insurance liabilities for Product; and license fees, royalties and other payments under licenses to the extent attributable to, and based on, the Development, Manufacture or Commercialization of Product.

“Marketing Management” shall mean expenses for product management and sales promotion management, including, but not limited to, costs associated with developing overall sales and marketing strategies at the global and country level (e.g., product line or customer segment); launch meetings; advertising and public relations agencies, including development and distribution of selling and advertising and promotional materials; developing reimbursement programs; call center set-up, maintenance and operation for personnel used in connection therewith as well as planning and programs for Product in the Territory. In addition, payments to Third Parties in connection with trademark selection, filing, prosecution and enforcement in the Territory will be included in this category.

“Market Research” shall mean expenses for primary and secondary market and consumer research personnel and payments to Third Parties related to conducting and monitoring professional and consumer appraisals of Product in the Territory, such as primary and secondary market share services (e.g., IMS data), special research testing and focus groups.

“Promotion” shall mean the expenses associated with programs to promote Product in the Territory directly to the prescriber or end user, including, but not limited to, expenses associated with promoting products directly to the professional community such as professional literature; costs associated with patient assistance programs; promotional material costs; patient aids and detailing aids; sales force tools and aids; managed care programs charged directly to the brand (including speaker programs, distribution of promotional material, contract administration, etc.); field force meetings and training; professional agency fees; direct field funding; public relations; pharmacy programs; coupons and voucher programs; advocacy; sponsorships; scientific and medical promotion, including expenses associated with grants and medical education, conventions, non-certified medical expense medical activities, scientific publications, commercial and medical advisory boards, field medical events, evidence-based medicine non-research projects; and Product samples (which, for the avoidance of doubt, will not be double counted with associated costs contained in Paid Price or Cumulative COGS), including associated expenses such as per unit costs, costs of distributing samples from the warehouse to sales representatives or fulfillment warehouses, and any other costs related to Product samples such as sample fulfillment, sample optimization programs, and management fees for sample voucher programs (i.e., vouchers provided by the physicians to patients in order to obtain free trade units at the pharmacy).

“Selling Expenses” shall mean the following costs directly associated with the efforts of field sales representatives with respect to Product in the Territory: field sales force; field

medical liaisons, field sales offices; home offices; staffs directly involved in the management of and the performance of the selling functions; and payments to Third Parties under contract sales and marketing agreements. The costs of detailing sales calls will be allocated at an accounting charge rate consistently applied within and across Sanofi's operating units consistent with the internal charge rate used by Sanofi for its own internal cost accounting purposes for products other than the Product (excluding internal profit margins and markups). Selling Expenses may be allocated differently on a country-by-country basis but in any event shall be determined consistently with the manner in which Sanofi prepares its internal financial statements.

5.4 "**Cost of Goods**" shall have the meaning set forth in the Supply Agreement.

5.5 "**Development Expenses**" shall mean, with respect to the applicable Calendar Quarter, the costs and expenses incurred by a Party or any of its Affiliates after the Execution Date in conducting or performing Development activities in the Field in the Territory in such Calendar Quarter in accordance with the Development Plan and the Development Budget, excluding the Cost of Goods for Product used in conducting or performing such studies and other activities, calculated on a fully burdened basis (*i.e.*, Development Expenses shall include Allocable Overhead specifically attributable thereto). Development Expenses shall include all Regulatory Expenses and payments and accruals recorded in such Party's accounting system according to its standard accounting practices and IFRS.

5.6 "**Regulatory Expenses**" shall mean, with respect to the applicable Calendar Quarter, the costs and expenses incurred by a Party or any of its Affiliates after the Execution Date in connection with filing, revising, obtaining or maintaining Regulatory Filings with respect to Product in the Field in the Territory in such Calendar Quarter in accordance with the Development Budget, excluding the Cost of Goods for Product used in conducting or performing such activities, calculated on a fully burdened basis (*i.e.*, Regulatory Expenses shall include Allocable Overhead specifically attributable thereto). Regulatory Expenses shall include payments and accruals recorded in such Party's accounting system according to its standard accounting practices and IFRS.

5.7 "**Replacement Supply Costs**" shall mean costs and expenses incurred by Sanofi in connection with establishing replacement source(s) of supply and associated supply chain following a Trigger Event (as defined in the Supply Agreement) except to the extent reimbursed by MannKind under the Supply Agreement.

SCHEDULE B-1

PROFIT/LOSS STATEMENT

	<u>Sanofi</u>	<u>MannKind</u>	<u>Total</u>
<u>REVENUES</u>			
Sublicensing Revenue			
Total Net Sales			
Paid Price			
Distribution			
Gross Profit			
<u>OPERATING EXPENSES</u>			
Development Expenses:			
Clinical trials			
CMC development			
Allocable Overhead			
Total Development Expenses			
Commercial Expenses:			
Advertising			
Education			
Legal and Litigation			
Marketing Management			
Market Research			
Promotion			
Selling Expenses			
Allocable Overhead			
Total Commercial Expenses			
Profit (loss)			
Adjustments per Section 4.1:			
Balancing Payment			
Interest on outstanding payments of Profit or Loss			
Total			

EXAMPLE OF PROFIT/LOSS SHARE CALCULATIONS

[...***...]

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1.

EXHIBIT C
MANKIND PATENTS

Attached.

C-1.

Reference #	Country Name	Serial #	Filed Date	Patent #	Issue Date	Status	*Anticipated Expiration Date	**PRODUCT-specific or Platform
[...***...]			[...***...]					
[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]	[...***...]

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<u>Reference #</u>	<u>Country Name</u>	<u>Serial #</u>	<u>Filed Date</u>	<u>Patent #</u>	<u>Issue Date</u>	<u>Status</u>	<u>*Anticipated Expiration Date</u>	<u>**PRODUCT-specific or Platform</u>
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* Expiration dates are computer generated and may not take into account patent term adjustments, patent term extensions, terminal disclaimers or the like. These dates should be used as general guides only.

** The classification of pending applications as Product-specific or Platform must be considered tentative until such time as a patent is allowed.

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***Text Omitted and Filed Separately with
the Securities and Exchange Commission.
Confidential Treatment Requested Under
17 C.F.R. Sections 200.80(b)(4) and 240.24b-2.

EXECUTION VERSION

SUPPLY AGREEMENT

This **SUPPLY AGREEMENT** (together with all schedules attached hereto, the “**Agreement**”) is entered into as of August 11, 2014 (the “**Execution Date**”) and is effective as of the Effective Date (as defined in the License Agreement (as defined below)) between **MANNKIND CORPORATION**, a Delaware corporation (“**MannKind**”), having a principal place of business at 28903 North Avenue Paine, Valencia, California 91355, USA, and **SANOFI-AVENTIS DEUTSCHLAND GMBH**, a company organized and existing under the laws of Germany (“**Sanofi**”), with a place of business at 65926 Frankfurt am Main, Germany.

RECITALS

WHEREAS, MannKind has developed and has obtained approval in the United States of Product for improvement of glycemic control in adult patients with diabetes and owns or controls certain patents, know-how and other intellectual property related to Product;

WHEREAS, Sanofi is engaged in the development and commercialization of pharmaceutical products;

WHEREAS, MannKind, Technosphere International C.V., a Dutch limited partnership, MannKind Netherlands B.V., a Dutch limited liability company, and Sanofi are entering into a License and Collaboration Agreement of even date herewith (as may be amended, the “**License Agreement**”) under which Sanofi is receiving licenses to develop and commercialize Product in the Territory; and

WHEREAS, MannKind desires to supply Product to Sanofi and its Affiliates in connection with the License Agreement on the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, MannKind and Sanofi hereby agree as follows:

ARTICLE 1

DEFINITIONS

Capitalized terms used herein and not otherwise defined herein shall have the meanings set forth for such terms in the License Agreement. The following terms used herein shall have the following meanings:

- 1.1 “**Amphastar**” shall mean Amphastar France Pharmaceuticals S.A.S.
- 1.2 “[...***...] **Insulin**” shall have the meaning set forth in Article 13.
- 1.3 “**Arbitration Deadline**” shall have the meaning set forth in Section 12.2.

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1.4 “**Audit Disagreement**” shall have the meaning set forth in Section 4.4(d).

1.5 “**Binding Forecast**” shall have the meaning set forth in Section 3.2.

1.6 “**Certificate of Conformance**” shall have the meaning set forth in Section 5.2(b).

1.7 “**cGMP**” shall mean the current good manufacturing practices for the manufacture and testing of pharmaceutical materials and devices required by the FDA or other Regulatory Authority(ies).

1.8 “**Clinical Supply Agreement**” shall have the meaning set forth in Section 2.1(a)(ii).

1.9 “**Clinical Supply Quality Agreement**” shall have the meaning set forth in Section 2.1(a)(ii).

1.10 “**COGS Cap**” shall have the meaning set forth in Section 4.1.

1.11 “**Commercially Reasonable Manufacturing Efforts**” shall mean, with respect to the efforts and resources required to fulfill any Manufacturing obligation hereunder, the use of reasonable efforts and resources, in good faith, consistent with the customary legal, medical, scientific judgment and business practices of large or medium size Manufacturing companies in the pharmaceutical industry or the biotech industry.

1.12 “**Cost of Goods**” shall mean, with respect to any Product supplied within the scope of this agreement the unit cost of manufacture consisting of (a) Direct Material Costs, (b) Direct Operating Labor Costs and (c) Indirect Expenses, each as defined below, all as fairly and reasonably attributable to the Product within the scope of this Agreement.

(a) “**Direct Material Costs**” means the cost of purchased materials used in the manufacture or packaging of the Product, including costs of Raw Materials, excipients, intermediates and laboratory reagents and consumables, and costs of packaging materials, labels and other printed materials used in the production of Product;

(b) “**Direct Operating Labor Costs**” means the personnel cost of employees directly employed in the manufacturing, packaging, quality testing or release of the Product, including basic wages, labor and related payroll taxes and benefits; and

(c) “**Indirect Expenses**” means:

(i) Depreciation costs or lease/rental for manufacturing buildings and equipment and costs for maintenance and repair of such buildings and equipment. The depreciation costs shall be allocated using an appropriate methodology. Costs of equipment shall be based on a planned utilization of equipment. Facility and equipment depreciation and/or lease/rental shall be allocated to production proportionate to the usage of the Manufacturing facility and equipment for the actual Manufacturing of Product;

(ii) Allocable Overhead, as such term is defined in Exhibit B to the License Agreement;

(iii) Quality assurance activities;

(iv) Interim transportation, or any related transportation cost including tertiary packaging and storage of Product, as incurred or spent in connection with this Agreement;

(v) Costs of approved Third Party manufacturers (such costs will include the actual amount paid including the benefit of any price reductions, payment or terms discounts or other reimbursements, such as volume discounts, that may be applicable to such purchases); and

(vi) Subject to Section 6.4, costs associated with changes of the Product Specifications or the Manufacturing Process.

For the avoidance of doubt, the following expenses will not be included in Cost of Goods:

(A) Expenses associated with excess or idle capacity (including insurance and maintenance thereof), subject to Section 2.1(b)(ii);

(B) The value of any stock provisions or write-offs, either due to quality non-compliance, or obsolescence and any associated costs for physical destruction;

(C) Project related costs (*e.g.*, process development, plant commissioning, process improvement projects);

(D) Support functions not allocated to the Product within the scope of this Agreement;

(E) Costs of asset write off;

(F) Indemnities incurred by the supplier; and

(G) Business interruption insurance and product liability insurance.

1.13 "*CPI*" shall have the meaning set forth in Section 4.1(b).

1.14 "*Cumulative COGS*" shall have the meaning set forth in Section 4.1(c)(i).

1.15 "*Due Date*" shall have the meaning set forth in Section 4.3(b).

1.16 "*Estimated Annual Volume*" shall have the meaning set forth in Section 3.2.

1.17 "*Estimated COGS*" shall have the meaning set forth in Section 4.1.

1.18 "*Forecast*" shall have the meaning set forth in Section 3.2.

1.19 “*Grace Period*” shall have the meaning set forth in Section 6.7(c).

1.20 “*Hardship*” shall have the meaning set forth in Section 4.1(b)(ii).

1.21 “*IBA Guidelines on Evidence*” shall have the meaning set forth in Section 12.2.

1.22 “*ICH*” shall mean the International Conference on Harmonization (of Technical Requirements for Registration of Pharmaceuticals for Human Use).

1.23 “*Indemnitee*” shall have the meaning set forth in Section 11.3.

1.24 “*Indemnitor*” shall have the meaning set forth in Section 11.3.

1.25 “*Insulin Exercise Notice*” shall have the meaning set forth in Article 13.

1.26 “*Insulin Price*” shall have the meaning set forth in Article 13.

1.27 “*Insulin Put Option*” shall have the meaning set forth in Article 13.

1.28 “*Intervening Event*” shall have the meaning set forth in Section 14.1.

1.29 “*Launch Quantities*” shall have the meaning set forth in Section 3.1.

1.30 “*License Agreement*” shall have the meaning set forth in the Recitals to this Agreement.

1.31 “*Losses*” shall have the meaning set forth in Section 11.1.

1.32 “*MannKind Facility*” shall mean MannKind’s facility located in Danbury, Connecticut, USA, where Product shall be Manufactured for Sanofi under this Agreement.

1.33 “*MannKind Indemnitees*” shall have the meaning set forth in Section 11.1.

1.34 “*Manufacturing Process*” shall have the meaning set forth in Section 6.4.

1.35 “*Manufacturing Right*” shall have the meaning set forth in Section 6.7(b).

1.36 “*Manufacturing Technology*” shall mean all MannKind Technology that is necessary or useful for the Manufacture of Product, including such Information contained in the CMC section of any applicable Regulatory Filing and trade secrets, and including materials receiving and inspection procedures, Product work instructions and standard operating procedures, records of yield for each Manufacturing step, Product engineering reports and improvement plans, list of instrumentation and description of the analytical methods used for the testing of the Product and the materials, device master file, device design history file and mold process documentation.

1.37 “*Objection Notice*” shall have the meaning set forth in Section 5.3(b).

1.38 “*Paid Price*” shall have the meaning set forth in Section 4.1.

1.39 “**Party**” shall mean MannKind or Sanofi individually, and “**Parties**” shall mean MannKind and Sanofi collectively.

1.40 “**Product Specifications**” shall mean the specifications for Product contained in the NDA for Product or in the applicable Marketing Approval of any country or jurisdiction in the Territory other than the United States, as applicable, and any other specifications mutually agreed to in writing by the Parties and changes to such specifications made at the request of a Regulatory Authority in a given country or jurisdiction in the Territory or by written agreement of the Parties from time to time, including the specifications set forth in the Quality Agreement.

1.41 “**Put Closing Date**” shall have the meaning set forth in Article 13.

1.42 “**Quality Agreement**” shall have the meaning set forth in Section 5.1.

1.43 “**Raw Materials**” shall have the meaning set forth in Section 6.1(a).

1.44 “**S&OP Process**” shall have the meaning set forth in Section 2.3(b).

1.45 “**Sanofi Indemnitees**” shall have the meaning set forth in Section 11.2.

1.46 “**Sanofi Site**” shall have the meaning set forth in Section 2.1(b)(ii).

1.47 “**Semi-Finished Product**” shall have the meaning set forth in Section 6.5(b).

1.48 “**SKU**” shall mean stock keeping unit.

1.49 “**Term**” shall have the meanings provided in Section 10.1.

1.50 “**Testing Technology/Processes**” shall mean all technology and processes in the possession, custody or control of MannKind that are necessary or useful for the testing of Product or any component thereof to determine whether it meets Product Specifications.

1.51 “**Third Party Claims**” shall have the meaning set forth in Section 11.1.

1.52 “**Trigger Event**” shall have the meaning set forth in Section 6.7(b).

ARTICLE 2

PURCHASE AND SUPPLY

2.1 Supply by MannKind.

(a) Supply Obligation.

(i) **Commercial Supply.** Subject to the terms and conditions of this Agreement (including Sections 2.1(b)(ii) and 6.7), MannKind will Manufacture or have Manufactured and supply or have supplied to Sanofi or its Affiliates or its sublicensees such quantities and SKUs of Product as requested by Sanofi to cover total commercial requirements of

Sanofi (for Sanofi and its Affiliates and its sublicensees) for Product in the Field in the Territory, including Product requested by Sanofi for promotional activities.

(ii) Clinical Supply. As soon as reasonably practicable after the Effective Date, the Parties shall enter into a written agreement (the “**Clinical Supply Agreement**”) setting forth terms and conditions pursuant to which MannKind will Manufacture or have Manufactured and supply or have supplied to Sanofi such quantities and SKUs of Product as requested by Sanofi for any Development activities in the Field in the Territory as well as a quality agreement that details the quality assurance obligations of each Party relating thereto (the “**Clinical Supply Quality Agreement**”). Prior to effectiveness of the Clinical Supply Agreement and the Clinical Supply Quality Agreement, MannKind will Manufacture or have Manufactured and supply or have supplied to Sanofi in accordance with the terms of this Agreement and the Quality Agreement, as applicable, such quantities and SKUs of Product as requested by Sanofi for any Development activities in the Field in the Territory.

(b) Exclusivity.

(i) Exclusive Supply. Subject to the terms and conditions of this Agreement (including Sections 2.1(b)(ii) and 6.7), (a) MannKind will be the exclusive supplier to Sanofi and its Affiliates and its sublicensees of Product during the Term, and (b) Sanofi agrees that in no event shall Sanofi or its Affiliates or its sublicensees Manufacture or have Manufactured Product, or purchase Product from any party other than MannKind. Notwithstanding the foregoing, the Parties shall upon Sanofi’s request discuss in good faith the possibility that Sanofi perform final packing of Product (insertion of Device and sealed foil packages containing blister cards of cartridges).

(ii) Sanofi Option. Notwithstanding the foregoing, the Parties acknowledge and agree that Sanofi shall have the option (the “**Sanofi Option**”), exercisable at Sanofi’s sole discretion upon written notice to MannKind, to establish another facility of Sanofi or its Affiliate in which Product will be Manufactured (such facility, the “**Sanofi Site**”), it being understood that such Sanofi Option shall not be exercised before MannKind has committed the capital investment required to bring the MannKind Facility to a level of capacity representing approximately [...***...] percent ([...***...]%) of its maximum capacity (corresponding under MannKind’s current investment plan to the Manufacture of approximately [...***...] cartridges of Product annually). For the avoidance of doubt, development of capacity at the MannKind Facility and/or the Sanofi Site shall be submitted to the approval of the JAC.

