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, 2018

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	**13-3607736**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
30930 Russell Ranch Road, Suite 300 Westlake Village, California	**91362**
(Address of principal executive offices)	**(Zip Code)**

(818) 661-5000

(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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

As of October 22, 2018, there were 159,597,573 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, 2018

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MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except per share data)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,446	$ 43,946
Restricted cash	527	4,409
Accounts receivable, net	2,752	2,789
Inventory	2,785	2,657
Deferred costs from commercial product sales	—	405
Prepaid expenses and other current assets	3,015	3,010
Total current assets	19,525	57,216
Property and equipment, net	25,632	26,922
Other assets	199	437
Total assets	$ 45,356	$ 84,575
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 5,815	$ 6,984
Accrued expenses and other current liabilities	13,434	12,449
Facility financing obligation	14,202	52,745
Deferred revenue, net	—	3,038
Deferred payments from collaboration - current	10,095	250
Recognized loss on purchase commitments - current	16,081	12,131
Total current liabilities	59,627	87,597
Note payable to related party	72,143	79,666
Accrued interest - note payable to related party	5,692	2,347
Senior convertible notes	19,133	24,411
Recognized loss on purchase commitments - long term	84,362	97,585
Deferred payments from collaboration - long term	2,638	500
Milestone rights liability	7,202	7,201
Total liabilities	250,797	299,307
Commitments and contingencies (Note 12)		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value - 10,000,000 shares authorized; no shares issued or outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value - 280,000,000 shares authorized, 159,497,573 and 119,053,414 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	1,594	1,192
Additional paid-in capital	2,723,232	2,638,992
Accumulated other comprehensive loss	(18)	(18)
Accumulated deficit	(2,930,249)	(2,854,898)
Total stockholders' deficit	(205,441)	(214,732)
Total liabilities and stockholders' deficit	$ 45,356	$ 84,575

See notes to condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Net revenue - commercial product sales	$ 4,387	$ 1,981	$ 11,542	$ 4,726
Net revenue - collaborations	82	62	232	187
Revenue - other	—	—	53	2,302
Total revenues	4,469	2,043	11,827	7,215
Expenses:				
Cost of goods sold	5,303	4,575	14,406	12,210
Research and development	2,043	4,361	7,653	10,611
Selling, general and administrative	19,394	17,725	61,740	51,681
Property and equipment impairment	—	92	—	203
(Gain) Loss on foreign currency translation	(728)	3,684	(3,107)	12,077
Gain on purchase commitments	—	(215)	—	(215)
Total expenses	26,012	30,222	80,692	86,567
Loss from operations	(21,543)	(28,179)	(68,865)	(79,352)
Other (expense) income:				
Change in fair value of warrant liability	—	(1,289)	—	5,488
Interest income	144	65	305	178
Interest expense on notes	(993)	(2,310)	(4,496)	(7,438)
Interest expense on note payable to related party	(1,074)	(1,173)	(3,234)	(2,608)
Loss on extinguishment of debt	(712)	—	(765)	(830)
Other income	10	—	71	13
Total other expense	(2,625)	(4,707)	(8,119)	(5,197)
Loss before provision for income taxes	(24,168)	(32,886)	(76,984)	(84,549)
Income tax expense	—	—	(240)	—
Net loss	$ (24,168)	$ (32,886)	$ (77,224)	$ (84,549)
Net loss per share - basic and diluted	$ (0.16)	$ (0.31)	$ (0.56)	$ (0.84)
Shares used to compute basic and diluted net loss per share	153,597	104,703	138,307	100,136

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$ (24,168)	$ (32,886)	$ (77,224)	$ (84,549)
Other comprehensive income:				
Cumulative translation gain (loss)	—	1	(1)	4
Comprehensive loss	$ (24,168)	$ (32,885)	$ (77,225)	$ (84,545)

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (77,224)	$ (84,549)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation, amortization and accretion	2,489	2,707
Stock-based compensation expense	5,715	3,763
Loss on extinguishment of debt, net	765	830
(Gain) Loss on sale, abandonment/disposal or impairment of property and equipment	(10)	179
(Gain) Loss on foreign currency translation	(3,107)	12,077
Gain on purchase commitments	—	(215)
Interest on note payable to related party	3,345	2,608
Change in fair value of warrant liability	—	(5,488)
Write-off of inventory	1,792	1,793
Other, net	106	44
Changes in operating assets and liabilities:		
Accounts receivable, net	(74)	(1,502)
Receivable from Sanofi	—	30,557
Inventory	(1,920)	(2,591)
Deferred costs from commercial product sales	—	(234)
Prepaid expenses and other current assets	(5)	1,303
Other assets	200	166
Accounts payable	(1,169)	2,099
Accrued expenses and other current liabilities	560	2,889
Deferred revenue	—	(398)
Deferred payments from collaborations	11,983	(187)
Recognized loss on purchase commitments	(6,165)	(648)
Net cash used in operating activities	(62,719)	(34,797)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net proceeds from sale of asset held for sale	—	16,651
Proceeds from sale of property and equipment	10	24
Net cash provided by investing activities	10	16,675
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from direct placement of common stock	28,000	—
Issuance cost associated with direct placement	(1,610)	—
Principal payments on facility financing obligation	(2,000)	(4,000)
Borrowings on note payable to related party	—	19,429
Payment of employment taxes related to vested restricted stock units	(184)	(110)
Proceeds from issuance of common stock pursuant to at-the-market issuance	819	—
Issuance cost of at-the-market transactions	(33)	—
Proceeds from market price stock purchase plan	335	—
Net cash provided by financing activities	25,327	15,319
NET DECREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(37,382)	(2,803)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	48,355	22,895
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 10,973	$ 20,092
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash, net of amounts capitalized	$ 2,895	$ 6,373
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Payment of note obligations through common stock issuance	$ 42,912	$ 11,000
Payment of note payable to related party through common stock issuance	$ 8,160	$ —
Capitalization of interest on note payable to related party	$ —	$ 10,716
Accrued but unpaid debt issuance costs	$ 146	$ —
Reclassification of warrant liability to Additional paid-in capital	$ —	$ 1,893

See notes to condensed consolidated financial statements.

1. Description of Business and Significant Accounting Policies

The accompanying unaudited condensed consolidated financial statements of MannKind Corporation and its subsidiaries ("MannKind," the "Company," "we" or "us"), 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, 2017 filed with the SEC on February 27, 2018 (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. The results of operations for the three and nine months ended September 30, 2018 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. Management considers many factors in selecting appropriate financial accounting policies, and in developing the estimates and assumptions that are used in the preparation of the financial statements. Management must apply significant judgment in this process. The more significant estimates reflected in these accompanying condensed consolidated financial statements include revenue recognition and gross-to-net adjustments, product return, assessing long-lived assets for impairment, clinical trial expenses, inventory costing and recoverability, recognized loss on purchase commitments, milestone rights liability, stock-based compensation and the determination of the provision for income taxes and corresponding deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets.

Business — MannKind is a biopharmaceutical company focused on the development and commercialization of inhaled therapeutic products for diseases such as diabetes and pulmonary arterial hypertension. The Company's only approved product, Afrezza (insulin human) Inhalation Powder, is a rapid-acting inhaled insulin that was approved by the U.S. Food and Drug Administration (the "FDA") in June 2014 to improve glycemic control in adults with diabetes. Afrezza became available by prescription in United States retail pharmacies in February 2015. Currently, the Company promotes Afrezza to endocrinologists and certain high-prescribing primary care physicians in the United States through its own specialty sales force. Outside of the United States, subject to receipt of the necessary foreign regulatory approvals, the Company's strategy is to establish regional partnerships for the commercialization of Afrezza in foreign jurisdictions where there are commercial opportunities.

Basis of Presentation - The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company is not currently profitable and has rarely generated positive net cash flow from operations. As of September 30, 2018, the Company had an accumulated deficit of $2.9 billion. In order to conform to the 2018 presentation in the Statement of Cash Flows, we reclassified approximately $1.8 million from changes in inventory to inventory write-off in 2017 and $0.2 million from other to loss on sale, abandonment/disposal or impairment of property and equipment in 2017.

At September 30, 2018, the Company's capital resources consisted of cash and cash equivalents of $10.4 million and $0.5 million of restricted cash. The Company expects to continue to incur significant expenditures to support commercial manufacturing, sales and marketing of Afrezza, collaboration work and the development of product candidates in the Company's pipeline. The facility agreement (as amended, the "Facility Agreement") with Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (collectively, "Deerfield") that resulted in the issuance of 9.75% Senior Convertible Notes due 2019 ("2019 notes") and 8.75% Senior Convertible Notes due 2019 ("Tranche B notes") (see Note 7 — Borrowings) requires the Company to maintain at least $20.0 million in cash and cash equivalents as of October 31, 2018 and December 31, 2018 and $25.0 million in cash and cash equivalents as of the end of each fiscal quarter after December 31, 2018.

As of September 30, 2018, the Company had $104.7 million principal amount of outstanding borrowings. The Company entered into certain transactions related to these borrowings during 2017 and 2018 that are more fully described in Note 6 — Related-Party Arrangements, Note 7 – Borrowings.

The Company's currently available cash and financing sources will not be sufficient to continue to meet its current and anticipated cash requirements. The Company plans to raise additional capital, whether through a sale of equity or debt securities, strategic business collaboration agreements with other companies, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to continue the development and commercialization of Afrezza and other product candidates and to support its other ongoing activities. The Company cannot provide assurances that such additional capital will be available on acceptable terms or at all. Successful completion of these plans is dependent on factors outside of the Company's control. As such, management cannot be certain that such plans will be effectively implemented within one year after the date that the financial statements are issued. These factors raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Reverse Stock-Split - On March 1, 2017, following stockholder approval, the Company's board of directors approved a 1-for-5 reverse stock split of the Company's outstanding common stock. On March 1, 2017, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment of the Company's Amended and Restated Certificate of Incorporation (the "Charter Amendment") to effect the 1-for-5 reverse stock split of the Company's outstanding common stock (the "Reverse Stock Split") . The Company's common stock began trading on the Nasdaq Global Market on a split-adjusted basis when the market opened on March 3, 2017.

As a result, prior to March 3, 2017, all common stock share amounts included in these condensed consolidated financial statements have been retroactively reduced by a factor of five, and all common stock per share amounts have been increased by a factor of five, with the exception of the Company's common stock par value.

Principles of Consolidation – The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. Intercompany balances and transactions have been eliminated.

Segment Information – Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as one segment operating in the United States of America.

Revenue Recognition — The Company adopted Accounting Standards Codification ("ASC") Topic 606 - *Revenue from Contracts with Customers* ("the new revenue guidance"), on January 1, 2018. Under Topic 606, the Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services. See below for more information about the impact of adoption of the new revenue guidance.

To determine revenue recognition for arrangements that are within the scope of Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract under Topic 606, including when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company has three types of contracts with customers: contracts with wholesale distributors and specialty pharmacies for commercial product sales, collaboration arrangements, and arrangements with parties to whom it has sold intellectual property.

Revenue Recognition – Net Revenue – Commercial Product Sales – The Company sells Afrezza to a limited number of wholesale distributors and specialty pharmacies in the U.S. (collectively, its "Customers"). These Customers subsequently resell the Company's product to retail pharmacies and certain medical centers or hospitals. Specialty pharmacies sell directly to patients. In addition to distribution agreements with Customers, the Company enters into arrangements with health care providers and payors that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's product.

The Company recognizes revenue on product sales when the Customer obtains control of the Company's product, which occurs at a point in time (based on the terms of the relevant contracts which are at delivery for wholesale distributors and at shipment for specialty pharmacies). Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

Voucher Program – Under the voucher program, potential new patients are given vouchers which they can provide to retailers for a free product. The retailers provide the product to the patient for free and pay the wholesaler for the product, who pays the Company. The retailers submit the vouchers to a program administrator who pays the retailer for the product. The administrator then invoices the Company for the amount of vouchers paid plus a fee. Accordingly, on a net basis, it is not probable that the Company will receive the consideration to which it is entitled from the sale of product under the voucher program. Therefore, the Company excludes such amounts from both gross and net revenue. The cost of product associated with the voucher program is included in cost of goods sold.