(iii) Effect of Exercise of the Sanofi Option and Qualification of the Sanofi Site. Upon the exercise of the Sanofi Option, (x) the Parties will coordinate the planning for the Sanofi Site with any further expansion of the MannKind Facility to minimize underutilization of both the MannKind Facility and the Sanofi Site after the Sanofi Site is subsequently qualified, and (y) MannKind will perform those technology transfer obligations triggered by exercise of the Sanofi Option set forth in Section 6.6. Upon qualification of the Sanofi Site, Section 2.1(b)(i) shall be deemed amended so that all references to “MannKind” therein shall be deemed to be references to “MannKind and the Sanofi Site”. From and after qualification of the Sanofi Site, the MannKind Facility and the Sanofi Site shall each be entitled

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to Manufacture and supply one-third (1/3) of total Product volumes (at their respective Cost of Goods and without reference to any COGS Cap), with the last one-third (1/3) of Product volumes being allocated to the MannKind Facility and/or the Sanofi Site in a manner that minimizes the overall Cost of Goods; *provided, however*, that if such allocation of Product volumes results in underutilization of either the MannKind Facility or the Sanofi Site, then notwithstanding Section 1.12, (1) during such period(s) that MannKind delivers all of its volume allocation within the tolerances set forth in Section 3.4, then the costs of such underutilization shall be included in the Cost of Goods for Product Manufactured and supplied from the MannKind Facility at all times that the MannKind Facility is under-utilized as a result of such allocation of Product volumes between the MannKind Facility and the Sanofi Site; and (2) the costs of such underutilization shall be included in the Cost of Goods for Product Manufactured and supplied from the Sanofi Site at all times that the Sanofi Site is under-utilized as a result of such allocation of Product volumes between the MannKind Facility and the Sanofi Site.

2.2 Form of Supply. MannKind shall supply Product to Sanofi in the form of finished Product (i.e., individual doses, final packaging, etc.) ready and suitable for distribution and sale to the market in the relevant jurisdiction in the Territory (or as otherwise reasonably requested by Sanofi with respect to Product for any Development activities permitted under the License Agreement). Without limiting the foregoing, MannKind shall be responsible for packaging Product in blister cards contained in a foil overwrap and supplying Product to Sanofi in finished packaging, including (a) all labeling and other written, printed or graphic content (i) affixed to Product or any container or wrapper utilized with Product or (ii) accompanying Product, including package inserts, and (b) all containers for Product, including cartons, shipping cases or any other like matter used in packaging or accompanying Product. All such packaging shall be in a form approved in advance by Sanofi and MannKind shall include Sanofi's name on such packaging in the manner and format specified by Sanofi. MannKind shall be responsible for ensuring that all labels and packaging for Product supplied hereunder shall, at the time of supply, conform to the labels for the Product approved by Sanofi.

2.3 Cooperation.

(a) Monthly Review. Each Party shall forthwith upon execution of this Agreement, appoint one (1) of its employees to be a relationship manager responsible for acting as liaison between the Parties with regard to matters described in this Agreement. The relationship managers shall meet (either in person or by phone) not less than monthly to review the current status of the business relationship and manage any issues that have arisen.

(b) Sales and Operational Planning. The Parties, through their relationship managers, shall establish a process for aligning Sanofi's sales plans with MannKind's operations plans in order to (i) optimize Product supply taking into account the utilization of production resources and any equipment and material constraints, (ii) manage inventory levels and order backlogs, and (iii) establish metrics for the measurement of effective performance (the "**S&OP Process**"). The Parties agree that the S&OP Process will form the basis for MannKind's master production schedule and for decisions about material and labor resources. Accordingly, Sanofi acknowledges the need for accurate and timely adjustments to Forecasts so that supply capacity can be managed appropriately.

(c) Person-in-Plant. Upon MannKind's receipt of at least seven (7) days' prior notice from Sanofi during the Term and at no additional cost to Sanofi, Sanofi may place up to two (2) employees or authorized representatives (with such authorized representatives being subject to MannKind's prior approval, such approval not to be unreasonably withheld, conditioned or delayed) on-site at the MannKind Facility during the Term. Sanofi's representatives shall have access to MannKind's production and quality control areas related to the Product (including when in operation) and to Product documentation, it being understood that Sanofi's representatives at the MannKind Facility shall accept MannKind's procedures regulating external customer relationships (including cGMP training, hygiene, confidentiality and controlled access to facilities and documents) and will obtain MannKind's written agreement (such agreement not to be unreasonably withheld, conditions or delayed) prior to any active participation in the Manufacture or testing of Product. MannKind will make available office space to any such Sanofi representatives on-site at the MannKind Facility, and any reasonable and customary related office resources and support services (such as telephone and data communications wiring in such facilities and patch cables located in network wiring closets in such facilities, parking privileges, access cards or badges, and furniture), at a level of support that MannKind provides such items to its own comparable employees.

(d) Continuous Improvement. MannKind shall continuously seek to improve the actual Cost of Goods throughout the Term, and, at the request of Sanofi, provide Sanofi with written evidence demonstrating the efforts and activities undertaken by MannKind in furtherance thereof through the Manufacturing working group of the JAC. At the request of MannKind, Sanofi shall provide reasonable support to MannKind therefor, such as offering (i) certain Manufacturing services related to the Product at their fully burdened manufacturing cost without any markup, as well as (ii) the supply of certain Raw Materials under the conditions set forth in Section 6.1(a). Notwithstanding the foregoing, MannKind acknowledges and agrees that (x) MannKind is and shall remain solely responsible for the negotiation and execution of supply agreements with all suppliers of Insulin and other Raw Materials; and (y) Sanofi shall not have any obligation with respect to the negotiation or execution of such supply agreements. The Manufacturing working group of the JAC shall discuss and oversee the efforts to reduce Cost of Goods and approve in advance any costs to be incurred by MannKind for such efforts.

(e) Manufacturing Prioritization. MannKind will dedicate to the Manufacture of Products for Sanofi hereunder the first priority with respect to facilities, equipment, and Raw Materials used therefor. If there is a conflict between Manufacture of Product for Sanofi hereunder and the Development or Manufacture of any other product, the conflict will be resolved in favor of Manufacture of Product for Sanofi hereunder.

(f) CAPA Obligations. The Parties acknowledge that (i) prior to the execution of this Agreement, Sanofi performed a formal quality audit and inspection of the MannKind Facility, and (ii) as a result of such audit and inspection, Sanofi identified those corrective actions and preventive actions (each, a "CAPA") set forth on **SCHEDULE D** hereto. As soon as reasonably practicable after the Execution Date, but in any event prior to the receipt of Sanofi's written purchase order for Product, MannKind shall perform each CAPA to the reasonable satisfaction of Sanofi.

ARTICLE 3

FORECASTS AND PURCHASE ORDERS

3.1 Commercial Launch. Sanofi shall notify MannKind approximately [...***...] months in advance of the anticipated First Commercial Sale of Product in the Field in the Territory. Such notification shall include a preliminary estimate of the quantity of Product needed for the commercial launch. Sanofi may change the estimated date of the First Commercial Sale and the estimated quantity of Product needed for such commercial launch at any time by notifying MannKind; *provided, however*, that Sanofi will provide MannKind with its binding forecast for the amount of Product that will be necessary for commercial launch upon achievement of the [...***...] Milestone, and in any event, at least [...***...] months prior to such launch (the “**Launch Quantities**”).

3.2 Forecasts. In the first week of each month, Sanofi shall provide MannKind with a written eighteen (18) month rolling forecast of its anticipated requirements for Product in the Territory (each a “**Forecast**”). Sanofi’s initial Forecast is attached hereto as **SCHEDULE E**. Each Forecast is a non-binding estimate and shall not obligate Sanofi to purchase the volume of Product set forth in such Forecast; *provided, however*, that, from and after achievement of the [...***...] Milestone, the volume forecasted for the first (1st) three (3) months of each Forecast shall be binding upon Sanofi (such first (1st) three (3) months, the “**Binding Forecast**”). MannKind shall not be obligated to Manufacture or supply Sanofi with quantities of Product in excess of one hundred ten percent (110%) of the most recent Binding Forecast provided to MannKind but agrees to use Commercially Reasonable Manufacturing Efforts to satisfy Sanofi’s requirement of Product in excess of one hundred ten percent (110%) of the Binding Forecast quantities in accordance with the terms of this Agreement. In addition to the Forecast, the Parties shall by October 1 of each Calendar Year agree upon an annual Product volume forecast, expressed in number of cartridges, for the following Calendar Year (the “**Estimated Annual Volume**”) for the purpose of determining, in accordance with Section 4.1, the Estimated COGS and the COGS Cap for purchase orders of Product submitted during such Calendar Year.

3.3 Purchase Orders. Sanofi shall order Product by submitting written purchase orders, in such form as the Parties shall agree from time to time, to MannKind specifying the quantities of Product ordered, the desired delivery date for such Product and any special shipping instructions. Sanofi shall order Product in lots of a defined number of units/lot pursuant to each purchase order as reasonably specified by MannKind. Sanofi shall submit each purchase order to MannKind at least ninety (90) days in advance of the desired delivery date specified in such purchase order. MannKind shall confirm acceptance of the purchase order within five (5) days of receipt of the purchase order from Sanofi. If MannKind fails to confirm acceptance of a purchase order within five (5) days of receipt of the purchase order from Sanofi, then such purchase order shall be deemed to have been accepted by MannKind. MannKind shall accept all purchase orders for quantities of Product that are within the amounts specified in the applicable Binding Forecast. MannKind shall make (or in the case of orders in excess of one hundred ten percent (110%) of the Binding Forecast, use Commercially Reasonable Manufacturing Efforts to make) each delivery of Product in the quantity and on the delivery date specified for it on Sanofi’s purchase order, via the mode(s) of transportation and to the party and destination

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specified on such purchase order. Any purchase orders for Product submitted by Sanofi to MannKind shall reference this Agreement and shall be governed exclusively by the terms contained herein. The Parties hereby agree that the terms and conditions of this Agreement shall supersede any term or condition in any purchase order, confirmation or other document furnished by Sanofi or MannKind that is in any way inconsistent with the terms and conditions contained herein.

3.4 Delivery. MannKind will ship Product to Sanofi in such quantities and on such monthly delivery dates as are specified in purchase orders (with a tolerance of plus/minus five percent (5%) for the quantity, and a tolerance of minus three (3) / plus zero (0) days for the delivery date). Deliveries shall be made FCA ("Free Carrier," as such term is defined in INCOTERMS 2010) from the location of final Product completion. All deliveries of Product to Sanofi shall be made via such carrier(s) as Sanofi may direct.

3.5 Shelf Life.

(a) For the period prior to FDA or other Regulatory Authority approval of a total shelf life of the Product that is greater than twenty-four (24) months in a particular jurisdiction: Upon delivery for that jurisdiction, the residual shelf life of Product shall, unless otherwise approved by Sanofi, be at least fifteen (15) months; *provided, however,* that MannKind shall use Commercially Reasonable Manufacturing Efforts to deliver Product with residual shelf life of at least eighteen (18) months; and

(b) For the period from and after FDA approval or other Regulatory Authority of a total shelf life of the Product that is greater than twenty-four (24) months in a particular jurisdiction: Upon delivery for that jurisdiction, the residual shelf life of Product shall, unless otherwise approved by Sanofi, be at least eighty percent (80%) of the Product's total approved shelf life in the relevant jurisdiction.

3.6 Changes to Purchase Orders. MannKind shall use Commercially Reasonable Manufacturing Efforts to comply with unplanned changes in purchase orders requested by Sanofi either in terms of quantities or delivery dates. In no event shall MannKind implement such unplanned changes without the prior written approval of Sanofi if such changes result in supplementary costs for Sanofi.

ARTICLE 4

PAYMENT TERMS

4.1 Price.

(a) **Paid Price, Estimated COGS and COGS Cap.** No later than October 2 of each Calendar Year during the Term, the JAC shall determine the price to be paid by Sanofi to MannKind for each unit (*i.e.*, each cartridge) of Product supplied by MannKind to Sanofi during the subsequent Calendar Year (the "**Paid Price**"), which price shall equal the lower of the Estimated COGS per unit for that year and the COGS Cap per unit, in each case, at the Estimated Annual Volume. The Paid Price shall subsequently be subject to true-up as described in Section 4.1(c). For purposes of this Agreement:

(i) “**Estimated COGS**” shall mean the estimated Cost of Goods for Product to be supplied by MannKind to Sanofi or its Affiliates or sublicensees under this Agreement for a specified annual volume of cartridges and at the estimated weighted average Insulin price for a Calendar Year, as adjusted pursuant to Section 4.1(b). The Parties agree that the Estimated COGS for the period from the Effective Date to December 31, 2015, shall be as set forth in **SCHEDULE A** to this Agreement; and

(ii) “**COGS Cap**” shall be the maximum price for Product, for a specified annual volume of cartridges and at the weighted average Insulin price determined in accordance with Section 4.1(b)(i), which (A) for the period from the Effective Date until December 31, 2019, shall be as set forth in **SCHEDULE B**, subject to adjustment in accordance with Section 4.1(b); and (B) for the Calendar Year starting January 1, 2020 and all subsequent Calendar Years during the Term, shall be determined by the JAC for each five-year period prior to the commencement of each such five-year period and shall be subject to adjustment in accordance with Section 4.1(b); in each case, provided that there shall be no COGS Caps from and after qualification of the Sanofi Site.

(b) **Adjustments.** On January 1, 2016 and at the beginning of each Calendar Year thereafter, the COGS Cap shall be adjusted in accordance with any increase or decrease in the U.S. Consumer Price Index for Prescription Drugs (seasonally adjusted) published by the U.S. Bureau of Labor Statistics (“**CPI**”) during the previous Calendar Year up to a maximum increase of five percent (5%) per Calendar Year. The Parties acknowledge and agree that unless mutually agreed by the Parties in writing, the COGS Cap shall be calculated in accordance with the values, model and methodology set forth on **SCHEDULE B** and as exemplified in **SCHEDULE C** to this Agreement, except that the values reflecting the prices for Insulin and critical Raw Materials (other than Insulin) may be adjusted in accordance with Sections 4.1(b)(i) and 4.1(b)(ii), respectively.

(i) **Insulin.** The Parties acknowledge and agree that the COGS Cap set forth in **SCHEDULE B** shall assume the following prices paid by MannKind for Insulin supply: (A) for [...***...] an Insulin price of \$[...***...]/gram, (B) for [...***...], subject to Section 4.1(b), an Insulin price of \$[...***...]/gram, and (C) for [...***...], subject to Section 4.1(b), [...***...], an Insulin price of \$[...***...]/gram.

(ii) **Hardship.** If, due to any reason or cause beyond MannKind’s reasonable control (including market shortage, market embargo, etc.) (a “**Hardship**”), MannKind is prevented from procuring any critical Raw Material (other than Insulin) at a price reasonably equivalent to that used to calculate the applicable COGS Cap, then MannKind shall promptly inform Sanofi of such Hardship and Parties shall meet to discuss appropriate means, if any, to adjust the values for such critical Raw Material used in the calculation of the COGS Cap to alleviate or mitigate the effects of such Hardship. If the Parties cannot agree upon an appropriate adjustment, the matter shall be referred to the JAC, which shall determine whether to adjust the COGS Cap during the period of such Hardship (and if so, the terms and conditions of such

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modification). For the avoidance of doubt, “**Hardship**” shall not include MannKind’s mere failure to negotiate or execute a supply agreement with its Raw Material suppliers.

(c) True-Up. Within forty-five (45) days after the end of the Calendar Year in which First Commercial Sale of Product occurs and each subsequent Calendar Year of the Term (each, a “**Sales Period**”), the Parties shall calculate an annual true-up payment as follows:

(i) The Parties shall compute (A) the cumulative Paid Price for all Product supplied by MannKind in such Sales Period (the “**Cumulative Price Paid**”); and (B) the lower of (x) the actual cumulative Cost of Goods for all Product supplied by MannKind in such Sales Period, and (y) the COGS Cap determined on the basis of the total annual volume for such Sales Period (such lower amount, the “**Cumulative COGS**”); provided, however, that if in any Calendar Year the actual cumulative Cost of Goods exceeds the applicable COGS Cap (such difference, the “**Overage**”), and in the immediately following Calendar Year the actual cumulative Cost of Goods is less than the applicable COGS Cap, then MannKind shall be entitled to add to the Cumulative COGS, for such successive Calendar Year only, an amount equal to the Overage up to, but not exceeding, the COGS Cap.

(ii) (A) If the Cumulative COGS exceeds the Cumulative Price Paid, Sanofi shall pay the difference to MannKind no later than forty-five (45) days after calculation of the true-up payment is due; and (B) if the Cumulative COGS is lower than the Cumulative Price Paid, the difference shall be, at Sanofi’s option, either (1) a credit to be applied against any or all subsequent purchases of Product hereunder or (2) reimbursed to Sanofi no later than forty-five (45) days after calculation of the true-up payment is due.

(d) True-Up Estimates. Within thirty (30) days of each Quarter, MannKind shall provide to Sanofi with MannKind’s then-current estimates of the total true-up amount that MannKind expects to be paid to or by Sanofi at the end of such Calendar Year pursuant to Section 4.1(c).

4.2 Taxes. All payments payable hereunder shall be paid without any reduction or offset for taxes. MannKind shall pay any and all U.S. federal, state, and local income taxes levied on payments to MannKind hereunder and Sanofi shall, in addition to amounts payable pursuant to Section 4.1, pay all other taxes levied on amounts payable hereunder. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use their reasonable efforts to cooperate and coordinate with each other to achieve such objective as allowed under Applicable Laws. Each Party shall cooperate with the other to the extent reasonably requested for the purpose of filing any tax returns relating sales, use, transfer, stamp, VAT, withholding, or similar taxes, if any, levied on amounts payable hereunder.