Reserves for Variable Consideration — Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its Customers, payors, and other indirect customers relating to the Company's sale of its product. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and result in a reduction of accounts receivable or establishment of a current liability.

Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reduce recognized revenue to the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplate application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of September 30, 2018 and, therefore, the transaction price was not reduced further during the nine months ended September 30, 2018. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net revenue – commercial product sales and earnings in the period such variances become known.

Trade Discounts and Allowances — The Company generally provides Customers with discounts which include incentive fees, such as prompt pay discounts, that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company compensates (through trade discounts and allowances) its Customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of product to the Customers and, therefore, these payments have been recorded as a reduction of revenue and a reduction to accounts receivable, net.

Product Returns — Consistent with industry practice, the Company generally offers Customers a right of return for unopened product that has been purchased from the Company for a period beginning six months prior to and ending twelve months after its expiration date, which lapses upon shipment to a patient. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as reductions to accounts receivable, net. The Company currently estimates product returns using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company's current return reserve rate is estimated to be 3.8%.

Provider Chargebacks and Discounts — Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is recorded in accrued expenses and other current liabilities. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that Customers have claimed, but for which the Company has not yet issued a credit.

Government Rebates — The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Payor Rebates — The Company contracts with certain private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities.

Other Incentives — Other incentives which the Company offers include voluntary patient support programs, such as the Company's co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities.

As of December 31, 2017, prior to the adoption of Topic 606, the ending balance for net deferred revenue, was $3.0 million, on the Company's condensed consolidated balance sheets, which is presented net of $1.5 million in gross-to-net revenue adjustments. On January 1, 2018, deferred revenue was adjusted to zero as a result of the adoption of Topic 606 as disclosed below. For the three and nine months ended September 30, 2018, shipments to three wholesale distributors represented 90% and 89%, respectively, of total shipments, compared with 92% for each of the same two periods in 2017.

Revenue Recognition – Net Revenue – Collaborations — The Company enters into out-licensing agreements under which the Company licenses certain rights to its product candidates to third parties. The terms of these arrangements may include payment to the Company of one or more of the following: non-refundable, up-front license fees; development, regulatory, and commercial milestone payments; payments for manufacturing supply services the Company provides; and royalties on net sales of licensed products and sublicenses of the rights. Each of these payments may result in license, collaborations, or other revenue, except revenue from royalties on net sales of licensed products, which would be classified as royalty revenue.

As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success.

Licenses of Intellectual Property — If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company will evaluate the measure of progress for each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Revenue from licenses of intellectual property is included in Net revenue - collaborations in the condensed consolidated statement of operations.

Milestone Payments — At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the customer, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as, or when, the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaborations, other revenue, and earnings in the period of adjustment.

Manufacturing Supply Services — Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply, at the customer's discretion, are generally considered as options. The Company assesses if these options provide a material right to the licensee and, if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the licensee exercises these options, any additional payments are recorded in license, collaborations, or other revenue when the customer obtains control of the goods, which is upon delivery.

Royalties — For licensing arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all the royalty has been allocated has been satisfied (or partially satisfied). For sales of intellectual property that include sales-based royalties, the Company estimates the amount of variable consideration that it will receive from the sales-based royalty. The Company has not recognized any royalty revenue in 2017 or 2018 resulting from the sale of its intellectual property which is more fully described in Note 9, Sale of Intellectual Property.

Revenue Recognition — Revenue — Other — Revenue-other consists of revenue from revenue from research and development work on behalf of a third party as well as bulk insulin sales. For the nine months ended September 30, 2017, revenue – other consists of $2.3 million of revenue from bulk insulin sales and sale of intellectual property to Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. ("Fosun") which is more fully described in Note 9 – Sale of Intellectual Property.

Cost of Goods Sold — A significant component of cost of goods sold is current period manufacturing costs in excess of costs capitalized into inventory (excess capacity costs). These costs, in addition to the impact of the annual revaluation of inventory to standard costs (and the annual revaluation of deferred costs of commercial sales to standard costs in 2017), and write-offs of inventory (and write-offs of deferred costs of commercial sales in 2017) are recorded as expenses in the period in which they are incurred, rather than as a portion of inventory costs. Cost of goods sold also includes the standard cost related to Afrezza sold during the period and related variances and realized currency gain or loss in connection with the Amphastar insulin contract. The cost of goods sold also excludes the write off of cost of insulin held in inventory at the end of 2015.

Restricted Cash – The Company records restricted cash when cash and cash equivalents are restricted as to withdrawal or usage. The Company presents amounts of restricted cash that will be available for use within 12 months of the reporting date as restricted cash in current assets. Restricted cash amounts that will not be available for use in the Company's operations within 12 months of the reporting date are presented as restricted cash in long term assets.

Accounts Receivable and Allowance for Doubtful Accounts — Accounts receivable are recorded at the invoiced amount and are not interest bearing. Accounts receivable are presented net of an allowance for doubtful accounts if there are estimated losses resulting from the inability of its customers to make required payments. The Company makes ongoing assumptions relating to the collectability of its accounts receivable in its calculation of the allowance for doubtful accounts. Accounts receivable are also presented net of an allowance for product returns and trade discounts and allowances because the Company's customers have the right of setoff for these amounts against the related accounts receivable.

Inventories — Inventories are stated at the lower of cost or net realizable value. The Company determines the cost of inventory using the first-in, first-out, or FIFO, method. The Company capitalizes inventory costs associated with the Company's products based on management's judgment that future economic benefits are expected to be realized; otherwise, such costs are expensed as incurred as cost of goods sold. The Company periodically analyzes its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value and writes down such inventories, as appropriate. In addition, the Company's products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or may become obsolete or are forecasted to become obsolete due to expiration, the Company will record a charge to write down such unmarketable inventory to its estimated net realizable value. The cost of goods sold also excludes the write off of insulin held in inventory at the end of 2015.

Leases – The Company records rent expense for leases that contain scheduled rent increases on a straight-line basis over the lease term which begins with the point at which the Company obtains control and possession of the leased property.

Recognized Loss on Purchase Commitments — The Company assesses whether losses on long term purchase commitments should be accrued. Losses that are expected to arise from firm, non-cancellable, commitments for the future purchases are recognized unless recoverable. When making the assessment, the Company also considers whether it is able to renegotiate with its vendors. The recognized loss on purchase commitments is reduced as inventory items are received. If, subsequent to an accrual, a purchase commitment is successfully renegotiated, the gain is recognized in the Company's consolidated statement of operations. The liability balance of the recognized loss on purchase commitments is $100.4 million as of September 30, 2018. No new contracts were identified in 2018 or 2017 that required a new loss on purchase commitment accrual.

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:

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.

Contingencies — The Company records a loss contingency for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These accruals represent management's best estimate of probable loss. Disclosure also is provided when it is reasonably possible that a loss will be incurred or when it is reasonably possible that the amount of a loss will exceed the recorded provision. On a quarterly basis, the Company reviews the status of each significant matter and assesses its potential financial exposure. Significant judgment is required in both the determination of probability and the determination as to whether an exposure is reasonably estimable. Because of uncertainties related to these matters, accruals are based only on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation and may revise its estimates.

Stock-Based Compensation — Share-based payments to employees, including grants of stock options, restricted stock units, performance-based awards and the compensatory elements of employee stock purchase plans, are recognized in the condensed consolidated statements of operations based upon the fair value of the awards at the grant date subject to an estimated forfeiture rate. The Company uses the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options and the compensatory elements of employee stock purchase plans. Restricted stock units are valued based on the market price on the grant date. 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.

Clinical Trial Expenses — Clinical trial expenses, which are primarily reflected in research and development expenses in the accompanying condensed consolidated statements of operations, result from obligations under contracts with vendors, consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The appropriate level of trial expenses are reflected in the Company's condensed consolidated financial statements by matching period expenses with period services and efforts expended. These expenses are recorded according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. Clinical trial accrual estimates are determined through discussions with internal clinical personnel and outside service providers as to the progress or state of completion of trials, or the services completed. Service provider status is then compared to the contractually obligated fee to be paid for such services. During the course of a clinical trial, the Company may adjust the rate of clinical expense recognized if actual results differ from management's estimates.

Net Income (Loss) Per Share of Common Stock — Basic net income or loss per share excludes dilution for potentially dilutive securities and is computed by dividing net income or loss by the weighted average number of common shares outstanding during the period. Diluted net income or loss per share reflects the potential dilution under the treasury method that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. For periods where the Company has presented a net loss, potentially dilutive securities are excluded from the computation of diluted net loss per share as they would be anti-dilutive.

The computation of basic and diluted net loss per share for the nine months ended September 30, 2018 and 2017 excludes the common stock equivalents of the following potentially dilutive securities because their inclusion would be anti-dilutive:

	September 30,	
	2018	2017
Vesting of restricted stock units	1,169,340	1,147,688
Employee stock purchase plan	97,598	142,888
Exercise of common stock options	11,431,526	7,183,837
Conversion of convertible notes into common stock	3,629,627	814,561
Conversion of convertible related party notes into common stock	21,909,541	—
Exercise of common stock warrants	31,856	31,856
Exercise of warrants associated with direct placement	14,000,000	—
	52,269,488	9,320,830

Impact of Adoption of the New Revenue Guidance – The Company applied the new revenue guidance using the modified retrospective approach to all contracts with the cumulative effect of initial application recognized as of January 1, 2018. Revenue amounts and comparative information prior to this adoption date have not been restated and continue to be accounted for under the previous accounting guidance.

The previous accounting guidance required the Company to reliably estimate returns in order to recognize revenue upon shipment. While the Company could estimate returns within a range, it was not sufficiently precise to meet those requirements. Accordingly, under the previous guidance, the Company deferred recognition of revenue on Afrezza product deliveries to wholesalers until the right of return no longer existed, which occurred at the earlier of the time Afrezza was dispensed from pharmacies to patients or expiration of the right of return. Therefore, for deliveries to wholesalers, the Company recognized revenue based on estimated Afrezza patient prescriptions dispensed, a sell-through model.

Upon adoption of the new revenue guidance, the Company moved from the sell-through model to a sell-to model for revenue related to commercial sales of Afrezza to wholesalers and now records revenue when its customers take control of the product along with an estimate of potential returns as variable consideration. For sales of Afrezza to specialty pharmacies, the Company previously recognized revenue at the time of shipment because specialty pharmacies generally purchase on demand and estimated returns are minimal. Therefore, there was no impact upon adoption for sales to specialty pharmacies.

Additionally, the Company has historically entered into collaborative agreements and sales of intellectual property to third parties under which periodic payments have been received. In February 2017, the FASB issued ASU 2017-05 *Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets to ASC Subtopic 610-20, Other Income-Gains and Losses from the Derecognition of Nonfinancial Assets* which further clarified the new revenue recognition guidance under ASC Topic 606. The Company adopted the guidance on January 1, 2018 using the modified retrospective method. There was no impact upon adoption related to these arrangements. These transactions are more fully described in Note 8 - Collaborative Arrangements and Note 9 - Sale of Intellectual Property.

The cumulative effect of the changes made to the condensed consolidated January 1, 2018 balance sheet for the adoption of the new revenue guidance was as follows (in thousands):

	Balance at December 31, 2017	Adjustments due to new revenue guidance	Balance at January 1, 2018
Assets			
Accounts receivable, net	$ 2,789	$ (111) (1)	$ 2,678
Deferred costs from commercial product sales	405	(405) (2)	—
Liabilities			
Accrued expenses and other current liabilities	$ 12,449	$ 649 (3)	$ 13,098
Deferred revenue, net	3,038	(3,038) (4)	—
Equity			
Accumulated deficit	$ (2,854,898)	$ 1,873 (5)	$ (2,853,025)

(1) To establish a reserve for product returns
(2) To eliminate deferred costs from commercial product sales previously required by the sell-through method
(3) To record additional accrual for estimated voucher payments related to inventory remaining in the distribution channel at January 1, 2018
(4) To eliminate deferred revenue previously required by the sell-through method
(5) To record the net impact of (1)-(4) in opening accumulated deficit

In accordance with the new revenue guidance, the disclosure of the impact of adoption on the condensed consolidated balance sheet and the condensed consolidated statement of operations and cash flows was as follows (in thousands):

Condensed Consolidated Balance Sheet

	For the nine months ended September 30, 2018		
	As Reported	Adjustments	Balances without adoption of Topic 606
Assets			
Accounts receivable, net	$ 2,752	$ 417	$ 3,169
Deferred costs from commercial product sales	—	763	763
Liabilities			
Accrued expenses and other current liabilities	$ 13,434	$ (588)	$ 12,846
Deferred revenue, net	—	3,601	3,601
Equity			
Accumulated deficit	$ (2,930,249)	$ (1,833)	$ (2,932,082)

Condensed Consolidated Statement of Operations

	For the nine months ended September 30, 2018		
	As Reported	Adjustments	Balances without adoption of Topic 606
Revenue			
Net revenue - commercial product sales	$ 11,542	$ (778)	$ 10,764
Expenses			
Cost of goods sold	$ 14,406	$ (975)	$ 13,431
Net loss	(77,224)	(196)	(77,420)

	For the three months ended September 30, 2018		
	As Reported	Adjustments	Balances without adoption of Topic 606
Revenue			
Net revenue - commercial product sales	$ 4,387	$ (654)	$ 3,733
Expenses			
Cost of goods sold	$ 5,303	$ (790)	$ 4,513
Net loss	(24,168)	(137)	(24,305)

	For the nine months ended September 30, 2018		
	As Reported	Adjustments	Balances without adoption of Topic 606
Cash Flows from Operating Activities			
Net loss	(77,224)	$ (196)	$ (77,420)
Change in:			
Accounts receivable, net	(74)	111	37
Deferred costs from commercial product sales	—	358	358
Accrued expenses and other current liabilities	560	(588)	(28)
Deferred revenue, net	—	(563)	(563)
Cash (used in) provided by operating activities	(62,719)	(878)	(63,597)

Recently Issued Accounting Standards – From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's condensed consolidated financial position or results of operations upon adoption.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842*). The new standard requires that all leasees recognize the assets and liabilities that arise from operating leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The new standard will be effective on January 1, 2019 and will result in an increase of assets and liabilities of approximately $6.0 million.

On June 20, 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock-based compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting*. The new standard simplifies the account for share-based payments made to nonemployees for goods and services as most of the new guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The new standard will be effective for interim and annual reporting periods beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact that the adoption of this ASU will have on its condensed consolidated financial statements.

2. Accounts Receivable

Accounts receivable, net consists of the following (in thousands):

	September 30, 2018	December 31, 2017
Accounts receivable, gross	$ 3,944	$ 2,842
Wholesaler distribution fees and prompt pay discounts	(775)	(53)
Reserve for returns	(417)	—
Accounts receivable, net	$ 2,752	$ 2,789

As of December 31, 2017 the Company did not have a return reserve as the Company was on the sell-through method (as described in Note 1 – Description of Business and Significant Accounting Policies).

As of September 30, 2018 and December 31, 2017, the allowance for doubtful accounts was *de minimis*. As of September 30, 2018 and December 31, 2017, the Company had three wholesale distributors representing approximately 94% and 93% of gross accounts receivable, respectively.

3. Inventories

Inventories consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 951	$ 572
Work-in-process	732	1,273
Finished goods	1,102	812
Total inventory	$ 2,785	$ 2,657

Work-in-process and finished goods as of September 30, 2018 and December 31, 2017 include conversion costs but not all material costs because much of the materials used in its production were previously written off.

The Company analyzed its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value. The Company performed an assessment of projected sales and evaluated the lower of cost or net realizable value and the potential excess inventory on hand at September 30, 2018. For the three and nine months ended September 30, 2018 the Company recorded a $1.0 million and $1.8 million write-off, respectively.

4. Property and Equipment

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

	Estimated Useful Life (Years)	September 30, 2018	December 31, 2017
Land	—	$ 875	$ 875
Buildings	39-40	17,389	17,389
Building improvements	5-40	34,957	34,957
Machinery and equipment	3-15	62,615	62,681
Furniture, fixtures and office equipment	5-10	3,106	3,556
Computer equipment and software	3	8,416	8,416
		127,358	127,874
Less accumulated depreciation		(101,726)	(100,952)
Total property and equipment, net		$ 25,632	$ 26,922

Depreciation expense related to property and equipment for the three and nine months ended September 30, 2018 and 2017 was as follows (in thousands):

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Depreciation Expense	$ 404	$ 454	$ 1,289	$ 1,350

During the nine months ended September 30, 2018, the Company disposed of $0.5 million of certain fully depreciated furniture, fixtures and office equipment which were no longer in service. Therefore, the cost and associated accumulated depreciation for these items were removed from the balance sheet.

5. Accrued Expenses and Other Current Liabilities

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

	September 30, 2018	December 31, 2017
Salary and related expenses	$ 7,358	$ 7,260
Current portion of milestone rights liability	1,643	1,643
Professional fees	830	1,007
Discounts and allowances for commercial product sales	1,868	873
Sales and marketing services	162	147
Restructuring	—	362
Accrued interest	767	567
Other	806	590
Accrued expenses and other current liabilities	$ 13,434	$ 12,449

Accrued salary and related expenses includes $0.5 million in selling, general and administrative costs related to transitioning certain corporate support functions from Connecticut to the corporate headquarters in California.

6. Related Party Arrangements

Related party debt consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Principal amount	$ 71,506	$ 79,666
Unamortized premium	699	—
Unaccreted debt issuance costs	(62)	—
Net carrying amount	$ 72,143	$ 79,666

In October 2007, the Company entered into a loan arrangement (the “Mann Group Loan Arrangement”) with The Mann Group LLC (the “The Mann Group”), which has been amended from time to time. At that time, Alfred Mann, the Company’s then Chairman and Chief Executive Officer, was the managing member of The Mann Group LLC. On October 31, 2013, the promissory note underlying the Mann Group Loan Arrangement, described in the Company’s condensed consolidated balance sheets as Note Payable to Related Party, 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 Mann Group Loan Arrangement to December 31, 2019, increase the aggregate borrowing amount under the Mann Group Loan Arrangement from $350.0 million to $370.0 million and provide that repayments or cancellations of principal under the Mann Group Loan Arrangement will not be available for reborrowing. At various times over the years that the Mann Group Loan Arrangement has been outstanding, the Company and The Mann Group have agreed to exchange portions of the outstanding principal for shares of the Company’s common stock.

On June 27, 2017, the Company entered into an agreement with The Mann Group, pursuant to which the parties agreed to, among other things, (i) capitalize $10.7 million of accrued and unpaid interest as of June 30, 2017, resulting in such amount being classified as outstanding principal under The Mann Group Loan Arrangement; (ii) advance to the Company approximately $19.4 million of cash, the remaining amount available for borrowing by the Company under The Mann Group Loan Arrangement after the foregoing capitalization of accrued and unpaid interest; and (iii) defer all interest payable on the outstanding principal until July 1, 2018, unless such payments are otherwise permitted under the subordination agreement with Deerfield, and subject to further deferral pursuant to the terms of the subordination agreement with Deerfield which terms are more fully disclosed below.

On March 11, 2018, the Company amended and restated the Mann Group Loan Arrangement with The Mann Group to, among other things, (i) reflect the current outstanding principal balance of the existing loan of $71.5 million, after giving effect to the partial cancellation of principal in exchange for shares of the Company’s common stock described below; (ii) extend the maturity date of the loan to July 1, 2021; (iii) for periods beginning after April 1, 2018 require interest to compound quarterly; and (iv) permit the principal and any accrued and unpaid interest under the Mann Group Loan Arrangement to be converted, at the option of The Mann Group, at any time on or prior to close of business on the business day immediately preceding the stated maturity date, into shares of the Company’s common stock. The conversion rate of 250 shares per $1,000 principal amount of the Note, which is equal to $4.00 per share subject to adjustment under certain circumstances as described in the Mann Group Loan Arrangement.

The Company analyzed this amendment and concluded that the transaction represented an extinguishment of the related party note and recorded a $0.8 million loss on extinguishment of debt. As a result of the extinguishment the Company recorded a debt premium of $0.7 million and debt issuance costs of $0.1 million during the nine months ended September 30, 2018.

On March 11, 2018, the Company and The Mann Group entered into a common stock purchase agreement pursuant to which the Company agreed to issue to The Mann Group and The Mann Group agreed to purchase 3,000,000 shares of the Company's common stock at a price per share of $2.72, which represented the closing price of the Company's common stock on March 9, 2018. As payment for the purchase price for the shares, The Mann Group agreed to cancel $8.2 million in principal amount under the Mann Group Loan Arrangement, with the principal payment to be reflected in the amended and restated Mann Group Loan Arrangement. The purchased shares were issued in a private placement.

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. Under the agreement, accrued and unpaid interest may be paid-in-kind. 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 $113.2 million aggregate principal amount that has been cancelled in connection with three 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 Mann Group 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 Mann Group 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 Mann Group Loan Arrangement are unsecured. The Mann Group Loan Arrangement contains no financial covenants.

As of September 30, 2018 and December 31, 2017, the Company had accrued unpaid interest related to the above note of $5.7 million and $2.3 million, respectively. As of September 30, 2018 and December 31, 2017 there were no additional amounts available for future borrowings. Interest expense (excluding the amortization of debt premium and debt issuance costs) for the three and nine months ended September 30, 2018 and 2017 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Interest expense on note payable to related party	$ 1,074	$ 1,173	$ 3,234	$ 2,608

Amortization of the premium and accretion of debt issuance costs related to the related party notes for the three and nine months ended September 30, 2018 and 2017 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Amortization of debt premium	$ 59	$ —	$ 125	$ —
Accretion expense - debt issuance cost	$ 6	$ —	$ 13	$ —

In May 2015, the Company entered into a sublease agreement with the Alfred Mann Foundation for Scientific Research (the "Mann Foundation"), a California not-for-profit corporation. The lease was for approximately 12,500 square feet of office space in Valencia, California, which expired in April 2017 and was renewed on a month-to-month basis at a rate of $20,000 per month until August 31, 2017 at which time the Company moved into its new corporate headquarters in Westlake Village, California (see Note 12 — Commitments and Contingencies). Lease Payments to the Mann Foundation for the three and nine months ended September 30, 2017 were $40,000 and $161,000, respectively.

The Company has entered into indemnification agreements with each of its directors and executive officers, in addition to the indemnification provided for in its amended and restated certificate of incorporation and amended and restated bylaws (see Note 12 —Commitments and Contingencies).

On October 10, 2017, the Company entered into securities purchase agreements with certain institutional investors and a charitable foundation. Included in this offering were 166,600 shares at a purchase price of $6.00 per share issued to the Kresa Family Foundation, of which Kent Kresa, the Company's Chairman of the Board, is the President.

7. Borrowings

Borrowings consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Facility Financing Obligation (2019 Notes and Tranche B Notes)		
Principal amount	$ 14,495	$ 54,407
Unamortized debt issuance costs and debt discount	(293)	(1,662)
Net carrying amount	$ 14,202	$ 52,745
Senior Convertible Notes (2021 Notes)		
Principal amount	$ 18,690	$ 23,690
Unamortized debt issuance costs and debt premium	443	721
Net carrying amount	$ 19,133	$ 24,411
Note payable to related party - net carrying amount	$ 72,143	$ 79,666
Total debt - net carrying amount	$ 105,478	$ 156,822

In addition to the Mann Group Loan Arrangement described in Note 6, as of September 30, 2018, the Company's outstanding borrowings consisted of $18.7 million principal amount of the Senior Convertible Notes due 2021 bearing interest at 5.75% per annum and maturing on October 23, 2021, as well as $14.5 million principal amount of the Facility Financing Obligation, which is comprised of the following:

- A principal amount of $12.0 million of 2019 notes bearing interest at 9.75% per annum. Interest is payable in cash quarterly in arrears in the last business day of March, June, September and December of each year. As of September 30, 2018, the principal amounts due and payable were as follows: $3.0 million at the earlier of October 31, 2018 or the first business day following the date the Company receives a specified payment from United Therapeutics Corporation ("United Therapeutics") as described below and $9.0 million in July 2019, and
- A principal amount of $2.5 million of Tranche B notes due and payable in May 2019 and bearing interest at 8.75% per annum. Interest is payable in cash quarterly in arrears on the last business day of March, June, September and December of each year.