4.3 Invoices; Method of Payments.

(a) MannKind shall invoice Sanofi for the aggregate Estimated COGS or COGS Cap, as applicable, of each shipment of Product at the time of such delivery.

(b) All payments due hereunder to MannKind shall be paid to MannKind in U.S. Dollars not later than forty-five (45) days following the date of receipt of the applicable

invoice but not earlier than the date of delivery (the “**Due Date**”), unless such shipment of Product is rejected in accordance with the provisions of Section 5.3. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to a U.S. account designated in writing by MannKind or by other mutually acceptable means. Payments hereunder will be considered to be made as of the day on which they are received by MannKind’s designated bank.

4.4 Records.

(a) During the Term, and for a period of three (3) years thereafter, MannKind shall, and shall ensure that its Affiliates shall, keep at either its normal place of business, or at an off-site storage facility, detailed, accurate and up to date: (i) records and books of account sufficient to confirm the calculation of the Paid Price, Estimated COGS, actual Cost of Goods and COGS Cap; and (ii) information and data contained in any invoices provided to Sanofi in connection with this Agreement.

(b) On no less than sixty (60) days’ prior written notice from Sanofi, MannKind shall make all such records, books of account, information and data concerning the Paid Price, Estimated COGS, actual Cost of Goods and COGS Cap available for inspection during normal business hours by an independent, certified public accountant selected by Sanofi and reasonably acceptable to MannKind, which acceptance will not be unreasonably withheld or delayed, for the purpose of general review or audit; provided that Sanofi may not request such inspection more than once in any Calendar Year. As a condition to such inspection, the independent public accountant selected shall execute a written agreement, reasonably satisfactory in form and substance to MannKind, to maintain in confidence all information obtained during the course of any such examination and all reasonable documents will be disclosed to the accountant under these confidential terms. Additionally no accountant may be employed on a contingency basis.

(c) Sanofi shall be solely responsible for its costs in making any such review and audit, unless such review and audit discloses that the Cumulative COGS for a Sales Period, after true-up in accordance with Section 4.1(c), were overstated by more than five percent (5%) by MannKind, in which event MannKind shall be solely responsible for the cost of such review and audit. Any underpayment by Sanofi shall be promptly paid to MannKind, and any overpayment to MannKind by Sanofi shall be promptly refunded to Sanofi or credited toward any unpaid invoice by MannKind to Sanofi. All information disclosed by MannKind or its Affiliates pursuant to this Section 4.4 shall be deemed Confidential Information of MannKind.

(d) If there is a dispute between the Parties related to compliance with applicable accounting standards following any audit performed pursuant to Section 4.4, either Party may refer the issue (an “**Audit Disagreement**”) to an independent certified public accountant for resolution. In the event an Audit Disagreement is submitted for resolution by either Party, the Parties shall comply with the following procedures:

(i) The Party submitting the Audit Disagreement for resolution shall provide written notice to the other Party that it is invoking the procedures of this Section.

(ii) Within thirty (30) days of the giving such notice, the Parties shall jointly select a recognized international accounting firm to act as an independent expert to resolve such Audit Disagreement.

(iii) The Audit Disagreement submitted for resolution shall be described by the Parties to the independent expert, which description may be in written or oral form, within ten (10) days of the selection of such independent expert.

(iv) The independent expert shall render a decision on the matter as soon as practicable.

(v) The decision of the independent expert shall be final and binding and shall not be subject to Article 12 hereof, unless such Audit Disagreement involves alleged fraud, breach of this Agreement or construction or interpretation of any of the terms and conditions hereof.

(vi) All fees and expenses of the independent expert, including any Third Party support staff or other costs incurred with respect to carrying out the procedures specified at the direction of the independent expert in connection with such Audit Disagreement, shall be borne by the Party against whom such expert rules.

ARTICLE 5

QUALITY ASSURANCE; ACCEPTANCE

5.1 Quality Agreement. Within ninety (90) days from the Effective Date (or such longer period as agreed by the Parties but in any event at least three (3) months prior to the first delivery of Product to Sanofi), the Parties will enter into an agreement that details the quality assurance obligations of each Party (the "**Quality Agreement**"). In the event of a conflict between the terms of the Quality Agreement and the terms of this Agreement, the provisions of this Agreement shall govern; *provided, however*, that the Quality Agreement shall govern in respect of quality issues.

5.2 Specifications; Testing.

(a) **Batch Testing.** MannKind will have standard analytical testing performed on each Manufactured batch of Product to be shipped to Sanofi to verify that it meets Product Specifications, according to the procedure described in the corresponding documentation, and that Product was Manufactured in accordance with Applicable Laws.

(b) **Certificate of Conformance.** In connection with delivery of any batch of Product, MannKind shall provide Sanofi with a certificate of conformance signed by an appropriately Qualified Person ("**QP**", as such term is defined under the European Union pharmaceutical regulation) or appropriately qualified quality assurance representative when the QP function does not exist, as applicable (the "**Certificate of Conformance**"). Such Certificate of Conformance shall certify with respect to each batch (identified by batch number) (i) that Product delivered conforms to Product Specifications (including that the Product is free of any viruses and/or transmissible spongiform encephalopathies), as well as any further information

required by the relevant Regulatory Authorities that Sanofi may have previously notified MannKind is necessary and (ii) that the Product batch has been Manufactured in accordance with cGMP. Sanofi shall be under no obligation to accept any shipment of Product without an accompanying Certificate of Conformance.

5.3 Acceptance and Rejection.

(a) Product Testing. Sanofi, at its expense, may from time to time, but shall have no obligation to, perform such samplings and tests that are designed, in accordance with the methods of analysis and Product Specifications, to determine whether each batch of Product shipped to Sanofi meets Product Specifications. Regardless of Sanofi's performance or absence of performance of testing, Sanofi may reject any shipment (or portion thereof) of Product if any Product fails to conform to any warranty set forth in Section 8.2 of this Agreement by providing to MannKind written notice of such rejection and the reasons therefor within 30 days of delivery of such Product; otherwise, Sanofi shall be deemed to have accepted such shipment of Product; *provided, however*, that in the case of Product having a defect that causes Product to fail to conform to any warranty set forth in Section 8.2 of this Agreement, which defect is not discoverable upon reasonable physical inspection of the shipping container (or upon any other inspection or testing that Sanofi, in its sole discretion, may decide to perform) but is discovered at a later time, Sanofi shall, once it discovers the possibility that a Product may have such a defect, notify MannKind within ten (10) days after such discovery of such possible defect.

(b) Replacement of Product and Dispute Procedure. If MannKind notifies Sanofi in writing, within thirty (30) days of MannKind's receipt of notice that Sanofi is rejecting Product, that MannKind disagrees with Sanofi's claim that the Product is defective (an "**Objection Notice**"), the following procedures shall apply. Sanofi and MannKind will review available documentation and perform re-testing of the Product as appropriate to attempt to reach agreement as to whether or not Product fails to conform to any warranty set forth in Section 8.2 of this Agreement. If Sanofi and MannKind fail within ten (10) days after delivery of the Objection Notice to agree as to whether Product is defective, representative samples of the batch of Product in question shall be submitted to a mutually-acceptable independent laboratory or consultant for analysis or review. The results of such evaluation shall be binding upon the Parties. The Parties shall share equally the cost of such evaluation except that the Party that is determined to have been incorrect in its determination of whether Product should be rejected shall assume the responsibility for, and pay, the costs of any such evaluation and reimburse the other for any amounts previously paid to the independent laboratory or consultant in connection with that determination.

(c) Cost of Replacement of Rejected Product. If any shipment of Product is rejected by Sanofi, Sanofi shall have no obligation or duty to pay any amounts payable to MannKind in respect of the rejected Product unless and until there is a determination by the independent laboratory or consultant in support of MannKind's Objection Notice in accordance with Section 5.3(b). If only a portion of a shipment is rejected, Sanofi shall have no obligation or duty to pay the amount allocable to the defective portion only.

(d) Return of Rejected Product. If a shipment or partial shipment is rejected by Sanofi pursuant to the provisions of this Section 5.3 and there is not a determination by the

independent laboratory or consultant in support of MannKind's Objection Notice in accordance with Section 5.3(c), Sanofi shall return to MannKind at MannKind's request and expense (or, at the election of MannKind, destroy at MannKind's cost and provide evidence of such destruction to MannKind) any such rejected Product. MannKind shall (i) credit the original invoice in respect of the rejected Product, and (ii) adjust the invoice to Sanofi for any Product that was not rejected, payment of which is due in accordance with the terms of the original invoice.

(e) Supply of Replacement Product. During the pendency of any rejection discussions MannKind shall use Commercially Reasonable Manufacturing Efforts to supply Sanofi with additional Product which Sanofi shall purchase on the same terms as Product that is the subject of the rejection discussions.

ARTICLE 6

MANUFACTURE OF PRODUCT

6.1 Raw Materials.

(a) Procurement. MannKind shall be responsible for obtaining, and shall store any Insulin, raw materials, components, devices, other ingredients and packaging materials required for the Manufacture of Product ("**Raw Materials**"), in reasonable quantities consistent with Sanofi's Forecasts and purchase orders. MannKind shall ensure that all Raw Materials conform to their respective specifications and are stored and handled in accordance with cGMP and the Quality Agreement. MannKind shall use Commercially Reasonable Manufacturing Efforts to procure all Raw Materials (other than Insulin) based on tiered pricing (i.e., lower prices for higher volumes). In addition, within two (2) years after the Effective Date, MannKind shall (1) identify alternative suppliers for all critical Raw Materials, and (2) use Commercially Reasonable Manufacturing Efforts to start to qualify alternative suppliers for all critical Raw Materials, in each case, for the purpose of establishing dual-sourcing and back-up supply thereof. At Sanofi's request, Sanofi and MannKind will negotiate and enter into a separate supply agreement pursuant to which Insulin and, if agreed by the Parties, other Raw Materials, would be supplied by Sanofi or its Affiliates, at Sanofi's cost (calculated in accordance with IFRS as consistently applied) for such Insulin and other Raw Materials without markup, for use in the Manufacture of Product supplied by MannKind hereunder.

(b) Insulin Restrictions. Notwithstanding any other provision of this Agreement to the contrary, MannKind agrees that it shall not, without the prior written consent of Sanofi (in its sole discretion), use in the Manufacture of any Product hereunder any Insulin that was formulated more than [...***...] years prior to the desired date of use. Without limiting the foregoing, MannKind acknowledges and agrees that [...***...].

6.2 Manufacture of Product. MannKind will Manufacture Product in accordance with Product Specifications, cGMPs and Applicable Laws. The Parties shall notify each other within three (3) Business Days of any new instructions or specifications required by Regulatory

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Authorities with jurisdiction over the Manufacture, import, export, use, marketing or sale of Product in the Field in the Territory. The Parties shall confer with each other with respect to any response regarding such instruction or specification and the best means to comply with such requirements. To the extent the instruction or specification specifically relates to the Product (as opposed to a general requirement such as cGMPs), the costs for implementing such changes will be incorporated into the Estimated COGS and actual Cost of Goods. The Manufacturing working group of the JAC shall discuss the Manufacture of Product in accordance with cGMP outside of FDA or ICH requirements, if applicable.

6.3 Packaging. MannKind shall package Product to be supplied in accordance with MannKind's standard operating procedures, which shall comply and be in accordance with Product Specifications, cGMPs and Applicable Laws.

6.4 Changes to Product Specifications or to the Manufacturing Process.

(a) A Party proposing a change to Product Specifications or the Raw Materials, equipment, process or procedures used to Manufacture Product (the "**Manufacturing Process**") shall provide written notice to the other Party. If the proposed change is required by a Regulatory Authority, then such notice shall include disclosure of the Regulatory Authority request and relevant correspondence. Any changes to Product Specifications or to the Manufacturing Process shall be in compliance with the NDA and other Marketing Approvals for Product. Each Party shall notify the other Party of any proposed change to Product Specifications or to the Manufacturing Process.

(b) Any proposed change (other than changes required by a Regulatory Authority in the Territory) shall be subjected to a cost/benefit analysis and to the approval by the JAC, it being understood and agreed that:

(i) neither Party shall be obliged to accept or implement any change where the cost of such change to that Party is greater than the benefit of such change to that Party, and

(ii) neither Party shall withhold or delay acceptance of any change where the cost of such change to that Party is nil or borne by the other Party.

(c) If the change is required by a Regulatory Authority in the Territory, then:

(i) If, at the time of such change and at all times thereafter, no other products are Manufactured at the MannKind Facility, then any expenses of implementing such change shall be paid by MannKind and subsequently reflected in the Paid Price, Estimated COGS and Cost of Goods.

(ii) If, at or after the time of such change, other products are Manufactured at the MannKind Facility, then any expenses of implementing such change shall be paid by MannKind and the relative portion thereof shall be subsequently reflected in the Paid Price, Estimated COGS and Cost of Goods. For the sake of example only, if one (1) other product is Manufactured at the MannKind Facility and utilizes one-half (1/2) of the available capacity of such facility, then one-half (1/2) of such expenses shall be subsequently reflected in

the Paid Price, Estimated COGS and Cost of Goods; however, if such other product only utilizes one-third (1/3) of the available capacity, then two-thirds (2/3) of such expenses shall be subsequently reflected in the Paid Price, Estimated COGS and Cost of Goods.

(d) For the sake of clarity, MannKind shall bear all of the expenses incurred to implement a change that is necessary to bring MannKind back into compliance with the Product Specifications or remedy any non-compliance with a prior approval from a Regulatory Authority (and, for the further sake of clarity, such expenses shall not be reflected in the Paid Price, Estimated COGS and/or Cost of Goods).

6.5 Inventory.

(a) Sanofi shall carry a reasonable quantity of inventory of Product (i.e., at least [...***...] of inventory of Product (calculated based on the amounts of Product set forth in the [...***...] of the most current Forecast)). The cost of Sanofi carrying such inventory of Product and insuring the same shall be borne by Sanofi.

(b) Commencing on the Effective Date and subject to achievement of the [...***...] Milestone, MannKind shall use Commercially Reasonable Manufacturing Efforts to build at least [...***...] months of inventory of Semi-Finished Product (calculated based on the amounts of Product set forth in the first [...***...] months of the most current Forecast and inclusive of Launch Quantities) prior to the First Commercial Sale of Product in the Field in the Territory. For the period from and after the shipment to Sanofi of the Launch Quantities, MannKind shall carry at least [...***...] months of inventory of Semi-Finished Product (calculated based on the amounts of Product set forth in the most current Binding Forecast). The cost of MannKind carrying such inventories of Product and insuring the same shall be borne by MannKind. For purposes of this Agreement, "**Semi-Finished Product**" shall mean semi-finished Product (i.e., foil-wrapped blister packs) with remaining shelf life sufficient to allow the supply of finished Product that meets the minimum remaining shelf life requirements set forth in Section 3.5.

(c) MannKind shall use Commercially Reasonable Manufacturing Efforts to maintain at least [...***...] months of inventory (calculated based on the amounts of Product set forth in the first [...***...] months of the most current Forecast) of Insulin less than [...***...] years old, unless otherwise approved by Sanofi in accordance with Section 6.1(b).

6.6 Technology Transfer.

(a) **Testing Technology/Processes.** Upon Sanofi's request, MannKind will promptly: (i) transfer to Sanofi or its Affiliate any Testing Technology/Processes and other information necessary to enable Sanofi or its Affiliate to test Product to determine if such Product complies with Product Specifications; (ii) describe to Sanofi all testing equipment reasonably necessary to enable Sanofi or its Affiliate to test Product to determine if such Product complies with Product Specifications; (iii) otherwise provide the technology transfer services described in Section 6.6(c) reasonably necessary to enable Sanofi or its Affiliate to test Product to determine if such Product complies with Product Specifications; and (iv) perform parallel testing of the same Product in order to validate that full testing capabilities have been effectively

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transferred to Sanofi. For the sake of clarity, the obligations of MannKind pursuant to this Section 6.6(a) shall renew on a jurisdiction-by-jurisdiction basis outside of the United States with respect to any subsequent testing (or re-testing) that may be required by any applicable Regulatory Authority prior to any Commercialization of the Product in each such jurisdiction.

(b) Manufacturing Technology. Upon a Trigger Event or exercise of the Sanofi Option, MannKind will: (i) transfer to Sanofi or its Affiliate any and all Manufacturing Technology necessary to enable Sanofi or its Affiliate or sublicensee to Manufacture Product in accordance with the Product Specifications and (ii) otherwise provide Sanofi or its Affiliate the technology transfer services described in Section 6.6(c) reasonably necessary to enable Sanofi or its Affiliate or sublicensee to Manufacture and supply Product in accordance with Product Specifications. At Sanofi's request, MannKind shall promptly provide to Sanofi copies of all agreements between MannKind or its Affiliates and Third Party suppliers, vendors, or distributors that relate to the supply of any Raw Materials used in or in connection with the Products in the Territory. Upon a Trigger Event or exercise of the Sanofi Option, MannKind shall promptly and reasonably cooperate to assist Sanofi in obtaining the benefits of any Third Party agreements of MannKind relating to the Products (including assisting Sanofi in identifying and contacting such Third Party suppliers, agreeing to relieve such Third Party suppliers of any exclusivity obligations to MannKind, etc.). For the sake of clarity, the costs incurred by MannKind in performing such activities (i) in the event of a Trigger Event, shall be borne by MannKind and shall not be reflected in the Paid Price, Estimated COGS and/or Cost of Goods, and shall not be considered Allowable Expenses for purposes of Exhibit B to the License Agreement and (ii) in the event of the exercise of the Sanofi Option, shall be reimbursed by Sanofi and shall be considered Allowable Expenses for purposes of Exhibit B to the License Agreement.