These borrowings are further described below:

Facility Financing Obligation (2019 Notes and Tranche B notes) – The Facility Financing Obligation was initially entered into in 2013 between the Company and Deerfield through the issuance of multiple tranches of notes that provided for aggregate borrowings of $120.0 million in 2019 notes and $20.0 million in Tranche B notes. As individual tranches have neared their maturity dates, the Company has repaid such tranches in whole or in part or agreed with Deerfield to exchange all or a portion of the outstanding principal for shares of the Company's common stock as described more fully below.

On April 18, 2017, the Company entered into an Exchange Agreement with Deerfield pursuant to which the Company agreed to, among other things, (i) repay $4.0 million principal amount under the Tranche B notes; (ii) exchange $1.0 million principal amount under the Tranche B notes for 869,565 shares of the Company's common stock (the "Tranche B Exchange Shares"); and (iii) exchange $5.0 million principal amount under the 2019 notes for 4,347,826 shares of the Company's common stock (together with the "Tranche B Exchange Shares," the "April Exchange Shares"). The exchange price for the April Exchange Shares was at a discounted price of $1.15 per share.

The Company determined that, since the principal amount repaid and exchanged under the Tranche B notes and the principal amount exchanged under the 2019 notes represented the principal amount that would have otherwise become due and payable in May and July of 2017 under the Tranche B notes and 2019 notes, respectively, the extinguishment of the May and July 2017 payments was not considered to be a troubled debt restructuring. Accordingly, the Company accounted for the transaction by recording a loss on extinguishment of debt of $0.3 million at April 18, 2017 which was calculated as the difference between the reacquisition price and the net carrying value of the related debt. The reacquisition price was calculated using the $4.0 million cash repayment and the fair value of the April Exchange Shares on April 18, 2017. The fair value of the April Exchange Shares was determined to be $1.22 per share, which represents the closing price of the Company's common stock on April 18, 2017.

On June 29, 2017, the Company entered into the Third Amendment to the Facility Agreement with Deerfield, pursuant to which the Company agreed to, among other things, (i) exchange $5.0 million principal amount under the Company's 2019 notes for 3,584,230 shares of the Company's common stock (the "June Exchange Shares") at an exchange price of $1.395 per share and (ii) amend the Facility Agreement, to (A) defer the payment of $10.0 million in principal amount of the 2019 notes from the original July 18, 2017 due date to August 31, 2017, which was further deferred to October 31, 2017 upon the Company's delivery on August 31, 2017 and October 30, 2017 of a written certification to Deerfield that certain conditions had been met, including that no event of default under the Facility Agreement had occurred, Michael E. Castagna remains the Company's Chief Executive Officer, the Company received the advance from The Mann Group (see Note 6 — Related-Party Arrangements), the Company had at least $10.0 million in cash and cash equivalents on hand, no material adverse effect on the Company had occurred, the engagement letter between the Company and Greenhill & Co., Inc. ("Greenhill") remained in full force and effect and Greenhill had remained actively engaged in exploring capital structure and financial alternatives on behalf of the Company in accordance with such engagement letter (collectively, the "Extension Conditions"), and (B) amend the Company's financial covenant under the Facility Agreement to provide that, if the Extension Conditions remain satisfied, the obligation under the Facility Agreement to maintain at least $25.0 million in cash and cash equivalents as of the end of each quarter was reduced to $10.0 million as of August 31, 2017, September 30, 2017, October 31, 2017 and December 31, 2017 if certain conditions were met. We met the conditions at each of these month-ends.

The Company determined that the principal amount repaid and exchanged under the 2019 notes represented the principal amount that would have otherwise become due and payable under the 2019 notes. As a result, the $5.0 million prepayment was not considered to be a troubled debt restructuring. Accordingly, the Company accounted for the transaction by recording a loss on extinguishment of debt of $0.5 million on June 29, 2017 which was calculated as the difference between the reacquisition price and the net carrying value of the related debt. The net carrying value of the related debt includes the acceleration of the debt discount and issuance costs amounting to approximately $0.3 million as a result of the transaction. The reacquisition price was calculated using the fair value of the June Exchange Shares on June 29, 2017. The fair value of the June Exchange Shares was determined to be $1.45 per share which represented the closing price of the Company's common stock on June 29, 2017.

On October 23, 2017, the Company entered into a Fourth Amendment to the Facility Agreement with Deerfield, pursuant to which the parties (i) deferred the payment of $10.0 million in principal amount (the "October Payment") of the Facility Financing Obligation from October 31, 2017 to January 15, 2018, with the Company depositing an amount of cash equal to the October Payment into an escrow account until the October Payment has been satisfied in full (subject to early release to the extent that portions of the October Payment are satisfied through the exchange of principal for shares of the Company's common stock), and (ii) amended and restated the Facility Financing Obligation and the Tranche B notes to provide that Deerfield may convert the principal amount under such notes from time to time into an aggregate of up to 4,000,000 shares of the Company's common stock after the effective date of the Fourth Amendment. The conversion price will be the greater of (i) the average of the volume weighted average price per share of the Company's common stock for the three trading day period immediately preceding the date of any election by Deerfield to convert principal amounts of such notes and (ii) $3.25 per share, subject to adjustment under certain circumstances. Any conversions of principal by Deerfield under such notes will be applied first to reduce the October Payment, and after the October Payment has been satisfied, to reduce other principal payments due.

The Company determined that the Fourth Amendment did not include any concessions and that the addition of the conversion option was not substantive and therefore it was not considered to be a troubled debt restructuring. Accordingly, the Company accounted for the transaction as a modification. On November 6, 2017 Deerfield converted 1,720,846 shares under the conversion feature at a price of $3.25 per share, redeeming $5.6 million of principal amount.

On January 15, 2018, the Company entered into a Fifth Amendment to the Facility Agreement with Deerfield, pursuant to which the parties deferred the payment date for the $4.4 million remaining October 2017 Tranche 4 Principal Payment from January 15, 2018 to January 19, 2018. Concurrent with this amendment the Company entered into a First Amendment to Escrow Agreement to extend the escrow period to January 19, 2018 to align with the amended payment date under the Fifth Amendment.

On January 18, 2018, the Company entered into an Exchange and Sixth Amendment to Facility Agreement with Deerfield, pursuant to which, among other things, the Company agreed to issue to Deerfield an aggregate of 1,267,972 shares of its common stock, in exchange for $3.2 million of the 2019 notes, an exchange rate of $2.49 per share. In addition, the parties deferred the payment date for the $1.3 million remaining principal amount of the 2019 notes (the "Remaining Payment") from January 19, 2018 to May 6, 2018.

The Company and Deerfield also amended the outstanding 2019 notes and Tranche B notes to provide that Deerfield may, subject to the terms of the Sixth Amendment, convert principal amounts of the 2019 notes and Tranche B notes from time to time into an aggregate of up to 10,000,000 shares of the Company's common stock (excluding the exchange shares issued to Deerfield on January 18, 2018). The conversion price was set at the greater of (i) the average of the volume weighted average price per share of the Company's common stock for the three trading day period immediately preceding the date of any election by Deerfield to convert principal amounts and (ii) $2.75 per share, subject to adjustment under certain circumstances described in the 2019 notes and Tranche B notes. Any conversions of principal will be applied first to reduce the Remaining Payment, and thereafter to reduce other principal payments.

In connection with the Sixth Amendment, the Company also entered into a Second Amendment to Escrow Agreement, dated January 18, 2018, with Deerfield and US Bank, pursuant to which the parties extended the period of the escrow established thereunder to May 6, 2018, corresponding to the extended payment date.

The Company determined that the Fifth and Sixth Amendments did not include any concessions and that the change of the conversion option was not substantive and therefore it was not considered to be a troubled debt restructuring. Accordingly, the Company accounted for the transaction as a modification.

On March 6, 2018 Deerfield converted the remaining $1.3 million of principal amount due under the 2019 notes for 441,618 shares of the Company's common stock. The fair value of these exchange shares was determined to be $2.83 per share representing the average of the volume weighted average price per share of the Company's common stock for the three trading day period immediately preceding the date of the election by Deerfield to convert as reported on the Nasdaq Global Market. The Escrow Agreement with Deerfield and US Bank, was terminated as the required payment was satisfied in full as of March 12, 2018.

On March 12, 2018 the Company entered into an Exchange Agreement with Deerfield pursuant to which the Company agreed to, among other things, exchange $5.0 million of principal amount of the Tranche B notes for 1,838,236 shares of the Company's common stock. The fair value of these exchange shares was determined to be $2.72 per share representing the closing price of the Company's common stock on March 9, 2018 as reported on the Nasdaq Global Market. The principal amount being exchanged under the Tranche B notes represents the principal amount that would have otherwise become due and payable in May 2018.

On June 8, 2018, the Company entered into an Exchange and Seventh Amendment to Facility Agreement with Deerfield, pursuant to which, among other things, (i) the Company issued to Deerfield 3,061,224 shares of the Company's common stock in exchange for the cancellation of (a) $3.0 million of $5.0 million principal amount of 2019 notes that was due and payable on July 1, 2018 and (b) $3.0 million of $5 million principal amount of Tranche B notes that was due and payable on December 31, 2019, (ii) the Company's obligation under the Facility Agreement to maintain at least $25.0 million in cash as of the end of each quarter was reduced to $20 million through December 31, 2018, (iii) the minimum price at which the 2019 notes or Tranche B notes may be converted into shares of the Company's common stock was reduced from $2.75 to $2.01 per share and (iv) the parties agreed that, on or after June 8, 2018, the 2019 notes and Tranche B notes may be converted into a maximum of 9,558,382 shares of the Company's common stock. The fair value of the exchange shares issued to Deerfield on June 8, 2018 was determined to be $1.96 per share, representing the closing price of the Company's common stock on June 8, 2018 as reported on the Nasdaq Global Market.

On July 12, 2018, the Company entered into an Exchange and Eighth Amendment to Facility Agreement with Deerfield, pursuant to which the parties amended the Facility Agreement to, among other things, (i) issue to Deerfield 7,367,839 shares of the Company's common stock in exchange for the cancellation of (a) $7.0 million of $10.0 million principal amount of 2019 notes that was due and payable on July 18, 2018, (b) $3.0 million of $5.0 million principal amount of 2019 notes that was due and payable on December 31, 2019 and (c) $2.0 million of $2.0 million principal amount of Tranche B notes that was due and payable on December 31, 2019, (ii) defer the payment of $3.0 million in principal amount of 2019 notes from July 18, 2018 to August 31, 2018, (iii) reduce the minimum price at which the remaining notes issued under the Facility Agreement may be converted into shares of the Company's common stock from $2.01 to $1.80 per share and (iv) provide that, on or after July 12, 2018, such remaining notes may be converted into a maximum of 5,750,000 shares of the Company's common stock.

On September 5, 2018, the Company entered into a Ninth Amendment to Facility Agreement (the "Ninth Deerfield Amendment") with Deerfield, pursuant to which the parties amended the Facility Agreement to, among other things, further defer the payment of $3.0 million in principal amount of 2019 notes from August 31, 2018 to September 30, 2018.

Following the Ninth Deerfield Amendment, in September 2018 Deerfield converted $8.0 million in principal amount of 2019 notes and $2.5 million in principal amount of Tranche B notes into an aggregate of 5,749,500 shares of the Company's common stock in two transactions on September 6 and September 7, 2018. Accordingly, the Company accounted for the transactions by recording a loss on extinguishment of debt of $0.7 million for the three and nine months ended September 30, 2018 which was calculated as the difference between the reacquisition price and the net carrying value of the related debt. The net carrying value of the related debt includes the acceleration of the debt discount and issuance costs amounting to approximately $0.3 million as a result of the transaction. The fair value of the Exchange Shares was determined to be $2.04 and $1.78 per share representing the closing trading price of the Company's common stock on The Nasdaq Global Market on September 6 and September 7, 2018, respectively.

On September 26, 2018, the Company entered into a Tenth Amendment to Facility Agreement with Deerfield, pursuant to which the parties amended the Facility Agreement, to, among other things, (i) further defer the payment of $3.0 million in principal amount of 2019 notes from September 30, 2018 until the earlier of October 31, 2018 or the first business day following the date the Company receives an upfront payment of $45.0 million from United Therapeutics (See Note 8 – Collaboration Arrangements), and (ii) provide that the Company shall be obligated to maintain at least $20.0 million in cash and cash equivalents as of October 31, 2018 and December 31, 2018 and $25.0 million in cash and cash equivalents as of the end of each fiscal quarter after December 31, 2018. Subsequently, such payment was made to Deerfield on October 18, 2018.

In connection with the Facility Agreement, on July 1, 2013, the Company entered into a Milestone Rights Purchase Agreement (the "Milestone Agreement") with Deerfield and Horizon Santé FLML SÁRL (collectively, the "Milestone Purchasers"), which requires the Company to make contingent payments to the Milestone Purchasers, totaling up to $90.0 million, of which $75.0 million remain payable, upon the Company achieving specified commercialization milestones (the "Milestone Rights").

As of September 30, 2018 and December 31, 2017, the remaining milestone rights liability balance was $8.8 million. The Company currently estimates that it will reach the next milestone in the first quarter of 2019. Accordingly, $1.6 million in value related to the next milestone payment was recorded in accrued expenses and other current liabilities as of September 30, 2018 and December 31, 2017, resulting in $7.2 million being recorded in milestone rights liability, which is non-current, in the accompanying condensed consolidated balance sheets as of September 30, 2018 and December 31, 2017, respectively.

Accretion of debt issuance cost and debt discount during the three and nine months ended September 30, 2018 and 2017, are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Accretion expense - debt issuance cost	$ 14	$ 7	$ 32	$ 39
Accretion expense - debt discount	$ 375	$ 431	$ 1,072	$ 1,564

The Facility Agreement includes customary representations, warranties and covenants, including a restriction on the incurrence of additional indebtedness. As discussed in Note 1 – Description of Business and Summary of Significant Accounting Policies, the Company will need to raise additional capital to support its current operating plans. Due to the uncertainties related to maintaining sufficient resources to comply with the aforementioned covenant, the Facility Financing Obligation has been classified as a current liability in the accompanying condensed consolidated balance sheets as of September 30, 2018 and December 31, 2017. In the event of non-compliance, Deerfield may declare all or any portion of the Facility Financing Obligation to be immediately due and payable.

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 Company has initially recorded the Milestone Rights at their estimated fair value.

In connection with the Facility Agreement and Milestone Agreement, the Company and its subsidiary, MannKind LLC, entered into a Guaranty and Security Agreement (the "Security Agreement") with Deerfield and Horizon Santé FLML SÁRL (collectively, the "Purchasers"), pursuant to which the Company and MannKind LLC each granted the Purchasers a security interest in substantially all of their respective assets, including respective intellectual property, accounts receivables, equipment, general intangibles, inventory and investment property, and all of the proceeds and products of the foregoing. The Security Agreement includes customary covenants by the Company and MannKind LLC, remedies of the Purchasers and representations and warranties by the Company and MannKind LLC. The security interests granted by the Company and MannKind LLC will terminate upon repayment of the Facility Financing Obligation in full, if applicable.

The Company identified and evaluated a number of embedded features in the notes issued under the Facility Agreement to determine if they represented embedded derivatives that are required to be separated from the notes and accounted for as freestanding instruments. The Company analyzed the Tranche B notes and identified embedded derivatives which required separate accounting. All of the embedded derivatives were determined to have a *de minimis* value as of September 30, 2018 and December 31, 2017.

Senior Convertible Notes Due 2021 — On October 23, 2017, the Company entered into exchange agreements with the holders of the Company's 5.75% Senior Convertible Notes due 2018 (the "2018 notes"), pursuant to which the Company agreed to exchange all of the outstanding 2018 notes in the aggregate principal amount of $27.7 million for (i) $23.7 million aggregate principal amount of new 5.75% Senior Convertible notes due 2021 (the "2021 notes") and (ii) an aggregate of 973,236 shares of its common stock. In addition, the conversion rate was adjusted from $34 per share to $5.15 per share. The 2021 notes were issued at the closing of the exchange on October 23, 2017. The Company analyzed this exchange and concluded that the exchange represents an extinguishment of the 2018 notes and recorded a $0.8 million loss on extinguishment of debt during the last quarter of fiscal year 2017. In addition, unamortized debt issuance costs of $0.3 million and unamortized debt premium of $0.2 million were also written-off during the last quarter of fiscal year 2017.

On May 25, 2018, the Company entered into a privately-negotiated exchange agreement (the "Exchange Agreement") with certain holders of its 2021 notes, pursuant to which the Company agreed to issue 2,250,000 shares of its common stock in exchange for the cancellation of $5.0 million principal amount of the 2021 notes and unpaid accrued interest thereon. The exchange price for these exchange shares was approximately $2.2567 per share. The exchange was completed on May 31, 2018. As a result, the Company recognized approximately $0.8 million as extinguishment gain which was calculated based on the difference between the reacquisition price and the net carrying amount of the payment on the debt.

The 2021 notes are the Company's general, unsecured, senior obligations, except that they are subordinated in right of payment to the Facility Financing Obligation. The 2021 notes rank equally in right of payment with the Company's other unsecured senior debt. The 2021 notes bear interest at the rate of 5.75% per year on the principal amount, payable semiannually in arrears in cash or, at the option of the Company if certain conditions are met, in shares of the Company's common stock (the "Interest Shares"), on February 15 and August 15 of each year, beginning February 15, 2018, with interest accruing from August 15, 2017. To date, the interest on the Company's 2021 notes have been paid in cash and in converted shares. The Company converted $0.4 million accrued interest for 475,520 shares and the fair value of the exchange was $1.13 per share, representing the closing price of the Company's common stock on August 14, 2018 per the Nasdaq Global Market. The aggregate number of Interest Shares that the Company may issue may not exceed 13,648,300, unless the Company receives stockholder approval to issue Interest Shares in excess of such a number in accordance with the listing standards of the Nasdaq Global Market. Accrued interest related to these notes is recorded in accrued expenses and other current liabilities on the accompanying condensed consolidated balance sheets.

The 2021 notes are convertible, at the option of the holder, at any time on or prior to the close of business on the business day immediately preceding the stated maturity date, into shares of the Company's common stock at an initial conversion rate of 194.1748 shares per $1,000 principal amount of 2021 notes, which is equal to the conversion price of approximately $5.15 per share. The conversion rate is subject to adjustment under certain circumstances described in an indenture governing the 2021 notes.

If the Company undergoes certain fundamental changes, except in certain circumstances, each holder of 2021 notes will have the option to require the Company to repurchase all or any portion of that holder's 2021 notes. The fundamental change repurchase price will be 100% of the principal amount of the 2021 notes to be repurchased plus accrued and unpaid interest, if any.

The Company may elect at its option to cause all or any portion of the 2021 notes to be mandatorily converted in whole or part at any time prior to the close of business on the business day immediately preceding the maturity date, if the last reported sale price of its common stock exceeds 120% of the conversion price then in effect for at least 10 trading days in any 20 consecutive trading day period, ending within five business days prior to the date of the mandatory conversion notice. The redemption price is equal the sum of 100% of the principal amount of the 2021 notes to be redeemed, plus accrued and unpaid interest. Under the terms of the indenture, the conversion option can be net-share settled and the maximum number of shares that could be required to be delivered under the indenture 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 term of the 2021 notes under existing commitments. Applying the Company's sequencing policy, the Company performed an analysis at the time of the offering of the 2021 notes and each reporting date since and has concluded that the number of available authorized shares at the time of the offering and each reporting date since was sufficient to deliver the number of shares that could be required to be delivered during the term of the 2021 notes under existing commitments.

The 2021 notes provide that upon an acceleration of certain indebtedness, including the 2019 notes and the Tranche B notes issued to Deerfield pursuant to the Facility Agreement, the holders may elect to accelerate the Company's repayment obligations under the notes if such acceleration is not cured, waived, rescinded or annulled.

As a result of the exchange of the 2021 notes during the last quarter of 2017, the Company recorded approximately $0.8 million in debt premium, which is recorded with the 2021 notes, in the accompanying condensed consolidated balance sheets. The premium is being accreted to interest expense using the effective interest method over the term of the 2021 notes.

Amortization of the premium and accretion of debt issuance costs related to the 2021 and 2018 notes for the three and nine months ended September 30, 2018 and 2017 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Amortization of debt premium	$ 35	$ 62	$ 119	$ 182
Accretion expense - debt issuance cost	2	$ 70	$ 2	$ 204

Refer to Note 6 – Related Party Arrangements for information regarding the Note payable to related party.

8. Collaboration Arrangements

United Therapeutics Collaboration Agreement – In September 2018, the Company and United Therapeutics entered into an exclusive global license and collaboration agreement ("the UT License Agreement") for the rights to the Company's dry powder formulation of treprostinil (internally designated as "TreT") and associated inhalation delivery devices. Under the UT License Agreement, United Therapeutics will be responsible for global development, regulatory and commercial activities with respect to TreT. The Company will manufacture clinical supplies and initial commercial supplies of TreT, and long-term commercial supplies will be manufactured by United Therapeutics. As of September 30, 2018, no revenue has been recognized from the UT License Agreement.

Under the terms of the UT License Agreement, the Company received an upfront payment of $45.0 million on October 16, 2018 and may receive potential milestone payments of up to $50.0 million upon the achievement of specified development targets. The Company will also be entitled to receive low double-digit royalties on net sales of TreT. United Therapeutics, at its option, may expand the scope of the products covered by the UT License Agreement to include products with certain other active ingredients for the treatment of pulmonary hypertension. Each such optioned product would be subject to United Therapeutics' payment to the Company of up to $40.0 million in additional option exercise and development milestone payments, as well as a low double-digit royalty on net sales of any such product. The UT License Agreement became effective on October 15, 2018 following the expiration of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

United Therapeutics Research Agreement – In September 2018, the Company and United Therapeutics also entered into a research agreement (the "Research Agreement") for the conduct of research by the Company in connection with multiple potential products, including evaluating the feasibility of preparing a dry powder formulation of a compound for the treatment of pulmonary hypertension outside the scope of the UT License Agreement. In addition, United Therapeutics, at its option, may obtain a license to develop, manufacture and commercialize products based on specified compounds within the drug classes covered by the Research Agreement. Each specified compound advanced into development and commercialization under such a license would be subject to the payment to the Company of additional milestone payments of up to $30.0 million and a low double-digit royalty on net sales of such products. The Company received an upfront payment of $10.0 million, which it will recognize as revenue over time as the performance obligations under the Research Agreement are satisfied. As of September 30, 2018, no revenue has been recognized from the Research Agreement.

Cipla Distribution Agreement — In May 2018, the Company and Cipla Ltd. ("Cipla") entered into an exclusive agreement for the marketing and distribution of Afrezza in India and the Company received a $2.2 million nonrefundable license fee. Under the terms of the agreement, Cipla will be responsible for obtaining regulatory approvals to distribute Afrezza in India and for all marketing and sales activities of Afrezza in India. The Company is responsible for supplying Afrezza to Cipla. The Company has the potential to receive certain additional regulatory milestone payments, minimum purchase commitment revenue and royalties on Afrezza sales in India once cumulative gross sales have reached a specified threshold.

The nonrefundable licensing fee was recorded in deferred revenue and is being recognized in net revenue – collaborations over 15 years, representing the estimated period to satisfy the performance obligation. The additional potential milestone payments represent variable consideration for which the Company has not recognized any revenue because of the uncertainly of obtaining market approval. The Company also recognized $0.2 million as income tax expense for a payment made to the India tax authority.