(c) Technology Transfer Obligations. MannKind acknowledges and agrees that the technology transfer obligations pursuant to Sections 6.6(a) and 6.6(b) shall include MannKind's obligation to provide such support, cooperation, consulting, training and assistance as is reasonably requested by Sanofi, including: (i) permitting Sanofi and its representatives to observe the testing and Manufacture of the Products at the MannKind Facility, (ii) providing reasonable access to and consultation with MannKind personnel and consultants knowledgeable about, trained and experienced in the testing and Manufacture of Product, (iii) providing, organizing, explaining and interpreting any and all Product testing and/or manufacturing documentation, including, but not limited to, all Testing Technology/Processes and Manufacturing Technology; (iv) assisting and training Sanofi and its representatives how to select, design, configure, procure, produce, assemble, test, qualify, validate, calibrate, maintain, and operate the testing and Manufacturing processes, equipment and lines for testing and manufacturing the Products, or otherwise establish testing and Manufacturing operations at the Sanofi Site; (v) teaching Sanofi and its representatives about the MannKind Technology and its use in connection with the testing and Manufacturing of Products; and (vi) providing reasonable assistance to Sanofi in identifying, contacting and securing supply sources for Insulin and other Raw Materials.

6.7 Manufacturing Rights.

(a) MannKind acknowledges that the avoidance of shortfalls in the supply of Product in accordance with the purchase orders provided by Sanofi in accordance with the terms of this Agreement (i.e., on-time delivery in full) is critical and of the essence. Subject to Section 14.1, in the event MannKind anticipates that it will be unable to timely supply to Sanofi, in whole or in part for any month of the Forecast, all Product requested for any reason (except to the extent knowingly caused by Sanofi), then MannKind shall promptly notify Sanofi in writing of such shortage, or potential shortage, or inability to timely supply Product and, if possible, the date when MannKind will again be able to supply Product. MannKind will use Commercially Reasonable Manufacturing Efforts to remedy any shortfall of Product as soon as practicable.

(b) If, at any time during the Term, (A) MannKind notifies Sanofi under Section 6.6(a) that it is or will be unable to supply sufficient quantities of Product to meet the Forecasts provided by Sanofi for a period of three (3) consecutive months or longer, (B) MannKind has delivered over the immediately preceding twelve (12) months in aggregate less than ninety-five percent (95%) of the amount of Product specified in purchase orders provided and accepted in accordance with this Agreement by the specified delivery dates, (C) an arbitration panel determines in accordance with Section 12.2 that MannKind has committed an uncured material breach of this Agreement; or (D) MannKind files for protection under bankruptcy or insolvency laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver, administrator, manager, trustee or like official over its property that is not discharged within ninety (90) days, proposes a written agreement of composition or extension of its debts, is a party to any dissolution, winding-up or liquidation or has any bankruptcy or insolvency petition filed against it which involuntary petition is not discharged within sixty (60) days of the filing thereof or undergoes or suffers any analogous event or process in any jurisdiction (each of (A) through (D), a “**Trigger Event**”), then, in each case, in addition to all other remedies available to Sanofi under this Agreement, MannKind shall promptly, at Sanofi’s option: (i) select a Third Party contract manufacturer reasonably acceptable to Sanofi, and establish at its own cost the capability of such Third Party contract manufacturer to supply adequate quantities of Product to Sanofi on behalf of MannKind, or (ii) allow Sanofi or its Affiliates or sublicensees to Manufacture Product in the Territory solely for use and sale in the Field in the Territory under the Manufacturing Technology, in order to satisfy Sanofi’s and its Affiliates’ and sublicensees’ requirements of Product (the “**Manufacturing Rights**”). MannKind shall provide Sanofi with written notice of its ability to recommence Manufacturing and supplying Sanofi with its requirements of Product no less than six (6) months in advance, and the Parties shall discuss in good faith the conditions under which the Third Party contract manufacturer, or Sanofi as the case may be, shall continue to Manufacture certain quantities of the Product in order to maintain Product Manufacturing expertise. For the sake of clarity, MannKind shall solely bear one-hundred percent (100%) of all costs and expenses incurred by MannKind and/or Sanofi in connection with the establishment of the replacement source(s) of supply and associated supply chain described in this Section 6.7(b) (and such costs and expenses shall not be reflected in the Paid Price, Estimated COGS and Cost of Goods), but MannKind shall not be responsible for costs that would otherwise be included in Cost of Goods or for any capital expenditures incurred by Sanofi, its Affiliates, its sublicensees or Third Parties in connection with the establishment of alternate Manufacturing locations under this Section 6.7(b).

(c) Notwithstanding any other provision of this Agreement to the contrary and without limiting MannKind's performance of its obligations pursuant to this Agreement (including Section 6.7(b)), if MannKind fails to deliver at least ninety-five percent (95%) of Sanofi's deliveries by or within ten (10) days after the delivery date specified on the applicable purchase order, subject to the tolerances set forth in Section 3.4 (the "**Grace Period**"), then, in each case, unless otherwise agreed by Sanofi in writing, MannKind shall pay Sanofi liquidated damages in an amount equal to one-half of one percent (0.5%) of the amounts due per unit of Product that MannKind failed to deliver for each day after the Grace Period that such delivery is delayed (up to a maximum of ten percent (10%)).

ARTICLE 7

REGULATORY

7.1 Regulatory Compliance. MannKind shall comply with all regulatory requirements with respect to Product imposed by Applicable Laws upon MannKind as the Manufacturer of Product. MannKind shall also provide, upon request by Sanofi, information concerning its production processes and quality control procedures with respect to Product. MannKind acknowledges and agrees that (a) it is MannKind's sole responsibility and obligation to obtain and maintain all drug or device master files relating to Product in the United States; (b) it is MannKind's sole responsibility and obligation to use Commercially Reasonable Manufacturing Efforts to obtain all drug or device master files relating to Product for each relevant jurisdiction in the Territory other than the United States, and (c) it is MannKind's sole responsibility and obligation to maintain all obtained drug or device master files relating to Product for each relevant jurisdiction in the Territory other than the United States. MannKind represents and warrants that at the time of Manufacture of Product, the MannKind Facility shall have all approvals required from the FDA or any other Regulatory Authority or otherwise required by Applicable Laws. If MannKind receives a notice or request from the FDA or any other Regulatory Authority relating to the Manufacture of Product, then MannKind shall promptly (and in any event within five (5) business days of receipt of such notice or request) provide a copy of such notice or request to Sanofi. MannKind shall provide Sanofi with a copy of any response or other communication of MannKind to the FDA or any other Regulatory Authority and shall take into account any reasonable requests of Sanofi with respect to revisions or changes thereto.

7.2 FDA and Regulatory Support. MannKind will provide Sanofi and its Affiliates with necessary information and data regarding the Manufacture of Product to the extent necessary for Sanofi and its Affiliates to prepare and defend any inquiries from the FDA or other Regulatory Authorities to satisfy regulatory requirements with respect to Product in the Territory.

7.3 Regulatory Authorities' Right of Inspection. MannKind shall permit authorized officials of any Regulatory Authorities or other competent Governmental Authority to inspect its facilities, including the equipment used in the Manufacturing, testing, and shipping or receiving of Product, as required or necessary for the granting or maintaining of any Marketing Approval or compliance with Applicable Law. Prior to any such inspection, MannKind shall

notify Sanofi and Sanofi shall have the right to have its representatives present during such inspections.

7.4 cGMP Compliance and QA Audits. Upon no less than sixty (60) days' advance written notice to MannKind, Sanofi shall have the right to have representatives visit the MannKind Facility and any other locations at which any Manufacturing activities are undertaken, in each case, during normal business hours to discuss any related issues with MannKind's Manufacturing and management personnel and to review and inspect (a) MannKind's Manufacturing and storage facilities, (b) the quality control procedures, and/or (c) any records and reports pertinent to the Manufacture, disposition or transport of Product as may be necessary to evidence MannKind's compliance with all applicable Marketing Approvals for the Manufacture of Product, including compliance with cGMP. Such visits shall occur no more than once per year, except in the case of audits by Sanofi that are required by Applicable Laws, and except that additional visit(s) may occur in the event of shortages, significant deviations, quality problems or recalls requiring resolution by the Parties. Sanofi shall also have the right to be present at audits and inspections conducted by MannKind of its Third Party manufacturer(s) and Raw Materials suppliers, and MannKind shall give Sanofi thirty (30) days' notice of such audits and inspections. Sanofi representatives will be advised of the confidentiality obligations of Sanofi under this Agreement and will follow such security, safety and facility access procedures as are reasonably designated by MannKind and its Third Party manufacturer(s) and suppliers, as applicable. MannKind shall provide to Sanofi any audit reports generated by or prepared for MannKind in the conduct of any inspections or audits, which reports shall be deemed Confidential Information of MannKind. Each Party's costs in conducting inspections or audits under this Section 7.4 shall be borne by the respective Party and shall be considered Allowable Expenses for purposes of Exhibit B to the License Agreement.

7.5 Recall of Product. For any Product, in the event that: (a) any Regulatory Authority in the Territory issues a request, directive or order that Product be recalled or retrieved; (b) a court of competent jurisdiction orders that Product be recalled or retrieved; or (c) Sanofi reasonably determines, after reasonable, good faith discussion with MannKind, that Product should be recalled or retrieved, Sanofi shall promptly notify MannKind of such event (to the extent time allows) and shall conduct such activity and take appropriate corrective actions, and MannKind shall provide such assistance to Sanofi as is reasonably necessary to carry out such activities. All reasonable costs and expenses of such recall and corrective actions shall be equitably allocated between the Parties taking into account the relative fault of Sanofi and the relative fault of MannKind.

7.6 Compliance with Laws. MannKind shall comply with all Applicable Laws in performing its obligations under this Agreement. MannKind represents and warrants to Sanofi that it has and will maintain during the Term all government permits, including, health, safety and environmental permits, necessary for the conduct of the actions and procedures that it undertakes pursuant to the Agreement.

7.7 Documentation. MannKind shall keep complete, accurate and authentic accounts, notes, data and records of the work performed under this Agreement (including batch records) and shall maintain complete and adequate records pertaining to the methods and facilities used for the Manufacture, processing, testing, packing, labeling, holding and

distribution of a Product in accordance with Applicable Laws so that such Product may be used in humans.

7.8 Samples. MannKind shall retain samples of each batch of Product for a period equal to the Product shelf life plus one (1) year (or, if longer, the minimum period required by Applicable Law) after Sanofi's acceptance of such Product.

ARTICLE 8

REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party, as of the Effective Date, as follows:

(a) Duly Organized. Such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent such Party from performing its obligations under this Agreement.

(b) Due Authorization; Binding Agreement. The execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary corporate action. This Agreement is a legal and valid obligation binding on such Party and enforceable in accordance with its terms and does not: (i) violate any law, rule, regulation, order, writ, judgment, decree, determination or award of any court, governmental body or administrative or other agency having jurisdiction over such Party; nor (ii) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which such Party is a party or by which it is bound.

(c) Consents. Such Party has obtained, or is not required to obtain, the consent, approval, order or authorization of any Third Party, or has completed, or is not required to complete any registration, qualification, designation, declaration, or filing with, any Regulatory Authority or governmental authority, in connection with the execution and delivery of this Agreement and the performance by such Party of its obligations under this Agreement.

(d) No Conflicting Grant of Rights. Such Party has the right to grant the licenses and rights as contemplated under this Agreement and has not, and will not during the Term, grant any right to any Third Party which would conflict with the licenses and rights granted to the other Party hereunder.

8.2 Product Warranty. MannKind represents and warrants that Product delivered hereunder will (a) be Manufactured by MannKind in accordance with all applicable Marketing Approvals, cGMPs and other Applicable Laws, (b) conform to Product Specifications at the time of delivery, (c) not be adulterated or mislabeled under Applicable Laws, (d) at the time of delivery, be free and clear of any lien or encumbrance, (e) be supplied in accordance and compliance with the Quality Agreement, and (f) meet quality and purity characteristics that it purports or is represented to possess through its assigned expiry date. Sanofi's remedies and MannKind's liability with respect to this warranty are set forth in Section 5.3 and as otherwise

expressly set forth in this Agreement. In no event shall any failure to comply with any representation or warranty in this Section 8.2 that is caused by or results from any failure of Insulin supplied by Sanofi or its Affiliate to conform to any representations and warranties in the supply agreement for such Insulin, including the failure of such Insulin to conform to the specifications therefor, be deemed a breach of these representations and warranties or entitle Sanofi to any remedy or subject MannKind to any liability under this Agreement.

8.3 No Debarred or Disqualified Persons. MannKind represents and warrants that it shall not employ, contract with, or retain any person directly or indirectly to perform any services under this Agreement if such a person (a) is under investigation by the FDA for debarment or is presently debarred by the FDA pursuant to 21 U.S.C. § 335a or its successor provisions or by the applicable Regulatory Authority in any country or jurisdiction in the Territory outside the United States under comparable regulations, or (b) has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 C.F.R. § 312.70 or its successor provisions or by the applicable Regulatory Authority in any country or jurisdiction in the Territory outside the United States under comparable regulations. In addition, MannKind represents and warrants that it has not engaged in any conduct or activity which could lead to any of the above-mentioned disqualification or debarment actions. If, during the Term, MannKind or any person employed or retained by it to perform under this Agreement (i) comes under investigation by the FDA or by the applicable Regulatory Authority in any country or jurisdiction in the Territory outside the United States for a debarment action or disqualification, (ii) is debarred or disqualified, or (iii) engages in any conduct or activity that could lead to any of the above-mentioned disqualification or debarment actions, MannKind shall immediately notify Sanofi of same.

8.4 Insulin Supply. MannKind represents and warrants that it has provided Sanofi with a true and complete (except with respect to redactions of confidential information) copy of MannKind's binding and enforceable supply agreement for purchase of Insulin from Amphastar (the "**Amphastar API Supply Agreement**"). MannKind shall not, without the prior written approval of Sanofi (in its sole discretion), terminate, amend or otherwise modify the Amphastar API Supply Agreement in any manner that would reasonably be expected to result in the decrease (annually or in the aggregate) in the amount of Insulin supplied to MannKind thereunder.

8.5 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT OR THE LICENSE AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT, VALIDITY AND ENFORCEABILITY OF PATENTS, OR THE PROSPECTS OR LIKELIHOOD OF DEVELOPMENT OR COMMERCIAL SUCCESS OF PRODUCT.

8.6 Limitation of Liability. EXCEPT FOR LIABILITY FOR PAYMENTS IN ACCORDANCE WITH ARTICLE 4 AND LIABILITY FOR BREACH OF ARTICLE 9, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN

CONNECTION WITH THIS AGREEMENT OR ANY LICENSE OR RIGHT GRANTED HEREUNDER; *provided, however*, that this Section 8.6 shall not be construed to limit either Party's indemnification obligations with respect to Third Party Claims under Article 11.

ARTICLE 9

CONFIDENTIALITY

Confidential Information shall be treated in accordance with Article 8 of the License Agreement.

ARTICLE 10

TERM AND TERMINATION

10.1 Term. This Agreement shall commence on the Effective Date and shall continue until the expiration or termination of the License Agreement in its entirety unless this Agreement is terminated earlier pursuant to Section 10.2 (the "**Term**").

10.2 Early Termination. The Parties may terminate this Agreement in its entirety before the end of the Term as follows:

(a) by mutual written agreement of the Parties; or

(b) upon written notice to the other Party if such other Party is in material breach of this Agreement and has not cured such breach within ninety (90) days (forty-five (45) days with respect to any payment breach) after notice from the terminating Party requesting cure of the breach. Any such termination shall become effective at the end of such ninety (90) day (forty-five (45) days with respect to any payment breach) period unless the breaching Party has cured any such breach or default prior to the end of such period.

10.3 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein.

10.4 Effect of Expiration or Termination; Surviving Obligations.

(a) **Effect of Termination.** Upon termination or expiration of this Agreement all rights and obligations of the Parties under this Agreement shall terminate.

(b) **Return of Confidential Information.** Within thirty (30) days following the expiration or termination of this Agreement, each Party shall deliver to the other Party any and all Confidential Information of such Party then in its possession, except for one copy which may be kept in such Party's counsel's office for archival purposes and except to the extent a Party retains the right to use such Confidential Information pursuant to any license granted under the License Agreement which survives termination or expiration of the License Agreement, as applicable.

(c) Survival. Expiration or termination of this Agreement shall not relieve the Parties of any rights or obligation accruing prior to such expiration or termination. In addition, upon expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall terminate, except those described in the following Articles and Sections: Articles 1, 9, 12 and 14 and Sections 4.2, 4.4, 7.7, 7.8, 8.5, 8.6, 10.3, 10.4, 11.1, 11.2 and 11.3, which sections and Articles shall survive in accordance with their terms.

10.5 Exercise of Right to Terminate. The rightful use by either Party hereto of a termination right provided for under this Agreement shall not, in itself, give rise to the payment of damages or any other form of compensation or relief to the other Party with respect thereto.

10.6 Damages; Relief. Subject to Section 10.5 above, termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to upon such termination.

10.7 Rights Upon Bankruptcy. The Parties acknowledge and agree that for purposes of the Bankruptcy Laws, this Agreement and the License Agreement shall be deemed to be one integrated whole agreement and shall therefore be subject to the provisions of Section 13.4 of the License Agreement, which is incorporated herein by reference.

ARTICLE 11

INDEMNIFICATION

11.1 Indemnification of MannKind. Sanofi shall indemnify and hold harmless each of MannKind and its Affiliates and the directors, officers, shareholders and employees of such entities and the successors and assigns of any of the foregoing (the “**MannKind Indemnitees**”), from and against any and all losses, liabilities, damages, penalties, fines, costs and expenses (including reasonable attorneys’ fees and other expenses of litigation) (“**Losses**”) from any claims, actions, suits or proceedings brought by a Third Party (“**Third Party Claims**”) incurred by any MannKind Indemnatee, arising from, or occurring as a result of: (a) gross negligence or willful misconduct in connection with Sanofi’s performance of its obligations or exercise of its rights under this Agreement; or (b) any material breach of any representations, warranties or covenants by Sanofi under this Agreement, except to the extent such Third Party Claims fall within the scope of the indemnification obligations of MannKind set forth in Section 11.2.

11.2 Indemnification of Sanofi. MannKind shall indemnify and hold harmless each of Sanofi and its Affiliates and the directors, officers and employees of such entities and the successors and assigns of any of the foregoing (the “**Sanofi Indemnitees**”), from and against any and all Losses from any Third Party Claims incurred by any Sanofi Indemnatee, arising from, or occurring as a result of: (a) gross negligence or willful misconduct in connection with MannKind’s performance of its obligations or exercise of its rights under this Agreement; or (b) any material breach of any representations, warranties or covenants (including a failure to timely supply all required quantities ordered in accordance with the terms of this Agreement) by MannKind under this Agreement, except to the extent such Third Party Claims fall within the scope of the indemnification obligations of Sanofi set forth in Section 11.1.