Biomm Supply and Distribution Agreement – In May 2017, the Company and Biomm S.A. entered into a supply and distribution agreement for the commercialization of Afrezza in Brazil. Under this agreement, Biomm is responsible for preparing and filing the necessary applications for regulatory approval of Afrezza in Brazil, including from the Agência Nacional de Vigilância Sanitária and, with respect to pricing matters, from the Camara de Regulação de Mercado de Medicamentos. Upon satisfactory approval from these regulatory bodies, the parties will finalize the economic terms of the collaboration; thereafter, the Company will manufacture and supply Afrezza to Biomm, and Biomm will be responsible for promoting and distributing Afrezza within Brazil.

Receptor Collaborations and License Agreement — In 2016 the Company entered into a collaboration and license agreement (the "Receptor License") with Receptor Life Sciences, Inc. ("Receptor") pursuant to which Receptor obtained the option to acquire an exclusive license to develop, manufacture and commercialize certain products that use the Company's technology to deliver the compounds via oral inhalation.

On December 30, 2016 Receptor exercised its option and paid the Company a $1.0 million nonrefundable option exercise and license fee. Under the Receptor License, the Company may also receive nonrefundable milestone payments upon the completion of certain technology transfer activities and the achievement of specified sales targets as well as royalties upon Receptor's and its sublicensees' sale of products.

The $1.0 million license fee received in 2016 was recorded in deferred revenue from collaboration as of December 31, 2016 and is being recognized in net revenue — collaborations over four years, the estimated period over which the Company was required to satisfy the remaining performance obligations. The remaining performance obligations are to provide certain technology transfer activities and to maintain certain patents. Deferred payments from collaboration related to this contract was $0.6 million at September 30, 2018 of which $0.3 million was recorded in current liabilities.

The additional payments referred to above represent variable consideration for which the Company has not recognized any revenue because it is uncertain that Receptor will be able to successfully develop, manufacture or sell product related to this license. Therefore, the receipt of such payments is highly susceptible to factors outside of the Company's influence, the uncertainty regarding the receipt of these payments is not expected to be resolved for years, and the Company has limited experience with similar contracts. There was no change to the accounting for this contract as a result of the initial application of the new revenue guidance. See Note 1 – Description of Business and Summary of Significant Accounting Policies for additional information on the Company's revenue recognition accounting policy.

In 2017, the Company entered into a manufacturing and supply agreement with Receptor pursuant to which the Company will provide certain raw materials to Receptor and agreed to provide certain additional research and formulation consulting services to Receptor. For the three and nine months ended September 30, 2018 and 2017 the additional research and formulation services provided to Receptor were *de minimis*.

Sanofi License Agreement and Sanofi Supply Agreement — In 2014 the Company entered into a license and collaboration and supply agreement (the "Sanofi License Agreement") with Sanofi-Aventis U.S. LLC. ("Sanofi"), pursuant to which Sanofi was responsible for global commercial, regulatory and development activities for Afrezza. In 2016, the agreements were terminated and the Company assumed responsibility for the worldwide development and commercialization of Afrezza from Sanofi.

Also in 2016, the Company entered into a settlement agreement with Sanofi. The settlement was accounted for in 2016, except for a $30.6 million cash payment received under an insulin put option agreement which reduced the receivable from Sanofi in the first quarter of 2017.

9. Sale of Intellectual Property

In April, 2017 the Company entered into an agreement to sell certain oncology assets and patents to Shanghai Fosun Pharmaceuticals Industrial Development Co. Ltd. ("Fosun"). Fosun paid the Company a one-time nonrefundable payment of $0.6 million net of taxes in June 2017 and is required to pay royalties on net sales of products by Fosun and its affiliates and other consideration based on revenues from any licensees. The Company accounted for the transaction as a sale of assets. The Company recorded the $0.6 million in payments received in revenue – other during the second quarter of 2017 as the Company had performed substantially all of its obligations as of June 30, 2017. The royalties and other consideration referred to above represent variable consideration for which the Company has not recognized any revenue because it is uncertain whether and in what period Fosun will be able to sublicense this technology or have the ability to develop, manufacture or sell product utilizing this technology. Therefore receipt of such payments is highly susceptible to factors outside the Company's influence, the uncertainty regarding the receipt of these payments is not expected to be resolved for years, and the Company has limited experience with similar contracts.

See Note 1 — Description of Business and Summary of Significant Accounting Policies for additional information on the Company's revenue recognition policies.

10. Fair Value of Financial Instruments

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. The Company uses the exit price method for estimating the fair value of loans for disclosure purposes.

Cash Equivalents and restricted cash— Cash equivalents and restricted cash 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, 2018 and December 31, 2017, the Company held $10.4 million and $48.4 million, respectively, of cash equivalents. For the period ended September 30, 2018, restricted cash was held in an escrow account as well as used to collateralize a letter of credit. The Company held $0.5 million and $4.4 million in restricted cash as of September 30, 2018 and December 31, 2017, respectively. Both are comprised of money market funds. 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).

Note Payable to Related Party — As of December 31, 2017, prior to the adoption of ASC 2016-01, the fair value of the note payable to related party could not be reasonably estimated as the Company was not able to obtain a similar credit arrangement in the current economic environment. Therefore the fair value is based upon carrying value as of December 31, 2017. The fair value measurement of the note payable is sensitive to the change in yield. If the yield changes by approximately 1%, from 10% to 11%, the fair value of the note payable with the conversion feature would change from $83.6 million to $82.1 million, or $1.5 million and -1.8%. Similarly, if the yield changes by approximately 3% from 10% to 13%, the fair value of the note payable with the conversion feature would change from $83.6 million to $79.3 million, or $4.3 million and -5.1%. If the yield changes by approximately 4% from 10% to 14%, the fair value of the note payable with the conversion feature would change from $83.6 million to $78.0 million, or $5.6 million and -6.7%.

Financial Liabilities — The following tables set forth the fair value of the Company's financial instruments as of September 30, 2018 and December 31, 2017 (in millions):

		Fair Value	
September 30, 2018	**Carrying Value**	**Significant Unobservable Inputs (Level 3)**	**Total Fair Value**
Financial liabilities:			
Senior convertible notes (2021 notes)	$ 19.1	$ 19.7	$ 19.7
Facility financing obligation	14.2	11.4	11.4
Note payable to related party	72.1	80.7	80.7
Milestone rights	8.8	19.0	19.0
Total financial liabilities	$ 114.2	$ 130.8	$ 130.8

December 31, 2017	Carrying Value	Fair Value: Significant Unobservable Inputs (Level 3)	Fair Value: Total Fair Value
Financial liabilities:			
Senior convertible notes (2021 notes)	$ 24.4	$ 19.8	$ 19.8
Facility financing obligation	52.7	54.6	54.6
Milestone rights	8.8	19.1	19.1
Total financial liabilities	$ 85.9	$ 93.5	$ 93.5

Milestone Rights Liability — The fair value measurement of the milestone rights liability is sensitive to the discount rate and the timing and probability of making milestone payments. If the achievement of each of the milestones which require payments were to be six months later than in the current forecast, the fair value of the liability would decrease by 7%. If the probabilities of meeting the $50 to $200 million milestones were to decrease by 5% or 10%, the fair value of the liability would decrease by 13% and 25%, respectively. Over the long term, these inputs are interrelated because if the Company's performance improves, the timing of meeting the milestones would likely be earlier, the probability of making payments on the milestones would likely be higher and the discount rate would likely decrease, all of which would increase the fair value of the liability. The inverse is also true.

Embedded Derivatives — The Company identified and evaluated a number of embedded features in the notes issued under the Facility Agreement to determine if they represented embedded derivatives that are required to be separated from the notes and accounted for as freestanding instruments. The Company analyzed the Tranche B notes and identified embedded derivatives, which required separate accounting. All of the embedded derivatives were determined to have a *de minimis* value at September 30, 2018 and December 31, 2017.

11. Stock-Based Compensation Expense

Total stock-based compensation expense recognized in the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2018 and 2017 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Stock-based compensation	$ 1,562	$ 1,247	$ 5,715	$ 3,763

During the three months ended September 30, 2018, the Company granted certain employees stock options to purchase an aggregate of 311,800 shares of common stock at a weighted average exercise price of $1.10 per share. The options vest over a four year period. The grant date fair value of these awards is $0.4 million with a weighted average grant date fair value of $1.39 per share, as determined using a Black-Scholes option pricing model.

As of September 30, 2018, there were $1.9 million and $8.6 million of unrecognized compensation expense related to restricted stock units and options, respectively, that vest over the vesting period.

During the three and nine months ended September 30, 2018, the Company recognized $0.3 million and $1.7 million, respectively, of compensation costs related to the performance-based stock options. As of September 30, 2018, there was $1.6 million of unrecognized compensation costs related to stock options subject to performance conditions. The Company evaluates stock awards with performance conditions as the probability that the performance conditions will be met and uses that information to estimate the date at which those performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period.

12. 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. No such losses have been recorded to date.

Litigation — The Company is subject to legal proceedings and claims which arise in the ordinary course of its business. As of September 30, 2018, 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 and no accrual has been recorded. 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. The Company records 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. The Company's policy is to accrue for legal expenses in connection with legal proceedings and claims as they are incurred.

Following the public announcement of Sanofi's election to terminate the Sanofi License Agreement and the subsequent decline in the Company's stock price, two motions were submitted to the district court at Tel Aviv, Economic Department for the certification of a class action against the Company and certain of its officers and directors. In general, the complaints alleged that the Company and certain of its officers and directors violated Israeli and U.S. securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary damages. In November 2016, the district court dismissed one of the actions without prejudice. In the remaining action, the district court recently ruled that U.S. law will apply to this case. The plaintiff appealed this ruling to the Supreme Court of Israel, which upheld the ruling of the lower court. The Company will vigorously defend against the claims advanced.

Contingencies — In connection with the Facility Agreement, on July 1, 2013, the Company also entered into the Milestone Agreement with the Milestone Purchasers, pursuant to which the Company sold the Milestone Purchasers the Milestone Rights to receive payments up to $90.0 million, of which $75.0 million remain payable, upon the achievement of specified net sales figures (see Note 7 – Borrowings).

Commitments — On July 31, 2014, the Company entered into a supply agreement (the "Insulin Supply Agreement") with Amphastar France Pharmaceuticals S.A.S., a French corporation ("Amphastar"), pursuant to which Amphastar manufactures for and supplies to the Company certain quantities of recombinant human insulin for use in Afrezza. Under the terms of the Insulin Supply Agreement, Amphastar is responsible for manufacturing the insulin in accordance with the Company's specifications and agreed-upon quality standards.

On November 9, 2016, the supply agreement with Amphastar was amended to extend the term over which the Company is required to purchase insulin, without reducing the total amount of insulin to be purchased. Under the amendment, remaining annual minimum quantities of insulin to be purchased for calendar years 2018 through 2023 total an aggregate purchase price of €85.8 million at September 30, 2018. The Insulin Supply Agreement specifies that Amphastar will be deemed to have satisfied its obligations with respect to quantity, if the actual quantity supplied is within plus or minus ten percent (+/- 10%) of the quantity set forth in the applicable purchase order. In addition, the aggregate cancellation fees that the Company would incur in the event that certain insulin quantities are not purchased were reduced from $5.3 million for the period October 1, 2016 through 2018 to $3.4 million over the same period. As of September 30, 2018, the remaining annual purchase requirements under the contract are as follows:

2018	€	4.4 million
2019	€	11.6 million
2020	€	15.5 million
2021	€	15.5 million
2022	€	19.4 million
2023	€	19.4 million

The Company took delivery of the required amount of insulin under the contract in 2017 but was only obligated to pay for half prior to December 31, 2017. Accordingly, approximately $1.6 million was included in accounts payable at December 31, 2017 related to the 2017 purchase commitment, which was paid in January 2018.

Unless terminated earlier, the term of the Insulin Supply Agreement with Amphastar expires on December 31, 2023 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 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 Insulin 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 these two scenarios, the provisions of the Insulin 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. On April 2, 2018, the Company entered into a foreign currency hedging transaction to mitigate its exposure to foreign currency exchange risks. The hedging transaction hedges against short-term currency fluctuations for the remaining current year purchase requirement amount of €4.4 million and is renewable every 90 days. In 2018, the Company realized a currency loss of approximately $0.5 million in the second quarter of 2018 and $0.1 million in the third quarter of 2018. These amounts are recorded in cost of goods sold.

At September 30, 2018, the Company has other firm commitments with suppliers for an aggregate of $0.1 million.

Warrants - On April 5, 2018, the Company entered into securities purchase agreements with certain institutional investors. Pursuant to the terms of the purchase agreements, the Company sold to the purchasers in a registered offering an aggregate of 14,000,000 shares of its common stock and warrants to purchase up to an aggregate of 14,000,000 shares of its common stock at a combined purchase price of $2.00 per share and accompanying warrant. The shares of the common stock and the warrants were immediately separable. The warrants will be exercisable at a price of $2.38 per share beginning six months following the date of issuance and will expire six months thereafter. The net proceeds to the Company from the offering were approximately $26.4 million. The offering closed on April 9, 2018.

Vehicle Leases – The Company entered into a lease agreement with Enterprise for the lease of approximately 100 vehicles. The lease requires monthly payments of approximately $54,000 per month plus the cost of maintaining the vehicles. The leases commenced when the Company took possession of the majority of the vehicles in the second quarter of 2018. The leases expire 48 months after the delivery date.

On March 8, 2018 the Company entered into a standby letter of credit for a total of $0.5 million in connection with the Company's sales force vehicle lease program. The letter of credit is collateralized by a restricted cash account in the amount of $0.5 million. There were no amounts drawn down on this letter of credit as of September 30, 2018.

Office Lease — On May 5, 2017, the Company executed an office lease with Russell Ranch Road II LLC for the Company's corporate headquarters in Westlake Village, California. The office lease commenced in August 2017. The lease requires monthly payments of $40,951, increased by 3% annually, plus the estimated cost of maintaining the property by the landlord with a five month concession from October 2017 through February 2018. The lease expires January 2023 and provides the Company with a five year renewal option.

On November 29, 2017, the Company executed an office lease with Russell Ranch Road II LLC to expand the office space for the Company's corporate headquarters in Westlake Village, California. The office lease will commence in October 2018. The lease requires monthly payments of $35,969, increased by 3% annually, plus the estimated cost of maintaining the property by the landlord. In addition, the Company was entitled to reimbursement from the landlord of up to $56,325 for tenant improvements. As the Company did not exercise the tenant improvement, the amount was used to offset monthly rent. The lease expires January 2023 and provides the Company with a five year renewal option.

Rental expense under all operating leases including office space and equipment was approximately $0.1 million and $0.4 million for the three and nine months ended September 30, 2018, respectively.

Future minimum lease payments are as follows:

2018	$ 396,000
2019	1,595,000
2020	1,624,000
2021	1,653,000
2022	1,197,000
Thereafter	88,000
	$ 6,553,000

13. Income Taxes

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.

The Company has assessed its position with regards to uncertainty in tax positions and 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 2012 remain subject to examination by the major tax jurisdictions in which the Company is subject to tax.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the “Act”) was signed into law making significant changes to the Internal Revenue Code of 1986, as amended. The adoption had no impact on its income tax expense upon adoption for the period in which the legislation was enacted. The provisional amount related to the remeasurement of certain deferred tax assets and liabilities is based on the rates at which they are expected to reverse in the future. The impact of this Act was a decrease of deferred tax assets of approximately $301.0 million, offset by a decrease in valuation allowance of $301.0 million, resulting in no additional income tax expense or benefit. No provisional amount was recorded related to the one-time transition tax on the mandatory deemed repatriation of foreign earnings.

14. Restructuring Charges

As of December 31, 2017, the Company had a remaining restructuring liability of $0.4 million, which is recorded in accrued expenses and other current liabilities in the condensed consolidated balance sheets. The Company has paid out the remainder of this obligation as of September 30, 2018.

15. Subsequent Events

On October 16, 2018, the Company received a $45.0 million upfront payment from United Therapeutics in accordance with the UT License agreement which became effective October 15, 2018.

Pursuant to the Tenth Amendment to Facility Agreement with Deerfield, on October 18, 2018, the Company repaid Deerfield $3.0 principal million amount of 2019 notes, which payment had previously been deferred until the earlier of October 31, 2018 and the first business day following the Company’s receipt of the $45.0 million upfront payment from United Therapeutics.

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

Statements in this report that are not strictly historical in nature are "forward-looking statements" within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would," and similar expressions intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. 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. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. 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, 2017 and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in 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 development and commercialization of inhaled therapeutic products for patients with diseases such as diabetes and pulmonary arterial hypertension. According to the Centers for Disease Control and Prevention, 30 million people in the United States had diabetes in 2015. Globally, the International Diabetes Federation has estimated that approximately 425 million people had diabetes in 2017 and approximately 629 million people will have diabetes by 2045. Our only approved product, Afrezza (insulin human) Inhalation Powder was approved by the U.S. Food and Drug Administration ("FDA") in June of 2014. Afrezza became available by prescription in United States retail pharmacies in February 2015.

Afrezza is a rapid-acting inhaled insulin used to improve glycemic control in adults with diabetes. The product consists of a dry powder formulation of human insulin delivered from a small portable inhaler. Administered at the beginning of a meal, Afrezza dissolves rapidly upon inhalation to the lung and delivers insulin quickly to the bloodstream. The first measurable effects of Afrezza occur approximately 12 minutes after administration.

Pursuant to the Sanofi License Agreement, Sanofi was responsible for global commercial, regulatory and development activities associated with Afrezza from August 2014 to April 2016, after which these responsibilities transitioned back to us. Currently, we promote Afrezza to endocrinologists and certain high-prescribing primary care physicians in the United States through our own specialty sales force. In the future, we may seek to supplement our sales force through a co-promotion arrangement with a third party that has an underutilized primary care sales force, which can be used to promote Afrezza to greater number of primary care physicians.

Our current strategy for future commercialization of Afrezza outside of the United States, subject to receipt of the necessary foreign regulatory approvals, is to seek and establish regional partnerships in foreign jurisdictions where there are commercial opportunities. In May 2017, we entered into a supply and distribution agreement with Biomm S.A. to pursue regulatory approval and commercialization of Afrezza in Brazil. In May 2018, we entered into an exclusive marketing and distribution agreement with Cipla Ltd. to pursue regulatory approval and commercialization of Afrezza in India.

We also believe our Technosphere formulations of active pharmaceutical ingredients have the potential to demonstrate clinical advantages over existing therapeutic options in a variety of therapeutic areas. As one example, we conducted a Phase 1 clinical study of TreT, which is a drug-device combination product for the treatment of patients with pulmonary arterial hypertension. In September 2018, we entered into the UT License Agreement, pursuant to which United Therapeutics became responsible for global development, regulatory and commercial activities with respect to TreT. As resources permit, we intend to explore the feasibility of other Technosphere formulations of active pharmaceutical ingredients.

As of September 30, 2018, we had an accumulated deficit of $2.9 billion and a stockholders' deficit of $205.4 million. We had a net loss of $24.2 million and $77.2 million for the three and nine months ended September 30, 2018, respectively. We have funded our operations primarily through the sale of equity securities and convertible debt securities, borrowings under the Facility Agreement with Deerfield, borrowings under the Mann Group Loan Arrangement, receipt of a $45.0 million upfront payment under the UT License Agreement, receipt of upfront and milestone payments under the Sanofi License Agreement, which was terminated in 2016, and borrowings under senior secured promissory note and a guaranty and security agreement with an affiliate of Sanofi, which was terminated in 2016. As discussed below in "Liquidity and Capital Resources," if we are unable to obtain additional funding, there is substantial doubt about our ability to continue as a going concern.

Our business is subject to significant risks, including but not limited to our need to raise additional capital to fund our operations, our ability to successfully commercialize Afrezza and manufacture sufficient quantities of Afrezza and the risks inherent in our ongoing clinical trials and the regulatory approval process for our product candidates. 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.

CRITICAL ACCOUNTING POLICES

Our critical accounting policies can be found in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Form 10-K for the year ended December 31, 2017. Material changes were made to the accounting policies for revenue recognition due to the adoption of ASC Topic 606 *Revenue from Contracts with Customers* on January 1, 2018. See Note 1 – Description of Business and Significant Accounting Policies in the condensed consolidated financial statements included in Part I – Financial Statements (Unaudited) for descriptions of the new accounting policies and impact of adoption.

RESULTS OF OPERATIONS

The following tables provides a comparison of the revenue categories for the three and nine months ended September 30, 2018 and 2017 (dollars in thousands):

	Three Months Ended September 30,			
	2018	2017	$ Change	% Change
Net revenue - commercial product sales:				
Gross revenue from product sales	$ 8,216	$ 2,823	$ 5,393	191%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(3,829)	(842)	(2,987)	(355%)
Net revenue - commercial product sales	4,387	1,981	2,406	121%
Net revenue - collaborations	82	62	20	32%
Total revenues	$ 4,469	$ 2,043	$ 2,426	119%

	Nine Months Ended September 30,			
	2018	2017	$ Change	% Change
Net revenue - commercial product sales:				
Gross revenue from product sales	$ 20,114	$ 7,091	$ 13,023	184%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(8,572)	(2,365)	(6,207)	(262%)
Net revenue - commercial product sales	11,542	4,726	6,816	144%
Net revenue - collaborations	232	187	45	24%
Revenue - other	53	2,302	(2,249)	(98%)
Total revenues	$ 11,827	$ 7,215	$ 4,612	64%

Gross revenue from the sales of Afrezza increased 191% and 184% during the three and nine months ended September 30, 2018, respectively compared to the corresponding periods in 2017.

This increase was primarily driven by higher product demand, price increases as well as a more favorable mix of cartridges. Effective as of the beginning of 2018, we adopted Topic ASC 606, the new revenue standard under which we now recognize revenue on a sell-to model rather than a sell-through model. Total estimated gross-to-net adjustments of $3.8 million (47% of gross revenue) and $8.6 million (43% of gross revenue) during the three and nine months ended September 30, 2018, respectively, compared to $0.8 million (30% of gross revenue) and $2.4 million (33% of gross revenue) during the three and nine months ended September 30, 2017 respectively, or an increase of approximately 355% and 262% compared to the same periods in 2017. These increases are due primarily to rebates related to increases in the wholesaler acquisition cost of Afrezza as well as estimated product returns. We were not required to reduce revenue in 2017 for product returns because at that time, we deferred recognition of revenue on Afrezza product delivered to wholesalers until the right of return no longer existed, which occurred at the earlier of the time Afrezza was dispensed from pharmacies to patients or expiration of the right of return.

Net revenue from collaborations recognized in the three and nine months ended September 30, 2018 was related to deferred revenue from Receptor and Cipla of a total of $0.1 million and $0.3 million, respectively, which is more fully described in Note 8 – Collaboration Arrangements of the Notes to the condensed consolidated financial statements included in Part I – Financial Statements (Unaudited).

Revenue – other for the nine months ended September 30, 2018 decreased by 98%. In 2017 we obtained additional revenue from bulk insulin sales to a third party of $1.7 million as well as $0.6 million from the sale of intellectual property.

Expenses

Total expenses are primarily comprised of costs of goods sold, research and development expenses, selling expenses, general and administrative expenses, and loss on foreign currency. Each is described in more detail below:

Costs of Goods Sold

A significant component of our cost of goods sold is current period manufacturing costs in excess of costs capitalized into inventory (excess capacity costs). These costs, in addition to the impact of the annual revaluation of inventory to standard cost (and the annual revaluation of deferred costs to standard costs in 2017), and write-offs of inventory (and write-offs of deferred costs in 2017) are recorded as expenses in the period in which they are incurred. Costs of goods sold also includes the standard cost of Afrezza sold during the period and realized currency gain or loss in connection with the Amphastar insulin contract.

Research and Development Expenses

Our research and development expenses include payroll, employee benefits, stock-based compensation expense, and other headcount-related expenses associated with research and development. Research and development expenses also include third-party clinical spending and clinical grants, manufacturing improvement and Technosphere development.

Selling Expenses

Selling expenses include payroll, employee benefits, stock-based compensation, and other headcount-related expenses associated with sales and marketing personnel, other commercial support personnel and the cost of advertising, promotions, trade shows, seminars and other commercial support programs.