11.3 Procedure. Any of the MannKind Indemnitees or Sanofi Indemnitees, as applicable, that intends to claim indemnification under this Article 11 (the “**Indemnitee**”) shall promptly notify the indemnifying Party (the “**Indemnitor**”) in writing of any Third Party Claim, in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense and/or settlement thereof. The indemnity arrangement in this Article 11 shall not apply to amounts paid in settlement of any action with respect to a Third Party Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 11 if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by this indemnification.

11.4 Insurance. Each Party, at its own expense, shall maintain appropriate general liability insurance and product liability insurance with respect to its activities under this Agreement in an amount consistent with industry standards during the Term. MannKind agrees that Sanofi may satisfy its obligations under this Section 11.4 through self-insurance.

ARTICLE 12

DISPUTE RESOLUTION AND GOVERNING LAW

12.1 Disputes. In the event of any dispute arising out of or relating to this Agreement or either Party’s rights or obligations hereunder, except as otherwise provided in this Agreement, the Party wishing to invoke dispute resolution proceedings shall send to the other Party, in accordance with the notice provisions set forth in Section 14.8, a written notice of dispute indicating that such notifying Party wishes to invoke such negotiations pursuant to this Section 12.1 and that sets out in reasonable detail the claims asserted, the nature of the dispute, any facts that are or are not in dispute, and the intended treatment and effect of such pending dispute (“**Notice of Dispute**”). The Parties shall, through their respective executive officers, first meet and attempt to resolve the dispute in face-to-face negotiations. Unless otherwise agreed in writing by the Parties, this meeting shall occur within fifteen (15) days after either Party provides such notice of dispute to the other Party. If the Parties are unable to resolve such dispute through such negotiations within the earlier of (x) sixty (60) days after the meeting referenced in this Section 12.1 or (y) sixty (60) days after receipt of the Notice of Dispute (or such longer period agreed in writing by the Parties) (“**Arbitration Deadline**”), then, except in the case of a dispute, controversy or claim that concerns (a) the validity or infringement of a patent, trademark or copyright, or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory, the dispute shall be resolved by binding arbitration in accordance with Section 12.2.

12.2 Arbitration. Any disputes to be resolved by binding arbitration pursuant to Section 12.1 shall be resolved in accordance with the rules of conciliation and arbitration of the International Chamber of Commerce of Paris by a panel of three (3) independent and neutral experienced arbitrators, one (1) chosen by MannKind, one (1) chosen by Sanofi, and the third (3rd) chosen by the foregoing two (2) arbitrators (with such third acting as the chairperson of the panel). The place of arbitration shall be New York, New York. Any arbitration shall be

conducted in the English language and the arbitrators shall use the governing law provided for in Section 12.4. The arbitration panel shall issue its decision and award by reasoned, written decision within one (1) year after appointment of the chairperson of the arbitration panel. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Except to the extent necessary to confirm or enforce an award or as may be required by law, neither a Party nor any arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both MannKind and Sanofi. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations. Each Party shall bear its own attorneys' fees, costs and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators; *provided, however*, that the arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for the fees and costs of the arbitrators. Each Party agrees to fully perform and satisfy any arbitration award made against it within fifteen (15) days of the service of the award. The taking of evidence in the arbitration shall be guided by the International Bar Association's 2010 Rules on the Taking of Evidence in International Commercial Arbitration ("**IBA Guidelines on Evidence**"); *provided, however*, that the arbitrators shall permit such pre-hearing discovery and such presentation of evidence at any Evidentiary Hearing (as defined in the IBA Guidelines on Evidence) as, in each case, is reasonably necessary for a full and fair understanding and resolution of any legitimate issue raised in the arbitration. The arbitration panel shall ensure that document disclosures are conducted on a timely basis. By agreeing to this binding arbitration provision, the Parties understand that they are waiving certain rights and protections which may otherwise be available if a dispute between the Parties were determined by litigation in court, including the right to seek or obtain certain types of damages precluded by this provision, the right to a jury trial, certain rights of appeal and a right to invoke formal rules of procedure and evidence. For the sake of clarity, any disputes that arise under both this Agreement and the License Agreement may be consolidated in a single arbitration. Any settlement discussions or arbitration proceedings occurring under this Agreement shall be conducted in strict confidence. Except as necessary to enforce an award or as required by law, no information or documents produced, generated or exchanged in connection with settlement discussions or arbitration proceedings (including any award(s) that might be rendered by the arbitration panel) shall be disclosed to any person other than counsel without the prior written consent of all Parties to the settlement or arbitration proceedings. This restriction shall not apply to public records or other documents obtained by the Parties in the normal course of business independent of any settlement discussions or arbitration proceedings.

12.3 Court Actions. Nothing contained in this Agreement shall deny either Party the right to seek, upon good cause, injunctive or other equitable relief from a court of competent jurisdiction in the context of an emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing dispute resolution discussions or arbitration proceedings.

12.4 Governing Law. This Agreement, and all questions regarding the existence, validity, interpretation, breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles with the exception of sections 5-1401 and 5-

ARTICLE 13

INSULIN PUT OPTION

For purposes of this Article 13, the following terms shall have the following meanings:

“[...***...] *Insulin*” means (i) [...***...], and (ii) [...***...].

“*Put Closing Date(s)*” means the date(s) that occur (i) thirty (30) days following delivery of the Insulin Exercise Notice by MannKind for [...***...] Insulin [...***...], and, if applicable, (ii) thirty (30) days following [...***...].

13.1 If this Agreement expires or terminates because the License Agreement is terminated by MannKind pursuant to Section 12.2 or 12.4 thereof, or by Sanofi pursuant to Section 12.3(a) thereof, MannKind shall have the option (the “*Insulin Put Option*”), exercisable by providing written notice (the “*Insulin Exercise Notice*”) to Sanofi within thirty (30) days following the effective date of such expiration or termination, to sell to Sanofi, and if such option is exercised by MannKind, Sanofi shall purchase, the lesser of (i) 65% of each lot of [...***...] Insulin, at the [...***...] (“*Insulin Price*”) and (ii) such equal percentage of each lot of [...***...] Insulin representing an Insulin Price of US\$50 million in the aggregate, at the Insulin Price. For the avoidance of doubt, in no event shall the aggregate Insulin Price payable by Sanofi pursuant to MannKind’s exercise of the Insulin Put Option exceed US\$50 million.

13.2 The closing of the transactions contemplated above shall occur on each Put Closing Date. The sale shall be Ex Works (INCOTERMS 2010) and upon each Put Closing Date MannKind shall make the purchased Insulin available to Sanofi at the location at which it is stored.

ARTICLE 14

GENERAL PROVISIONS

14.1 Intervening Events. If the performance of any part of this Agreement by either Party (other than making payment when due) is prevented, restricted, interfered with or delayed by any reason or cause beyond the reasonable control of such Party (including: fire, flood, embargo, power shortage or failure, acts of war, insurrection, riot, terrorism, strike, lockout or

***Confidential Treatment Requested

other labor disturbance (save where such strike, lockout, or other labor disturbance is initiated by the employees of the Party which seeks to rely on this clause), acts of God or any acts, omissions or delays in acting of the other Party) (an “**Intervening Event**”), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such Intervening Event, provided that the affected Party shall use its substantial efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. If either Party becomes aware that such an Intervening Event has occurred, is imminent or likely, it will immediately notify the other Party. The Party which is subject to such Intervening Event shall exert all reasonable efforts to overcome it. Such Party will keep the other informed as to the progress of overcoming such Intervening Event.

14.2 Waiver of Breach. The failure of either Party at any time or times to require performance of any provision of this Agreement shall in no manner affect its rights at a later time to enforce such rights. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

14.3 Performance by Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligation. Either Party may use one or more of its Affiliates to perform its obligation hereunder, provided that the Parties will remain liable hereunder for the prompt payment and performance of all their respective obligations hereunder.

14.4 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in a prior writing signed by both Parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by both Parties hereto.

14.5 Severability. In the event any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate, in good faith and enter into a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties. All other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

14.6 Entire Agreement. This Agreement (including the Schedules attached hereto and any letter delivering information referenced herein) and the License Agreement (including the Exhibits attached thereto) constitute the entire agreement between the Parties relating to the subject matter hereof and thereof and supersede and cancel all previous express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof and thereof. Each of the Parties acknowledges and agrees that in entering into this Agreement, and the documents referred to in it, it does not rely on, and shall have no remedy in respect of, any statement, representation, warranty or understanding (whether negligently or innocently made) of any Person (whether party to this Agreement or not)

other than as expressly set out in this Agreement or the License Agreement. Nothing in this clause shall, however, operate to limit or exclude any liability for fraud.

14.7 Language. The language of this Agreement and all activities to be pursued under this Agreement is English. Any and all documents proffered by one Party to the other in fulfillment of any provision of this Agreement shall only be in compliance if in English. Any translation of this Agreement in another language shall be deemed for convenience only and shall never prevail over the original English version. This Agreement is established in the English language.

14.8 Notices. Any notice or communication required or permitted under this Agreement shall be in writing in the English language, delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by internationally-recognized courier or sent by registered or certified mail, postage prepaid to the following addresses of the Parties (or such other address for a Party as may be at any time thereafter specified by like notice):

To MannKind:

MannKind Corporation
28903 North Avenue Paine
Valencia, California 91355 USA
Telephone: (661) 775-5300
Facsimile: (661) 775-2086
Attention: General Counsel

To Sanofi:

Sanofi
c/o Genzyme
500 Kendall Street
Cambridge, MA 02142
Telephone: +1 617 768 6527
Facsimile: +1 617 252 7600.
Attention: Vice President, Corporate
Business Development

with a copy to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
Telephone: (858) 550-6000
Facsimile: (858) 550-6420
Attention: L. Kay Chandler, Esq.

with a copy to:

Sanofi
54 Rue La Boétie, 75008
Paris, France
Telephone: +33 1 53 77 90 24
Facsimile: +33 1 53 77 43 03
Attention: General Counsel

Any such notice shall be deemed to have been given: (a) when delivered if personally delivered; (b) on the next Business Day after dispatch if sent by confirmed facsimile or by internationally-recognized overnight courier; and/or (c) on the third Business Day following the date of mailing if sent by mail or nationally recognized courier. Notices hereunder will not be deemed sufficient if provided only between or among each Party's representatives on the JAC.

14.9 Assignment. This Agreement shall not be assignable, pledged or otherwise transferred, nor may any right or obligations hereunder be assigned, pledged or transferred, by

either Party to any Third Party without the prior written consent of the other Party, which consent, in the event of a financing transaction by the Party asking for consent, shall not be unreasonably withheld, conditioned or delayed by the other Party; except either Party may assign or otherwise transfer this Agreement without the consent of the other Party to an entity that acquires all or substantially all of the business or assets of the assigning Party relating to the subject matter of this Agreement, whether by merger, acquisition or otherwise; provided that intellectual property rights that are owned or held by the acquiring Person to such transaction (if other than one of the Parties to this Agreement) shall not be included in the technology licensed hereunder. In addition, either Party shall have the right to assign or otherwise transfer this Agreement to an Affiliate upon written notice to the non-assigning Party; *provided, however*, the assigning or transferring Party shall continue to remain liable for the performance of this Agreement by such Affiliate, and, prior to the Effective Date, Sanofi may assign this Agreement to any Affiliate. Nothing herein shall be deemed to prohibit MannKind or any of its Affiliates from granting a security interest in this Agreement and any rights hereunder to any Third Party in connection with any financing transaction to the extent provided under (and subject to the restrictions on the rights of secured parties contained in) Sections 9-406 and 9-408 of the New York Uniform Commercial Code. In addition, MannKind or any Affiliate of MannKind shall have the right to sell, assign, pledge or otherwise transfer any accounts and payment intangibles (each as defined under the New York Uniform Commercial Code but including, for the avoidance of doubt, rights to payment of MannKind pursuant to Articles 4 and 13) in connection with any financing transaction. Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns. Any assignment of this Agreement in contravention of this Section 14.9 shall be null and void.

14.10 No Partnership or Joint Venture. Nothing in this Agreement or any action which may be taken pursuant to its terms is intended, or shall be deemed, to establish a joint venture or partnership between Sanofi and MannKind. Neither Party to this Agreement shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

14.11 Interpretation. The captions to the several Articles and Sections of this Agreement are not a part of this Agreement but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression; (b) the word “or” means “and/or” unless the context dictates otherwise because the subjects of the conjunction are mutually exclusive; (c) the words “herein,” “hereof” and “hereunder” and other words of similar import refer to this Agreement as a whole and not to any particular Article or Section or other subdivision; (d) references in this Agreement to “days” shall mean calendar days; (e) the singular shall include the plural and vice versa; and (f) masculine, feminine and neuter pronouns and expressions shall be interchangeable. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under IFRS, or if not defined by IFRS, the meaning applied to it by Sanofi in preparing its publicly reported financial statements, in each case, consistently applied, but only to the extent consistent with its usage and the other definitions in this Agreement.

14.12 Counterparts; Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

14.13 MannKind Third Party Manufacturer. The Parties acknowledge and agree that MannKind may, with the prior written approval of Sanofi (such approval not to be unreasonably withheld, conditioned or delayed), use Third Party manufacturers to Manufacture and supply Product under this Agreement and that the terms “MannKind shall” or “MannKind will” or the like, shall be deemed to be followed by the words “or MannKind’s designated Third Party manufacturer will” or “or “MannKind’s designated Third Party manufacturer shall” or “MannKind shall require that its designated Third Party manufacturer shall” or the like, with respect to MannKind’s Manufacturing and supply obligations herein. For the avoidance of doubt, no Third Party Manufacturing (other than Third Party Manufacturing as described in the Regulatory Filing on the Execution Date) shall be deemed to have been agreed upon by Sanofi by the sole virtue of this Article, and any additional Third Party manufacturer shall be subjected to the rules as set forth in the remainder of this Agreement, and the Quality Agreement. In the event that MannKind uses Third Party manufacturers to Manufacture and supply Product under this Agreement, MannKind shall be responsible for the performance of this Agreement by such Third Party manufacturers.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have executed this Supply Agreement as of the Execution Date.

SANOFI-AVENTIS DEUTSCHLAND GMBH

By: /s/ Siregar
Name: Siregar
Title: VP HR Sanofi Germany

By: /s/ ppa. Bergmann
Name: Bergmann
Title: Head of Finance

[SIGNATURE PAGE TO SUPPLY AGREEMENT]

IN WITNESS WHEREOF, the Parties have executed this Supply Agreement as of the Execution Date.

MANKIND CORPORATION

By: /s/ Matthew J. Pfeffer
Name: Matthew J. Pfeffer
Title: CFO

[SIGNATURE PAGE TO SUPPLY AGREEMENT]

SCHEDULE A

ESTIMATED COGS

(From the Effective Date until December 31, 2015)

Estimated Annual Volume (total cartridges, in millions)	Cost in US\$ per thousand cartridges for all such cartridges			
	4U cartridges	8U cartridges	12U cartridges	16U cartridges
Less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]

Notes:

In Calendar Year 2015, the Estimated COGS assumes [...***...] per gram Insulin.

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SCHEDULE B

COGS CAP

For purposes of determining Paid Price, the COGS Cap for a specified dosage strength shall be the sum of (i) the cost of Insulin, which is determined by multiplying the weighted average price of Insulin in US Dollars per gram (as specified in Section 4.1(b)(i)) for the applicable Calendar Year by the yield and potency factor set forth in Table B-1; and (ii) the corresponding amount set forth in Table B-2 contained in the volume band corresponding to the Estimated Annual Volume.

For purposes of determining Cumulative COGS, the COGS Cap shall be the aggregate sum for all dosage strengths of (i) the cost of Insulin, which is determined by multiplying the weighted average price of Insulin in US Dollars per gram (as specified in Section 4.1(b)(i)) for the applicable Calendar Year by the yield factors set forth in Table B-1; and (ii) the corresponding amounts set forth in Table B-2 contained in the volume band corresponding to the actual total volume of cartridges for the applicable Calendar Year.

Table B-1:

	Insulin cost per thousand cartridges for all such cartridges			
	4U cartridges	8U cartridges	12U cartridges	16U cartridges
At all volumes	Insulin Price x [...***...]	Insulin Price x [...***...]	Insulin Price x [...***...]	Insulin Price x [...***...]

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Table B-2

If Sanofi terminates this Agreement pursuant to Section 10.2(b) hereof, or the License Agreement pursuant to Section 12.2(a) or (b) thereof, the applicable annual volume used in computation of the COGS Cap shall be equal to the actual volume for such portion of the applicable Calendar Year divided by the number of days elapsed in the applicable Calendar Year prior to the effective date of such termination multiplied by 365.

Annual volume (total cartridges for all dosages, in millions)*	Maximum cost, not including Insulin, in \$US per thousand cartridges for all such cartridges			
	4U	8U	12U	16U
Less than [...***...] million	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]
Equal to or greater than [...***...] but less than [...***...]	[...***...]	[...***...]	[...***...]	[...***...]

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* For the avoidance of doubt, any Product which is ordered by Sanofi in accordance with the terms of this Agreement but not delivered by MannKind in a timely fashion (for whatever reason) shall be included for purposes of calculating the annual volume of cartridges.

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SCHEDULE C

SAMPLE COGS CALCULATIONS

Example 1. Determining Insulin cost

	Insulin cost per thousand cartridges for all such cartridges			
	4U cartridges	8U cartridges	12U cartridges	16U cartridges
At all volumes	Insulin Price x [...***...]	Insulin Price x [...***...]	Insulin Price x [...***...]	Insulin Price x [...***...]
Weighted average Insulin price of \$[...***...] per gram	\$ [...***...]	\$ [...***...]	\$ [...***...]	\$ [...***...]
Weighted average Insulin price of \$[...***...] per gram (i.e., [...***...])	\$ [...***...]	\$ [...***...]	\$ [...***...]	\$ [...***...]
Weighted average Insulin price of \$[...***...] per gram (i.e., [...***...])	\$ [...***...]	\$ [...***...]	\$ [...***...]	\$ [...***...]

Example 2 Determining the COGS Cap for purposes of Paid Price:

Estimated Annual Volume = [...***...]

Weighted average Insulin price: \$ [...***...]

For 4U cartridges: \$ [...***...] (per thousand)

For 8U cartridges: \$ [...***...] (per thousand)

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Example 3. Determining the COGS Cap for purposes of Cumulative COGS

Actual total volume = [...***...], of which [...***...] were 4U and [...***...] were 8U.

Weighted average Insulin price: \$ [...***...]

For 4U cartridges: \$ [...***...] (per thousand)
 \$ [...***...]

For 8U cartridges: \$ [...***...] (per thousand)
 \$ [...***...]

Cumulative COGS cannot exceed \$ [...***...].

Example 4. True-Up

Actual total volume = [...***...], of which [...***...] were 4U and [...***...] were 8U.

Weighted average insulin price: \$ [...***...]

Cumulative COGS Cap: \$ [...***...] (from Example 3)

A. If Cumulative COGS < Cumulative Price Paid

For 4U Cartridges (per thousand):
Price Paid: \$ [...***...]
Actual COGS: \$ [...***...]

For 8U Cartridges (per thousand):
Price Paid: \$ [...***...]
Actual COGS: \$ [...***...]

Cumulative Price Paid: \$ [...***...]

Cumulative COGS = \$ [...***...] (< Cumulative COGS Cap of \$ [...***...])

MannKind True-Up Payment to Sanofi: \$ [...***...]

B. Cumulative Price Paid < Cumulative COGS < COGS Cap

For 4U Cartridges (per thousand):
Price Paid: \$ [...***...]
Actual COGS: \$ [...***...]

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For 8U Cartridges (per thousand):
 Price Paid: \$[...***...]
 Actual COGS: \$[...***...]

Cumulative Price Paid: \$[...***...]

Cumulative COGS = \$[...***...] (< Cumulative COGS Cap of \$[...***...])

Sanofi True-Up Payment to MannKind: \$[...***...]

C. Cumulative Price Paid < Cumulative COGS but Cumulative COGS > COGS Cap

For 4U Cartridges (per thousand):
 Price Paid: \$[...***...]
 Actual COGS: \$[...***...]

For 8U Cartridges (per thousand):
 Price Paid: \$[...***...]
 Actual COGS: \$[...***...]

Cumulative Price Paid: \$[...***...]

Cumulative COGS = \$[...***...] (> Cumulative COGS Cap of \$[...***...])

Sanofi True-Up Payment to MannKind: \$[...***...]

Example 5. Effect of inflation on calculation of COGS Cap

CPI increase during 2015 – 4%

CPI increase during 2016 – 3%

Insulin ceiling price in Section 4.1(b)(i)(B) for 2017 = \$[...***...]

Insulin ceiling price in Section 4.1(b)(i)(C) for 2017 = \$[...***...]

Annual volume (total cartridges for all dosages, in millions)
 Equal to or greater than [...***...] but less than [...***...]

Maximum cost, not including Insulin, in \$US per thousand cartridges for all such cartridges			
4U	8U	12U	16U
\$[...***...]	\$[...***...]	\$[...***...]	\$[...***...]

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Example 6 Calculation of Price per SKU

If an SKU contains [...***...] cartridges of “4U” and [...***...] cartridges of “8U”, then the price applied during the Calendar Year for that SKU shall be [...***...] times the Paid Price of one “4U” cartridge plus [...***...] times the Paid Price of one “8U” cartridge.

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SCHEDULE D

CAPA OBLIGATIONS

[...***...]

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SCHEDULE E

INITIAL FORECAST

[...***...]

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28903 North Avenue Paine, Valencia, California 91355 USA
61 South Paramus Road, Paramus, New Jersey 07652 USA
One Casper Street, Danbury, Connecticut 06810 USA
www.mannkindcorp.com

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (the “**Agreement**”) is made as of the 31st day of July, 2014 (the “**Effective Date**”) by and between MannKind Corporation, a Delaware corporation (“**MannKind**”), with its principal office and place of business at 28903 North Avenue Paine, Valencia, CA 91355, U.S.A., and Amphastar France Pharmaceuticals S.A.S., a French corporation (“**AFP**”), with its principal office and place of business at Usine Saint-Charles, 60590 Eragny-Sur-Epte, France (each of MannKind and AFP, a “**Party**” and together, the “**Parties**”).

RECITALS

WHEREAS, MannKind has developed and obtained marketing approval for its product AFREZZA® (“**MannKind Product**”); and

WHEREAS, AFP is in the business of manufacturing and supplying recombinant human insulin, an active pharmaceutical ingredient (“**API**”); and

WHEREAS, MannKind and AFP desire to enter into this Agreement to provide the terms and conditions upon which AFP shall manufacture for and supply to MannKind recombinant human insulin API, SIHR Insulin (“**Product**”).

AGREEMENT

NOW THEREFORE, in consideration for the representations, warranties and covenants set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as set forth below.

1. CERTAIN DEFINITIONS.

1.1 “Affiliate” means, with respect to any Party, another entity or person which directly or indirectly, is controlled by, or controls, or is under common control with such Party, where, for purposes of this definition, the term “control” means ownership, directly or indirectly, of more than 50% of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or more than 50% of the equity interests in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby a Party controls or has the right to control the Board of Directors or equivalent governing body of a corporation or other entity, or if such level of ownership or control is prohibited in any country, any entity owning or controlling at the maximum control or ownership right permitted in the country where such entity exists.

1.2 “Confidential Information” means any confidential or proprietary information of a Party disclosed to the other Party or generated in the course of this Agreement, including inventions, know-how, works of authorship, software, data, software tools, designs, schematics, plans or other information relating to any work in process, future development, engineering, manufacturing, marketing or business plan, or financial or personnel matters relating to either Party, its present or future products, sales, suppliers, customers, employees, investors or business.

1.3 “Current Good Manufacturing Practices” or “cGMP” means the methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug or API to assure that such drug or API meets the regulatory requirements of the FDA and as further defined in 21 C.F.R. Parts 210 and 211 and the guidance of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and the European Commission Directive 2003/94/EC of October 8, 2003.

1.4 “Excluded Countries” means [...***...].

1.5 “FDA” means the United States Food and Drug Administration or any successor agency in the United States.

1.6 “Intellectual Property Rights” means any and all rights in and to discoveries, concepts, ideas, Technical Information, developments, specifications, methods, drawings, designs, flow charts, diagrams, models, formulae, procedures, processes, schematics, specifications, algorithms, apparatus, inventions, ideas, know-how, materials, techniques, methodologies, modifications, improvements, works of authorship and data (whether or not protectable under patent, copyright, trade secrecy or similar laws), including patents, copyrights, trade secrets, manufacturing documentation, and any other form of protection afforded by law to inventions, works of authorship, databases or technical information and applications and registrations with respect thereto.

1.7 “Non-conforming Product” means Product that does not conform to the Specifications, the Quality/Technical Agreement, or does not conform to cGMP, or is not free from defect, adulteration or contamination, or is not free and clear of all liens, claims and encumbrances upon delivery.

1.8 “Project Team” has the meaning set forth in § 2.2(a).

1.9 “Purchase Commitment Quantities” has the meaning set forth in § 6.1.

1.10 “Purchase Order” means a purchase order that is issued by MannKind and accepted by AFP for the purpose of obtaining the Product under this Agreement.

1.11 “Quality/Technical Agreement” or “QTA” means a separate agreement, executed subsequent to this Agreement, between the Parties which shall be incorporated herein by reference, and which sets forth, among other things, the quality control and quality assurance terms for the Product. In case of a discrepancy between this Agreement and the Quality/Technical Agreement, as to quality and technical matters the terms of the

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Quality/Technical Agreement shall govern, otherwise the provisions of this Agreement shall prevail.

1.12 “Quarter” shall mean a period of three consecutive months during a calendar year beginning on and including January 1st, April 1st, July 1st and October 1st.

1.13 “Specifications” means the technical specifications for the Product, as further described in the QTA.

1.14 “Technical Information” means either Party’s pre-existing technical documentation and information relating to manufacture of the Product, or to human insulin for use in the manufacture of the MannKind Product.

1.15 “Territory” means all countries in the world except the Excluded Countries.

2. PERFORMANCE OBLIGATIONS

2.1 Supply.

(a) Performance. AFP shall manufacture and supply the Product in accordance with the Specifications, Quality/Technical Agreement, and all applicable laws of the United States and European Union. AFP shall perform its activities in accordance with professional standards and practices including, but not limited to cGMP. AFP shall provide cGMP facilities as well as resources for such services including, but not limited to testing, release, storage, and manufacture of the Product. MannKind shall provide AFP, upon request and only for use in accordance with the terms of this Agreement, with any and all Technical Information of MannKind that AFP reasonably determines it may need to manufacture and supply the Product. Any distribution or sales by MannKind of the Product or the MannKind Product made using the Product shall be limited to the Territory until such time, if ever, as the geographical restrictions on the distribution and sale of the Product are no longer applicable under any third party license agreement with AFP.

(b) Manufacturing Site; Subcontracting. AFP shall manufacture the Product only at its facility in Eragny-Sur-Epte, France and shall not manufacture Product at any other site, except with MannKind’s prior written consent, which it may withhold in its reasonable discretion. AFP shall not delegate or subcontract the performance of activities under this Agreement to third party subcontractors, except with MannKind’s prior written consent, which it may withhold in its reasonable discretion, provided that, if MannKind provides consent to allow AFP to delegate or subcontract the performance of any such activities to a third party, such consent shall be subject to the condition that AFP shall control the performance of such activities and remains fully responsible to MannKind for the performance of such activities and any material breach of this Agreement by such third party subcontractor, and require that such third party subcontractor agrees in writing to comply with confidentiality restrictions at least as stringent as those set forth in this Agreement.

2.2 Project Team.

(a) Formation; Composition. The Parties shall form a team (“**Project Team**”), which shall be responsible for oversight of the activities under this Agreement. Each Party shall appoint to the Project Team an equal number of team members that have the requisite skills in the disciplines necessary for performance of activities under this Agreement. Each Party may change its Project Team members at any time by written notice to the other.

(b) Meetings. The Project Team shall meet at such times and locations as are agreeable to a majority of the Project Team members, but no less than once per year. Project Team meetings may take place in person or through video or telephone communications. At the initial meeting of the Project Team, the Project Team shall establish operating procedures for its meetings and activities. At each meeting of the Project Team, the Parties shall provide an update on the status of the activities conducted under this Agreement. Other personnel of each Party may attend Project Team meetings. Each Party shall bear the expense of participation of its respective Project Team members and other personnel in Project Team meetings. Written minutes shall be kept of all Project Team meetings and shall include material decisions made at such meetings.

2.3 Regular Communication. Each Party shall be available to the other Party for a reasonable number of telephone and written consultations on a schedule to be determined by mutual arrangement between the Parties. Each Party shall respond to all telephone and written (e.g. letters, e-mail, fax) communications within five (5) business days.

2.4 Regulatory Matters. The Parties shall cooperate diligently and in good faith to obtain any and all necessary approvals and permits for the manufacture and supply of the Product. The Parties shall bear their respective costs and shall pay all costs, consistent with industry practice, associated with obtaining such approvals or permits for the Product. The Parties shall provide such technical assistance to each other as is commercially reasonable for this purpose. AFP will provide MannKind with such information and data regarding the manufacture of Product to the extent necessary for MannKind and its Affiliates and licensees to prepare and defend any inquiries from regulatory authorities to satisfy regulatory requirements with respect to the Product. Only in the event that AFP needs to obtain third party services in order to support MannKind, its Affiliates, and licensee(s) to obtain or maintain approvals or permits with respect to the Product, as it specifically relates to the MannKind Product, MannKind and AFP agree to negotiate in good faith such services and the costs therefore.

2.5 Regulatory Compliance. In performing its obligations hereunder AFP shall comply with all applicable U.S. and foreign federal, state, municipal, or local laws, rules, regulations, orders, decisions or permits of any relevant jurisdiction relating to matters including, but not limited to employment, safety, health, environmental standards and requirements, non-discrimination, equal employment opportunity, import/export and privacy protection. Such laws include, but are not limited to the U.S. Occupational Safety and Health Act, the U.S. Fair Labor Standards Act, and the U.S. Food and Drug Cosmetic Act and all applicable laws of France.

3. SALE AND PURCHASE TERMS

3.1 Purchase. Subject to contractual obligations of MannKind and subject to the other provisions of this Agreement, AFP shall sell to MannKind and its Affiliates, and MannKind and its Affiliates shall purchase from AFP, at least the quantities of Product described in § 6.1.

3.2 Schedule for Delivery. Each year during the term of this Agreement, no later than December 1st, MannKind shall provide to AFP a schedule for delivery of the following calendar year's annual Product Purchase Commitment Quantities. Annual Product quantities must be requested with multiple delivery dates, and in all cases, the deliveries requested for the quantities shall be whole batch quantities (or multiples thereof, as applicable). Such requested deliveries shall not exceed quantity of [...***...] kg of Product per delivery. AFP shall be deemed to have satisfied its obligations with respect to quantity of Product if the actual quantity of Product supplied is within plus or minus [...***...] percent (+/-[...***...]%) of the quantity set forth in the applicable Purchase Order. No later than fifteen (15) calendar days prior to the end of each Quarter during the Term, MannKind shall provide AFP with the forecasted schedule of delivery of the Product for the next successive four (4) Quarters (or until the Term ends if shorter), on a rolling basis, the first two (2) Quarters of which shall be broken down on a month-by-month basis (the "**Forecast**"). Each Forecast shall be deemed to be an update of any Forecast previously provided by MannKind to AFP during the Term. The first two (2) Quarters of each Forecast shall be binding (the "**Firm Order Period**") and simultaneously with submission of the Forecast, MannKind shall submit any Purchase Order(s) for the quantities of the Product to be delivered during the second (2nd) Quarter of such Forecast (i.e., the last Quarter of the Firm Order Period). AFP will deliver the designated quantities to MannKind on the dates specified. Time is of the essence for delivery dates and quantities. If AFP cannot meet the dates specified or proposes alternate delivery dates, it must notify MannKind in writing within fifteen (15) calendar days after receipt of MannKind's most recent Forecast. In no event shall any delivery be later than one (1) month beyond MannKind's requested delivery date as long as the delivery per quarter of the Purchase Commitment Quantities does not exceed [...***...] kilograms ([...***...] kg).

Notwithstanding the foregoing, for the Purchase Commitment Quantity to be delivered in the 4th Quarter of 2014 and the 1st Quarter of 2015, MannKind shall issue a Purchase Order no later than thirty calendar days after execution of this Agreement ("Initial Order"). The Purchase Commitment Quantity of the Initial Order shall not be less than [...***...] kg for the 4th Quarter of 2014, except that the Purchase Commitment Quantity actually delivered under the Initial Order for the 4th Quarter of 2014 shall be limited by the amount that AFP can deliver in the 4th Quarter of 2014. The Purchase Commitment Quantity of the Initial Order for the 1st Quarter of 2015 shall not be less than [...***...] kg. For avoidance of doubt, the Purchase Commitment Quantity of the Initial Order shall not be less than [...***...] kg in total. MannKind and AFP shall mutually agree on specific delivery dates under the Initial Order, and, in the event AFP is unable to deliver the Purchase Commitment Quantity recited in the Initial Order for the 4th Quarter of 2014, MannKind and AFP shall mutually agree upon an altered quantity allocation of Product as between the 4th Quarter of 2014 and the 1st Quarter of 2015, which shall not be less than [...***...] kg total in any event..

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3.3 Purchase Orders. MannKind shall issue Purchase Orders to AFP based on the Forecast provided to AFP in accordance with the terms of § 3.2. All orders shall be evidenced by specific and separate Purchase Orders issued by MannKind to AFP pursuant to this § 3.3. Purchase Orders for Product may be submitted by MannKind to AFP in writing, or electronically pursuant to a mutually agreed upon process. All Purchase Orders shall contain: (a) the quantities ordered; (b) the purchase price for Product ordered in accordance with § 6; (c) delivery dates; and (d) delivery address as well as any other appropriate instructions. If MannKind issues any such Purchase Orders, AFP shall inform MannKind in writing of its acceptance or rejection thereof; provided that AFP may not reject any Purchase Order for quantities ordered in accordance with § 6.1 where the delivery dates are in accordance with the terms of § 3.2. Any deviation from an agreed upon scheduled delivery date for Product shall occur only upon written approval by the Parties. For the avoidance of doubt, this Agreement shall take precedence over the terms and conditions set forth in any Purchase Order; in other words, no additional, ambiguous or inconsistent terms in any Purchase Orders or Purchase Order acknowledgements shall have any legal effect.

3.4 Notice of Potential Product Delivery Delays. If AFP is unable to provide to MannKind the quantities of Product in accordance with the provisions of this Agreement, during any calendar year, then AFP shall inform MannKind in writing within ten (10) days of learning of such event. Such notice shall in no event be received by MannKind later than forty five (45) days prior to any delivery date, and AFP shall use commercially reasonable efforts to resolve the condition that caused such delay.

3.5 Additional Quantity. MannKind may submit a written request to AFP for quantities of Product in addition to the quantities set forth in § 6.1 of this Agreement. AFP will use commercially reasonable efforts to attempt to supply such additional quantities. AFP will respond in writing, within thirty (30) days, whether it can meet the additional quantities of Product. Upon agreement between AFP and MannKind of a specific quantity and delivery time, MannKind will submit a Purchase Order for such additional quantities of Product in accordance with the terms of § 3.3. The Parties shall negotiate in good faith the pricing for such additional quantities in no event shall the pricing be more than the amount as set forth in § 6.1.

4. MANUFACTURE

4.1 Raw Materials. AFP shall be responsible for obtaining, and shall store at no cost to MannKind, any and all materials required for the manufacture of the Product, in reasonable quantities consistent with MannKind's designated quantities and orders for the Product. AFP shall use and rotate all stock of materials on a first-in, first-out basis. AFP shall conduct on-site quality audits of its inclusion bodies supplier on a regular basis, but shall not be obligated to conduct more than one (1) such audit every calendar year. AFP represents and warrants that AFP has a long-term supply agreement with [...***...] for the sufficient supply of inclusion bodies to support AFP's obligations with respect to the Purchase Commitment Quantities and Purchase Price (without resorting to § 6.1(b)) under this Agreement and covenants that during the term of this Agreement AFP shall not unreasonably terminate such agreement or amend such agreement in a manner that would adversely affect AFP's ability to perform its obligations under this Agreement. If during the term of this Agreement AFP intends to qualify an appropriate alternate source of inclusion bodies to supplement or replace its supply

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from [...***...] then AFP must notify MannKind in writing and AFP agrees that such change shall not adversely affect AFP's ability to perform its obligations under this Agreement. AFP has provided or will provide to MannKind and its potential licensee(s) the opportunity to review a true and correct copy of such agreement, at AFP's location or Amphastar Pharmaceuticals, Inc.'s location, as in effect as of the Effective Date (as redacted to protect any proprietary information of AFP or [...***...])

4.2 Manufacture of Product. AFP shall reserve sufficient production capacity and inventory of Product in order to be able to supply to MannKind pursuant to the terms of this Agreement. AFP shall manufacture Product in accordance with § 2.1, § 2.5, and United States and European Union regulations applicable to the transportation, storage, use, handling and disposal of hazardous materials. Each Party shall promptly notify the other of any new instructions or specifications with respect to the Product required under any applicable laws and shall confer with each other with respect to the best means to comply with such requirements. AFP represents and warrants to MannKind that it has, and shall maintain during the term of this Agreement, all government permits, including without limitation health, safety and environmental permits, necessary for the conduct of the actions and procedures that it undertakes pursuant to this Agreement.

4.3 Product Specifications; Testing. Product supplied hereunder shall conform to the Specifications and the warranty set forth in § 7.2. AFP or applicable qualified contract laboratories shall perform quality control testing and quality oversight on the Product to be delivered to MannKind or its designee hereunder.

4.4 Audits. Upon MannKind's written request to AFP, which shall be not less than thirty (30) days in advance, MannKind, or its licensee(s) identified in such a written request, shall have the right to have its representatives visit AFP's facility during normal business hours to review and inspect AFP's manufacturing operations and quality systems related to the Product and to discuss any related issues with AFP's manufacturing and management personnel. Such audits of AFP shall not exceed one (1) time per calendar year for MannKind and shall not exceed one (1) time per year for MannKind's sole licensee. If MannKind adds additional licensee(s), only one (1) licensee is entitled to an audit per calendar year. For the avoidance of doubt, only two (2) audits total are allowed per calendar year. MannKind, or its licensee(s) will be entitled to perform additional audits, upon shorter notice, if Non-conforming Products are produced by AFP or complaints or other inquiries by regulatory authorities relating to the Products produced hereunder are received by either Party, or for any additional reasons where good cause is articulated in writing by MannKind.

4.5 Change in Manufacturing Process. AFP shall provide prior written notice to MannKind before AFP implements any change in the materials, suppliers, contract laboratories, equipment, processes, procedures, or test methods used to manufacture the Product, but only to the extent that such changes affect AFP's United States Drug Master File of the Product or any other regulatory filing throughout the Territory. If MannKind does not notify AFP of an objection within ten (10) business days of receipt of AFP's notice and, as far as AFP is aware having made due inquiry, such change would not require approval or notification of the applicable regulatory authorities with respect to the MannKind Product, then AFP may proceed with the change without the prior written approval of MannKind. If MannKind notifies AFP

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within such ten (10) business day period that such change would require approval or notification of the applicable regulatory authorities with respect to the MannKind Product, then AFP shall not make such change without the prior written consent of MannKind, which prior written consent shall not be unreasonably withheld. With respect to any changes that would not require approval or notification of the applicable regulatory authorities in connection with the MannKind Product, if MannKind notifies AFP of an objection to such change within such ten (10) business day period, the Parties will discuss the change in good faith for up to an additional ten (10) business days (or longer, if agreed by the Parties) in the interest of reaching a mutually agreeable resolution; provided, that if agreement is not reached on such change (and that change does not require notification or approval of the applicable regulatory authorities with respect to the MannKind Product) then AFP may proceed with such change following such discussions.

4.6 Documentation. AFP shall keep complete, accurate and authentic accounts, notes, data and records of the work performed under this Agreement adequate to comply with all applicable laws. AFP shall maintain complete and adequate records pertaining to the methods and facilities used by it for the manufacture, testing and supply of the Product. Upon MannKind's written request, AFP shall make these documents available for MannKind on-site review at AFP's facility. MannKind acknowledges that all of AFP's manufacturing records shall be protected under the confidentiality provisions of § 11.

4.7 Recall of Product. In the event that: (a) any regulatory authority issues a request, directive or order that the Product be recalled or retrieved; (b) a court of competent jurisdiction orders that the Product be recalled or retrieved; or (c) AFP determines that the Product should be recalled or retrieved, AFP shall promptly notify MannKind, in writing, of such event and shall conduct such activity and take appropriate corrective actions, at AFP's expense.

5. DELIVERY AND ACCEPTANCE

5.1 Time and Place of Delivery. AFP shall deliver the Product to MannKind DAT ("Delivered at Terminal," as such term is defined in INCOTERMS 2010) to John F. Kennedy International Airport ("**JFK**"), or other designated terminal within the United States ("Alternate Designated Terminal") at MannKind's reasonable discretion upon reasonable written notice to AFP, to arrive on or before the scheduled date as set forth in the Purchase Orders. AFP shall ensure that the shipping, handling and storage conditions are sufficiently maintained so that there is no adverse impact to Product quality. Upon delivery to MannKind, AFP shall ensure Product will have a remaining expiry date of not less than four (4) years.

5.2 Risk of Loss. AFP shall bear the risk of loss for the Product through delivery to, and unloading at, JFK or Alternate Designated Terminal, at which time title to the Product and the risk of loss shall pass to MannKind.

5.3 Documents. Each shipment of the Product shall be accompanied by relevant certificates of analysis and a copy of the invoice. Each certificate of analysis shall certify with respect to each shipment and batch (identified by batch number) (a) the quantity of the shipment, and (b) that Product delivered conforms to Specifications, as well as any further information required by the relevant regulatory authorities that MannKind may have previously notified AFP

is necessary. MannKind shall be under no obligation to accept any shipment of Product without an accompanying certificate of analysis.

5.4 Inspection, Acceptance and Rejection. MannKind shall have the right to inspect the Product as follows:

(a) Delivery Inspection. Upon delivery at MannKind's designated facility, MannKind shall perform testing to determine whether the Product is acceptable to MannKind, conforms with the Specifications and cGMPs, is free from defect, adulteration and contamination and is free and clear of all liens, claims and encumbrances.

(b) Acceptance; Rejection. If, after performing such testing MannKind determines and informs AFP in writing that any Product delivered is a Non-conforming Product, MannKind shall so notify AFP in writing within forty-five (45) days from receipt of the shipment. In the event that AFP agrees that the Product is Non-conforming Product, MannKind may, at its option, return such Non-conforming Product to AFP or request replacement of the Non-conforming Product at AFP's sole cost and at the earliest possible timeframe that is commercially reasonable. If MannKind exercises such return rights, MannKind shall return any such Non-conforming Product in accordance with AFP's then current return procedures, and AFP shall replace such Non-conforming Product. If AFP does not replace such Non-conforming Product so as to remedy any reported non-conformity within forty-five (45) days after such non-conformity is reported to AFP, then MannKind may reject such Non-conforming Product by providing prompt written notice of such rejection to AFP. In the event of such rejection of any Non-conforming Product, AFP shall promptly credit or refund the net purchase price paid by MannKind. MannKind may charge AFP for all costs of shipment of Non-conforming Product and for the cover costs of the Product. If MannKind does not notify AFP that any Product is a Non-conforming Product during the forty-five (45) day period following delivery of such Product at MannKind's designated facility, or does not reject any Non-conforming Product in accordance with the procedure described above, such Product shall be deemed to have been accepted by MannKind. Acceptance or deemed acceptance under this § 5.4 shall not limit AFP's warranty obligations or MannKind's warranty rights under § 7.2.

In the event of a discrepancy between MannKind and AFP as to whether the Product is Non-conforming Product or there otherwise exists a dispute between the Parties over the extent to which such non-conformity is attributable to a given Party, the Parties shall cause an independent laboratory promptly to review records, test data and perform comparative tests and analyses on samples of the Product that allegedly is Non-conforming. Such independent laboratory shall be mutually agreed upon by the Parties. The independent laboratory's results shall be in writing and shall be final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules.

6. PRICING; QUANTITIES; AND PAYMENT

6.1 Purchase Commitment and Purchase Price. MannKind shall purchase from AFP the minimum quantities of Product (the "**Purchase Commitment Quantities**") at the purchase price per gram (the "**Purchase Price**") in each calendar year as provided in the table set

forth below. In the event that MannKind fails to meet the Purchase Commitment Quantities in any given calendar year, MannKind shall pay AFP for the difference in the amount of the Purchase Commitment Quantities and the actual amount purchased for the corresponding calendar year (such difference, the “**Purchase Commitment Difference**”). AFP shall issue an invoice and MannKind shall pay the Purchase Commitment Difference no later than thirty (30) days after the close of the corresponding calendar year.

Calendar Year	Purchase Commitment Quantities (kg)	Purchase Price (per gram)	Comment
2015	[...***...]	EUR [...***...]	Up to [...***...] kg to be delivered in the fourth quarter of 2014.
2016	[...***...]	EUR [...***...]	
2017	[...***...]	EUR [...***...]	
2018	[...***...]	EUR [...***...]	
2019	[...***...]	EUR [...***...]	

All amounts due under this § 6.1 shall be due and payable by MannKind to AFP in EUR in accordance with § 6.2. In calendar year 2016 and thereafter, the Purchase Price shall be subject to adjustment as follows:

(a) The Purchase Price will be subject to an obligatory annual adjustment on January 1 of each calendar year equal to the percentage change in the [...***...] (the “**Index**”), where the annual adjustment is calculated using the historical twelve (12) month percentage change of the Index, as of December 1 of the immediate prior year; provided, however, that if the percentage change (either increase or decrease, as applicable) of the Index equals or exceeds [...***...] percent (i.e., +/- [...***...]%), the Purchase Price adjustment shall not be obligatory, but instead the Parties shall attempt in good faith to negotiate an adjusted Purchase Price based on such change, which attempted negotiations shall be concluded no later than February 15 of that calendar year.

(b) In addition to any adjustment to the Purchase Price pursuant to §6.1(a), if for causes beyond AFP’s reasonable control (including market shortage, market embargo, etc.), AFP has incurred any price increase(s) in its aggregate material and service costs (such increased costs measured on a per gram basis of Product, the “**Cost Excess**”) which are in excess of [...***...] percent ([...***...]%) of the Purchase Price in a given calendar year, then the Purchase Price for the next calendar year shall be increased by the percentage increase of the Cost Excess as compared to the aggregate costs for such materials and services during the prior calendar year.

(c) If AFP delivers any Product Purchase Commitment Quantities, as defined in the Firm Order Period through a Purchase Order accepted by AFP, beyond sixty (60) days after the committed delivery date, then such quantities shall be subject to a [...***...] percent ([...***...]%) discount off the Purchase Price.

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6.2 Payment. MannKind shall pay AFP for the Product within forty-five (45) days from shipment date of the Product. In the event the Product is detained due to Customs or FDA then MannKind shall notify AFP of such delay and the period for payment shall be extended for the period commensurate with such delay. AFP shall submit an invoice electronically to MannKind, Attention: Accounts Payable, valenciaap@mannkindcorp.com. If any portion of an invoice is disputed then MannKind shall pay the undisputed amount and the Parties shall use good faith efforts to reconcile the disputed amount as soon as practicable. AFP shall not suspend work or seek to terminate this Agreement or any Purchase Order solely on account of MannKind's failure to pay any invoiced amount which is the subject of a good faith bona fide dispute, provided that MannKind pays all non-disputed amounts.

6.3 Reservation Fee. No later than five (5) days after the Effective Date, MannKind shall make payment to AFP in the amount of EUR 11,000,000, which will be considered as partial payment for the calendar year 2015 Purchase Commitment Quantities of [...] kilograms of Product. This reservation fee is non-refundable and deemed fully earned by, and to be the property of AFP in all events, including but not limited to the event that MannKind fails to purchase the calendar year 2015 Purchase Commitment Quantities, except for and excluding only the event of a material breach of AFP's obligations under this Agreement that occurs prior to the delivery of the full amount of calendar year 2015 Purchase Commitment Quantities. Any invoice(s) for the calendar year 2015 designated quantities will be adjusted to reflect a credit for the reservation fee. For avoidance of doubt, this Reservation Fee will only be adjusted against the purchase of quantity that is delivered in calendar year 2015, and not calendar year 2014 or in any other calendar year.

6.4 Taxes. The Party receiving payments under this Agreement shall pay any and all taxes levied on account of such payment. If any taxes are required to be withheld by the paying Party, it shall (a) deduct such taxes from the remitting payment, (b) timely pay the taxes to the proper taxing authority, and (c) send proof of payment to the other Party and certify its receipt by the taxing authority within sixty (60) calendar days following such payment. AFP shall ensure that the proper harmonized code is used for Customs shipping documentation in accordance with 19 CFR 152.11.

7. REPRESENTATIONS AND WARRANTIES; COVENANTS

7.1 General Representations and Warranties. Each Party represents and warrants:

(a) **Corporate Power and Authorization.** It is duly organized and validly existing under the laws of the state of its incorporation, and has full corporate power and authority to execute and deliver this Agreement and to perform all of its obligations hereunder; and

(b) **Binding Agreement.** This Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms; and

(c) **No Conflict.** The execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written,

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to which it is a party or by which it may be bound, nor violate any law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it; and

(d) Resources. It has adequate resources, both financial and otherwise, to perform its duties hereunder.

7.2 AFP Warranty. AFP represents and expressly warrants that the Product provided hereunder shall be in compliance with all applicable laws and regulations, free from defect, adulteration and contamination and free and clear of all liens, claims and encumbrances upon delivery. In addition to § 5.4 upon any breach of the warranty AFP shall at AFP's sole expense promptly (and in no event longer than sixty (60) days) correct, at no cost to MannKind, and at MannKind's request, any such breach by replacement of any Non-conforming Product and shall provide technical assistance to MannKind to address the Product non-conformity issues. Any replacement shall be considered a new Product for purposes of this § 7.2.

AFP represents and expressly warrants that the Product provided hereunder shall conform to the Specifications, shall be supplied in compliance with the QTA and instructions from MannKind, except where MannKind has failed to notify AFP of any Product that does not so conform pursuant to the terms of § 5.4(b); provided, however, that AFP shall remain liable for Product having latent defects that could not have been discovered by MannKind within the applicable period described in § 5.4(b) despite reasonable inspection by MannKind.

AFP represents and expressly warrants that it has and shall at all times throughout the term of this Agreement has, whether by right, title, interest, including by license or otherwise, the Intellectual Property Rights that are required to use, manufacture, market, offer to sell, sell, import and export the Product, and that this Agreement shall not infringe any third party patent rights.

7.3 Limitation of Liability. THE EXPRESS WARRANTIES AND REPRESENTATIONS SET FORTH IN SECTION 7.2, AND ANY OTHER AFP WRITTEN PROMISE OR STATEMENT EXPRESSLY REFERRED TO AS A WARRANTY, REPRESENTATION OR COVENANT IN THE AGREEMENT, ARE IN LIEU OF ALL OTHER WARRANTIES AND REPRESENTATIONS, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE WHICH ARE HEREBY DISCLAIMED AND EXCLUDED BY AFP, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE, AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, INCLUDING PATENT RIGHTS.

7.4 Disclaimer of Consequential Damages. As used in this Section 7.4, the term "AFP LIABILITY" MEANS LIABILITY OF AFP OF ANY KIND, WHETHER UNDER CONTRACT, WARRANTY, TORT (INCLUDING LIABILITY FOR NEGLIGENCE), STRICT LIABILITY, STATUTE, OR ANY OTHER LEGAL OR EQUITABLE THEORY OF LIABILITY, ARISING OUT OF, CONNECTED WITH, OR RELATING IN ANY MANNER TO THIS AGREEMENT. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW AND NOTWITHSTANDING THAT ANY REMEDY REFERRED TO, OR LIMITATION OF CUMULATIVE LIABILITY SET FORTH, WITH THE EXCEPTION OF ANY WILLFUL MISCONDUCT, IN NO EVENT WILL AFP LIABILITY INCLUDE, AND

AFP SHALL NOT BE LIABLE FOR, ANY SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL LOSSES OR DAMAGES (INCLUDING LOSS OF PROFIT OR REVENUES, INJURY TO GOODWILL, LOSS OF THE USE OF GOODS OR EQUIPMENT, DAMAGE TO ANY ASSOCIATED EQUIPMENT, COST OF CAPITAL, DOWNTIME COSTS, OR CLAIMS OF MANNKIND'S CUSTOMERS, AFFILIATES, LICENSEES, DISTRIBUTORS OR OTHER THIRD PARTIES FOR SUCH DAMAGES OR LOSSES) EVEN IF AFP WAS ADVISED OF THE POSSIBILITY OF SUCH POTENTIAL DAMAGE OR LOSS;

7.5 Cumulative Liability. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, AFP LIABILITY WILL BE LIMITED TO DAMAGES AND LOSSES NOT TO EXCEED IN THE AGGREGATE [...***...] EUROS (EU [...***...]). IT IS UNDERSTOOD THAT THE FOREGOING MONETARY LIMITATION OF LIABILITY REPRESENTS AFP'S TOTAL AND CUMULATIVE LIABILITY FOR ALL AFP LIABILITY.

7.6 No Debarred or Disqualified Persons. AFP represents and warrants that it shall not employ, contract with, or retain any person directly or indirectly to perform any activities relating to the manufacture or supply of Product if such a person (a) is under investigation by the FDA for debarment or is presently debarred by the FDA pursuant to 21 U.S.C. § 335a or its successor provisions or by the applicable regulatory authority in any country or jurisdiction outside the United States under comparable regulations, or (b) has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 C.F.R. § 312.70 or its successor provisions or by the applicable regulatory authority in any other country or jurisdiction outside the United States under comparable regulations. In addition, AFP represents and warrants that it has not engaged in any conduct or activity which could lead to any of the above-mentioned disqualification or debarment actions. If, during the term of this Agreement, AFP or any person employed or retained by it to perform any activities relating to the manufacture or supply of Product (i) comes under investigation by the FDA or by the applicable regulatory authority in any country or jurisdiction outside the United States for a debarment action or disqualification, (ii) is debarred or disqualified, or (iii) engages in any conduct or activity that could lead to any of the above-mentioned disqualification or debarment actions, AFP shall immediately notify MannKind of same.

7.7 Covenants. Contemporaneous with the Effective Date, the Parties hereby agree to negotiate in good faith the execution of a Quality/Technical Agreement, incorporated hereby by reference, which sets forth, among other things, the quality control and quality assurance terms for the Product. Such Quality/Technical Agreement shall be mutually agreed to in writing prior to placement of any Purchase Order for the Product.

8. INDEMNIFICATION

8.1 Mutual Indemnification. Each Party (the "*Indemnifying Party*") shall indemnify and hold harmless the other Party and its Affiliates, and their respective directors, employees, consultants and agents (the "*Indemnified Parties*") from and against any and all liabilities, losses, damages, costs, and other expenses (including attorneys' and expert witnesses' costs and fees) ("*Losses*") incurred by the Indemnified Parties as a result of any claim, demand,

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action or proceeding by any third party (a **"Claim"**) to the extent arising from or relating to any breach of any representation, warranty, covenant, or obligation of the Indemnifying Party under this Agreement or any intentional misconduct or gross negligence by the Indemnifying Party or any of its employees, agents, or subcontractors, except, in each case, to the extent such Losses result from the intentional misconduct or gross negligence of, any of the Indemnified Parties.

8.2 Indemnification Procedures. In the event of any Claim for which any Indemnified Party is or may be entitled to indemnification hereunder, the Indemnified Party may, at its option, require the Indemnifying Party to defend such Claim at the Indemnifying Party's sole expense. Indemnifying Party may not settle any such Claim without the Indemnified Party's express prior written consent.

8.3 Failure to Defend or Settle. If the Indemnifying Party fails or wrongfully refuses to defend or settle any Claims, then the Indemnified Party shall, upon written notice to the Indemnifying Party, have the right to defend or settle (and control the defense of) such Claims. In such case, the Indemnifying Party shall cooperate, at its own expense, with the Indemnified Party and its counsel in the defense and settlement of such Claims, and shall pay, as they become due, all costs, damages, and reasonable legal fees incurred therefore.

9. INSURANCE PROTECTION. Each Party shall obtain and maintain during the term of this Agreement liability, comprehensive, and workers' compensation insurance with a reputable insurance company to help protect against those insurable risks that such Party may incur in connection with the performance of its obligations under this Agreement. Each Party shall provide, upon request, to the other Party any such policies of such insurance, and the premium receipt(s) and insurance certificate(s) therefore.

10. TERM; TERMINATION

10.1 Term. This Agreement shall begin on the Effective Date and, unless terminated sooner as provided in § 10.2, expire on December 31, 2019. The Parties may renew this Agreement for additional, successive two (2) year terms upon twelve (12) months written notice, given prior to the end of the initial or any additional two (2) year term.

10.2 Termination Events

(a) For Cause. A Party shall have the right to terminate this Agreement for cause if the other Party materially breaches this Agreement and fails to cure such breach within sixty (60) days after receiving written notice that specifies the particulars of such breach.

(b) Force Majeure. A Party shall have a right to terminate this Agreement in accordance with § 12.14.

(c) Without Cause. MannKind shall have the right to terminate this Agreement without cause upon two (2) years' prior written notice to AFP.

(d) Business Circumstances. A Party shall have the right to terminate this Agreement in the event of the other Party's liquidation, bankruptcy or state of insolvency upon written notice to such other Party.

(e) Regulatory Decisions. MannKind may terminate this Agreement upon a thirty (30) day written notice to AFP if a controlling regulatory authority withdraws approval of the MannKind Product.

10.3 Effects of Termination. Upon the expiration or earlier termination of this Agreement: (a) MannKind shall pay to AFP all amounts due to AFP under this Agreement, including any unpaid Purchase Commitment Difference within sixty (60) days of the effective date of such expiration or earlier termination; provided however, only in the event of a termination by MannKind pursuant to §10.2(c) or §10.2(e), MannKind shall pay to AFP within sixty (60) calendar days of the effective date of such expiration or earlier termination, the full payment for all remaining Purchase Commitment Quantities as provided in the table set forth in §6.1, as well as any unpaid Purchase Commitment Difference; and (b) each Party shall return to the other Party, upon the other Party's request, all tangible items of the other Party in its possession or under its control evidencing the Confidential Information of the other Party, if applicable. The expiration or earlier termination of this Agreement shall not affect any rights or claims of a Party hereunder that accrued prior to the date of such expiration or earlier termination.

10.4 Survival. Sections (§): § 1, §2.4, §2.5, §3.1, §6.1, §4.4, §4.6, §4.7, §7, §8, §9, §10.3, §10.4, §11, §12 shall survive the expiration or termination of this Agreement.

11. CONFIDENTIAL INFORMATION

11.1 Confidentiality Obligations. Each Party shall at all times, and notwithstanding any termination or expiration of this Agreement, hold in confidence and not disclose to any third party Confidential Information of the other Party, except as approved in writing by the other Party to this Agreement, and shall use the Confidential Information for no purpose other than the purposes expressly permitted by this Agreement. For clarification, all MannKind Intellectual Property Rights, shall be Confidential Information of MannKind. For clarification, all AFP Intellectual Property Rights shall be the Confidential Information of AFP. Each Party shall only permit access to Confidential Information of the other Party to those of its and its Affiliates' employees, consultants, agents, and attorneys and, in the case of MannKind, to its licensee of rights to the MannKind Product, in each case who have a need to know and are bound by confidentiality obligations at least as restrictive as those contained herein. The obligations in this § 11.1 shall terminate five years from the date of expiration or termination of this Agreement in accordance with § 10.

11.2 Exceptions to Confidentiality Obligations. A Party's obligations under this Agreement with respect to any portion of the other Party's Confidential Information shall terminate when the Party that is subject to such obligations can document in writing that such information: (a) entered the public domain through no fault of such Party; (b) was in such Party's possession free of any obligation of confidence at the time it was communicated to such Party by the other Party; (c) was rightfully communicated to such Party free of any obligation of confidence subsequent to the time it was communicated to such Party by the other Party; or (d) was developed by employees or agents of such Party independently of and without reference to any information communicated to such Party by the other Party.

11.3 Authorized Disclosure. Notwithstanding anything to the contrary, a Party shall not be in violation of § 11.1 with regard to a disclosure of the other Party's Confidential Information that is in response to a valid order by a court or other governmental body or necessary to comply with applicable law or governmental regulations, provided that if such Party is required to make any such disclosure of the other Party's Confidential Information it shall to the extent practicable give reasonable advance notice to the other Party of such disclosure requirement in order to permit the other Party to seek confidential treatment of or to limit the Confidential Information required to be disclosed.

11.4 Previous Confidential Disclosure Agreements. As of the Effective Date, the terms of this § 11 shall supersede any prior confidential disclosure agreements between the Parties dealing with the subject of this Agreement. Any information disclosed under such prior agreements shall be deemed disclosed under this Agreement.

11.5 Publicity; Filing of Agreement. Each Party shall have the right to issue from time to time press releases that disclose the relationship of the Parties under this Agreement upon the agreement of the Parties, which agreement shall not be unreasonably withheld, delayed, or conditioned. Any press releases that are to be issued by either Party shall be in a form and substance as may be mutually agreed upon by the Parties. The Parties will coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the U.S. Securities and Exchange Commission (the "**SEC**"), the NASDAQ stock exchange or any other stock exchange or governmental agency on which securities issued by a Party or its Affiliate are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided, that each Party will ultimately retain control over what information to disclose to the SEC, the NASDAQ stock exchange or any other stock exchange or governmental agency, as the case may be, and provided further that the Parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) will be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC, the NASDAQ stock exchange or any other stock exchange or governmental agency.

12. MISCELLANEOUS

12.1 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided, however, that either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent (a) in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates to a third party, whether by merger, sale of stock, sale of assets or otherwise, including, for greater certainty, by MannKind to its licensee(s) of the MannKind Product in connection with the transfer of manufacturing responsibility for the MannKind Product to such licensee, or (b) to any Affiliate. Notwithstanding the foregoing, any such assignment to an Affiliate or licensee(s) shall not relieve the assigning Party of its responsibilities for performance of its obligations under this Agreement, and the assigning Party hereby guarantees the performance of this Agreement by such Affiliate or licensee(s). The rights and obligations of the Parties under this Agreement shall

be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.

12.2 Ownership Rights. Each Party shall retain ownership and control of their respective works of authorship, inventions, know-how, information, data, and all Intellectual Property Rights therein that were in existence as of the Effective Date or are created thereafter, whether or not in the course of the performance of its obligations under this Agreement. The Parties hereby acknowledge that neither Party has, nor shall it acquire, any interest in any of the other party's Intellectual Property Rights, unless otherwise expressly agreed to in writing.

12.3 Relationship of the Parties. It is expressly agreed that AFP and MannKind shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency of any kind. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

12.4 Amendment. Unless otherwise provided herein, this Agreement may not be changed, waived, discharged, or terminated orally, but instead only by a written document that is signed by the duly authorized officers of both Parties.

12.5 Waiver. No failure or delay by either Party in exercising any right, power, or privilege under this Agreement shall operate as a waiver thereof, nor shall any single or partial waiver thereof include any other or further exercise thereof or the exercise of any other right, power, or privilege.

12.6 Severability. Whenever possible, each provision of the Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any term or provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of the Agreement and this Agreement shall be interpreted and construed as if such provision had never been contained herein.

12.7 Notices. All notices and statements to be given (which shall be in writing) and all payments to be made hereunder shall be given or made at the respective addresses of the Parties as set forth above, unless notification of a change of address is given. All notices, payments and statements to be made hereunder shall be mailed by certified or registered mail, return receipt requested, or sent by overnight courier, or by facsimile or other electronic means. Any notice given pursuant to this Agreement by mail shall be considered effective three (3) business days after mailing. Any notice sent by overnight courier shall be considered effective one day after mailing. The date of transmission of any notice sent by electronic means shall be deemed to be the date the notice or statement is transmitted.

12.8 Construction. The section headings of this Agreement are inserted only for ease of reference only, and shall not be used to interpret, define, construe, or describe the scope or extent of any aspect of this Agreement. Unless otherwise expressly stated, when used in this Agreement the word "including" means "including but not limited to." References to "days" shall mean calendar days unless reference to business days is made expressly. Each Party

represents that it has had the opportunity to participate in the preparation of this Agreement and hence the Parties agree that the rule of construction that ambiguities be resolved against the drafting Party shall not apply to this Agreement.

12.9 No Third Party Beneficiaries. Unless expressly provided, no provisions of this Agreement are intended or shall be construed to confer upon or give to any person other than MannKind and AFP any rights, remedies, or other benefits under or by reason of this Agreement.

12.10 Dispute Resolution. If a dispute arises under this Agreement, the Parties shall use reasonable efforts to attempt to resolve such dispute, including escalation of discussions to the appropriate level of management, as provided in § 12.13, prior to exercising any remedies that may exist before commencing an action against the other Party. Notwithstanding the foregoing, either Party may at any time seek equitable relief under § 12.11 without first attempting to resolve a dispute under this § 12.10 provided, however, that such Party notifies the other Party promptly after it files any such action.

12.11 Equitable Relief. Each Party acknowledges and agrees that any breaches or violations of § 3 or § 11 may cause the non-breaching Party irreparable damage for which the award of monetary damages would be inadequate. Consequently, the non-breaching Party may seek to enjoin the breaching Party from any and all acts in violation of any such provisions, which remedy shall be cumulative and not exclusive, and a Party may seek the entry of an injunction enjoining any breach or threatened breach of such provisions, in addition to any other relief to which the non-breaching Party may be entitled at law or in equity.

12.12 Governing Law. This Agreement shall be governed by and interpreted under the laws the State of Delaware, without regard to its conflict or choice of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

12.13 Alternative Dispute Resolution. The Parties shall attempt by direct negotiation, between the Project Team, or pertinent members, in good faith to resolve promptly any dispute arising out of or relating to this Agreement. If the matter cannot be resolved in the normal course of business either Party shall give the other Party written notice of any such dispute not resolved at which time the dispute shall be referred to the senior management of the respective Parties who shall likewise attempt to resolve the dispute.

If the dispute has not been resolved by negotiation as detailed above, or if the Parties fail to meet, within twenty (20) business days from such notice, either party may submit the dispute to arbitration to the International Institute for Conflict Prevention & Resolution (“CPR”) for resolution in accordance with the CPR Arbitration Rules and Commentary. A single, impartial arbitrator mutually acceptable to the Parties shall conduct the arbitration. In the event the Parties cannot agree on an arbitrator within ten (10) business days after the end of the aforesaid twenty (20) business days, either Party may have an arbitrator appointed by the CPR.

The location of the arbitration shall be in New York, NY, USA, unless the Parties agree otherwise. As a condition of appointment of the arbitrator, said arbitrator shall agree to use her/his best efforts to conclude the proceeding within thirty (30) business days. Said arbitrator

shall further have the authority to limit the volume of evidence and documents to be submitted by the Parties. Any court having jurisdiction thereof may enter judgment upon the award rendered by the arbitrator. This Section shall, however, not be construed to limit or to preclude either Party from bringing any action in any court of competent jurisdiction for injunctive or other provisional relief as necessary or appropriate.

12.14 Force Majeure. AFP shall not be liable to MannKind for any failure or delay in the performance of any of its obligations under this Agreement arising out of any event or circumstance beyond its reasonable control, including war, rebellion, terrorism, civil commotion, strikes, lock-outs or industrial or labor disputes; fire, explosion, earthquake, acts of God, flood, drought, or bad weather; or requisitioning or other act or order by any government or regulatory authority. If such failure or delay occurs, then AFP shall give MannKind notice of the circumstances causing such failure or delay, and AFP shall be excused from the performance of such of its obligations that it is thereby disabled from performing for so long as it is disabled and for sixty (60) calendar days thereafter; provided, however, that AFP commences and continues to take reasonable and diligent actions to cure such failure or delay. Notwithstanding the foregoing, if AFP is disabled from the performance of any material obligation under this Agreement for a period of ninety (90) calendar days or more, then MannKind shall have the right to terminate this Agreement upon written notice to AFP, in which event the provisions of § 10.3 shall apply.

12.15 Attorneys' Fees. If any claim, action, or dispute arises between the parties with respect to any matter covered by this Agreement that leads to a proceeding before a court of competent jurisdiction to resolve such claim, the Prevailing Party in such proceeding shall be entitled to receive from the other Party its reasonable attorneys' fees, expert witness fees, court costs and other out-of-pocket costs incurred in connection with such proceeding, in addition to any other relief that it may be awarded. For purposes of this Section, the term "Prevailing Party" means that Party in whose favor any monetary or equitable award is made or in whose favor any dispute is resolved, regardless of any settlement offers.

12.16 Entire Agreement. This Agreement includes all exhibits attached hereto and any Specifications that are executed by authorized representatives of the Parties, and constitutes the entire agreement by and between the Parties as to the subject matter hereof. This Agreement supersedes and replaces in its entirety all prior agreements, understandings, letters of intent, and memoranda of understanding by and between the Parties hereto, in either written or oral form. No amendment or modification of this Agreement shall be valid unless set forth in writing referencing this Agreement and executed by authorized representatives of both Parties.

12.17 English Language. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement, or delivered pursuant to the terms of this Agreement, shall be in the English language. Any proceedings related to dispute resolution including, but not limited to legal, equitable, or alternative dispute resolution, shall be conducted in the English language.

12.18 Counterparts; Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which

together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

12.19 Reservation of Rights. Except for the rights expressly provided in this Agreement, no other rights are granted by either Party to the other Party. Notwithstanding anything to the contrary, no rights or licenses are granted under this Agreement by either Party to the other for the use of any trade names, trademarks, and service marks.

IN WITNESS WHEREOF, the Parties hereto have this day caused this Agreement to be executed by their duly authorized officers.

Amphastar France Pharmaceuticals S.A.S.

By: /s/ Franck Vitali

Name: Franck Vitali

Title: Plant Manager

MannKind Corporation

By: /s/ Matthew Pfeffer

Name: Matthew Pfeffer

Title: CFO

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Alfred E. Mann, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended September 30, 2014 of MannKind Corporation;
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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2014

/s/ Alfred E. MannAlfred E. Mann
Chairman of the Board of Directors and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Matthew J. Pfeffer, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended September 30, 2014 of MannKind Corporation;
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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2014

/s/ Matthew J. Pfeffer

Matthew J. Pfeffer
Corporate Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATION OF
 CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
 PURSUANT TO
 RULE 13a-14(b) OR 15d-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AND SECTION 1350 OF
 CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE (18 U.S.C. § 1350)

In connection with the filing of the quarterly report of MannKind Corporation (the "Company") on Form 10-Q for the quarterly period ended September 30, 2014, as filed with the Securities and Exchange Commission on or about the date hereof to which this certification is attached as Exhibit 32 (the "Report") and 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. §1350), Alfred E. Mann, Chairman of the Board of Directors and Chief Executive Officer of the Company, and Matthew J. Pfeffer, Corporate Vice President and Chief Financial Officer of the Company, each hereby certifies that to the best of his knowledge:

1. The 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 Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2014

In witness whereof, the undersigned have set their hands hereto as of the 10th day of November 2014.

/s/ Alfred E. Mann

 Alfred E. Mann
 Chairman of the Board of Directors and Chief Executive Officer

/s/ Matthew J. Pfeffer

 Matthew J. Pfeffer
 Corporate Vice President and Chief Financial Officer

This certification is being furnished solely to accompany this quarterly report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not deemed filed for purposes of Section 18 of the Exchange Act or the Securities Act of 1933, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language contained in such filing.