General and Administrative Expenses

Our general and administrative expenses include payroll, employee benefits and stock-based compensation expense, severance expense, and other headcount-related expenses associated with executives, finance, legal, facilities, human resources and other administrative personnel, certain taxes, professional services, and legal and other administrative fees.

Gain or Loss on Foreign Currency Translation

Under the Insulin Supply Agreement with Amphastar, payment obligations are denominated in Euros. We are required to record the foreign currency translation impact of the U.S. dollar to Euro exchange rate associated with the recognized loss on purchase commitments.

The following table provides a comparison of the expense categories for the three and nine months ended September 30, 2018 and 2017 (dollars in thousands):

	Three Months Ended September 30,			
	2018	2017	$ Change	% Change
Expenses:				
Cost of goods sold	$ 5,303	$ 4,575	$ 728	16%
Research and development	2,043	4,361	(2,318)	(53%)
Selling	12,625	10,114	2,511	25%
General and administrative	6,769	7,611	(842)	(11%)
Property and equipment impairment	—	92	(92)	(100%)
(Gain) Loss on foreign currency translation	(728)	3,684	(4,412)	(120%)
Gain on purchase commitment	—	(215)	215	(100%)
Total expenses	$ 26,012	$ 30,222	$ (4,210)	(14%)

	Nine Months Ended September 30,			
	2018	2017	$ Change	% Change
Expenses:				
Cost of goods sold	$ 14,406	$ 12,210	$ 2,196	18%
Research and development	7,653	10,611	(2,958)	(28%)
Selling	35,946	31,191	4,755	15%
General and administrative	25,794	20,490	5,304	26%
Property and equipment impairment	—	203	(203)	(100%)
(Gain) Loss on foreign currency translation	(3,107)	12,077	(15,184)	(126%)
Gain on purchase commitment	—	(215)	$ 215	(100%)
Total expenses	$ 80,692	$ 86,567	$ (5,875)	(7%)

Cost of goods sold increased by $0.7 million (16%) and $2.2 million (18%) for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017.

The increase for the three months ended September 30, 2018 was primarily attributable to an inventory write off of $0.7 million.

The increase for the nine months ended September 30, 2018 was primarily attributable to a $1.2 million increase in costs associated with Afrezza sales, an increase of manufacturing in excess of costs capitalized into inventory of $0.9 million and realized currency loss in connection with an insulin purchase of $0.4 million. These increases were offset by a $0.3 million settlement of a credit related to a purchase of insulin.

Research and development expenses decreased by $2.3 million (53%) and $3.0 million (28 %) during the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017.

The decrease for the three months ended September 30, 2018 was primarily attributable to $1.0 million decrease in salary-related expenses for personnel who were engaged in research and development activities in the third quarter of 2017 and have transitioned to Afrezza commercial support activities, lower clinical trial spending of $0.9 million in relation the Treprostinil Phase 1 study that was completed the at the end of the second quarter of 2018, a decrease in headcount spending of $0.4 million, and a $0.2 million decrease in research and development supply costs. These were offset by a $0.2 million increase in stock-based compensation expenses and travel expenses.

The decrease for the nine months ended September 30, 2018 was primarily attributable to a $2.2 million decrease in salary-related expenses for personnel who were engaged in research and development activities in 2017 and have transitioned to Afrezza commercial support activities, a decrease in headcount spending of $0.7 million, a decrease in research and development supply costs of $0.5 million, and a decrease in salary related expenses for personnel supporting manufacturing and production activities of $0.4 million. These were offset by an increase in relocation and recruiting fees of $0.6 million and an increase in consulting services costs of $0.4 million in connection with international regulatory activities.

Selling expenses increased by $2.5 million (25%) and $4.8 million (15%) during the three and nine months ended September 30, 2018, respectively, compared to the same period in 2017.

The increase for the three months ended September 30, 2018 was primarily attributable to an increase in marketing and advertising costs of $1.2 million, an increase of $0.9 million related to personnel providing increased Afrezza commercial support as well as an increase in sample costs of $0.3 million.

The increase for the nine months ended September 30, 2018 was primarily attributable to an increase of $3.5 million in headcount-related expenses associated with supporting Afrezza sales in commercial operations and patient support, a $2.2 million increase in salary-related expenses for personnel who were engaged in research and development activities in 2017 and have transitioned to Afrezza commercial support activities such as pharmacovigilance, an increase in stock-based compensation costs of $0.6 million in connection with the performance-based stock options and an increase in our sales force travel costs of $0.6 million. These were offset by a decrease in on-line marketing and media spending of $1.6 million, lower conference spending of $0.3 million and lower facility spending of $0.2 million.

In order to conform to the 2018 presentation above, we reclassified approximately $0.9 million and $2.6 million of personnel costs related to Afrezza medical affair activities from general and administrative expenses to selling expenses. This resulted in a change in selling expenses from $9.2 million and $28.6 million as previously reported in our Form 10-Q filed on November 7, 2017, to $10.1 million to $31.2 million for the three and nine months ended September 30, 2017, respectively.

General and administrative expenses decreased by $0.8 million (11 %) and increased by $5.3 million (26 %) during the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017.

The decrease for the three months ended September 30, 2018 was primarily attributable to a $0.4 million decrease in facility cost and a $0.3 million decrease in severance costs. These were offset by an increase in sponsorship spending of $0.1 million.

The increase for the nine months ended September 30, 2018 was primarily attributable to an increase in spending of $2.5 million due to headcount increases in our human resources, accounting, corporate communications, and office support departments, a $1.3 million increase in stock-based compensation expense in connection with performance-based stock options, an increase of $1.1 million in transition costs due to the cost of transitioning certain corporate support functions from Connecticut to our headquarters in California and increase in consulting fees in connection with corporate strategies of $0.9 million. These were offset by a decrease in facility cost of $0.5 million.

In order to conform to the 2018 presentation above, we reclassified approximately $0.9 million and $2.6 million of personnel costs related to Afrezza medical affair activities from general and administrative expenses to selling expenses. This resulted in a change in general and administrative expenses from $8.5 million and $23.1 million as previously reported in our Form 10-Q filed on November 7, 2017, to $7.6 million to $20.5 million for three and nine months ended September 30, 2017, respectively.

Gain or loss on foreign currency translation decreased by $4.4 million (120%) and $15.2 million (126%) during three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017. This was primarily attributable to the favorable U.S. dollar to Euro exchange rates associated with the recognized commitment to purchase insulin from Amphastar.

Other Income (Expense)

The following table provides a comparison of the other income (expense) categories for the three and nine months ended September 30, 2018 and 2017 (dollars in thousands):

	Three Months Ended September 30,			
	2018	2017	$ Change	% Change
Change in fair value of warrant liability	$ —	$ (1,289)	$ 1,289	(100%)
Interest income	144	65	79	122%
Interest expense on notes	(993)	(2,310)	1,317	57%
Interest expense on note payable to related party	(1,074)	(1,173)	99	8%
Loss on extinguishment of debt	(712)	—	(712)	(100%)
Other income (expense)	10	$ —	10	100%
Total other income (expense)	$ (2,625)	$ (4,707)	$ 2,082	44%

	Nine Months Ended September 30,			
	2018	2017	$ Change	% Change
Change in fair value of warrant liability	$ —	$ 5,488	$ (5,488)	(100%)
Interest income	305	178	127	71%
Interest expense on notes	(4,496)	(7,438)	2,942	40%
Interest expense on note payable to related party	(3,234)	(2,608)	(626)	(24%)
Loss on extinguishment of debt	(765)	(830)	65	8%
Other income (expense)	71	13	58	446%
Total other income (expense)	$ (8,119)	$ (5,197)	$ (2,922)	(56%)

During the three months and nine months ended September 30, 2017 we recorded a $0.1 million and a $6.8 million change in fair value of warrant liability, respectively; there was no such impact on our consolidated statements of operations in 2018. On September 29, 2017, we and the four holders of all outstanding A Warrants and B Warrants entered into separate, privately-negotiated exchange agreements, pursuant to which we agreed to issue to such holders an aggregate of 1,292,510 shares of our common stock in exchange for such warrants. The warrant liability associated with the exchanged warrants was adjusted to fair value and reclassified into equity as of September 29, 2017.

Interest expense on notes decreased by $1.3 million (57%) and $2.9 million (40%) for the three and nine months ended September 30, 2018, respectively compared to the same periods in 2017. The decreases for both periods were primarily due to a reduction in principal debt balances.

Interest expense on note payable to related party decreased by $0.1 million (8%) and increased by $0.6 million (24%) for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017.

The decrease for the three months ended September 30, 2018 was primarily due a decrease in the principal by approximately $8.2 million in 2018 compared to 2017.

The increase for the nine months ended was primarily due to increased average principal since the second quarter of 2017.

Loss on extinguishment of debt increased by $0.7 million (100%) and decreased by $0.1 million (8%) for the three and nine months ended September 30, 2018, respectively, compared to the same periods in 2017.

The increase for the three months ended September 30, 2018 was primarily due to a $0.7 million loss on extinguishment resulting from two conversions related to our Deerfield exchange transaction entered into in September 2018.

The decrease for the nine months ended September 30, 2018 was primarily due to a $0.7 million loss on extinguishment resulting from two conversions related to our Deerfield exchange transaction entered into in September 2018. In the same period of 2017, we recorded a loss on extinguishment of $0.8 million related to the Deerfield exchange transaction entered into in April and June 2017.

LIQUIDITY AND CAPITAL RESOURCES

To date, we have funded our operations through the sale of equity securities and convertible debt securities, borrowings under the Mann Group Loan Arrangement, under which we can no longer borrow as we have used all amounts available for borrowing, borrowings under the Facility Agreement with Deerfield, receipt of upfront and milestone payments under the Sanofi License Agreement, and borrowings under a senior secured promissory note with Sanofi which was terminated in 2016.

As of September 30, 2018, we had $104.7 million principal amount of outstanding debt, consisting of:

- $18.7 million principal amount of 2021 notes bearing interest at 5.75% per annum and maturing on October 23, 2021, which are convertible;
- The following amounts under the Facility Financing Obligation with Deerfield:
  - $12.0 million of 2019 notes bearing interest at 9.75% per annum. Interest is payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. As of September 30, 2018, the principal amounts due and payable were as follows: $3.0 million at the earlier of October 31, 2018 or the first business day following the date the Company receives an upfront payment of $45.0 million under the UT License Agreement – See Note 7 -- Borrowings), and $9.0 million in July 2019;

- $2.5 million of Tranche B notes due and payable in May 2019 and bearing interest at 8.75% per annum. Interest is payable in cash quarterly in arrears on the last business day of March, June, September and December of each year;

- $71.5 million principal amount of indebtedness under the Mann Group Loan Arrangement bearing interest at a fixed rate of 5.84% per annum compound quarterly beginning April 1, 2018 and maturing on July 1, 2021, all of which is convertible. Interest is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, except that the lender has agreed to defer interest payments until July 1, 2018 unless otherwise permitted under the subordination agreement with Deerfield, and such interest payments are subject to additional deferral beyond July 1, 2018 until our payment obligations to Deerfield have been satisfied in full.

We have entered into certain transactions related to these borrowings during 2017 and 2018 that are more fully described in Note 6 – Related Party Arrangements, Note 7 – Borrowings, Note 10 – Fair Value of Financial Instruments and Note 12 – Commitments and Contingencies.

On October 10, 2017, we entered into securities purchase agreements with certain institutional investors and a charitable foundation. Pursuant to the terms of the purchase agreements, we sold to the purchasers in a registered offering an aggregate of 10,166,600 shares of our common stock at a purchase price of $6.00 per share. Included in this offering was 166,600 shares issued to The Kresa Family Foundation, of which Kent Kresa, the Chairman of our board of directors, is the President. The net proceeds from the offering were approximately $57.7 million, after deducting placement agent fees equal to 5.0% of the aggregate gross proceeds from the offering (except for the proceeds received from the sale of 166,600 shares issued to the charitable foundation) and offering expenses payable by us. The offering closed on October 13, 2017.

In November 2017, we sold an aggregate of 173,327 shares of our common stock for aggregate gross proceeds of approximately $0.5 million pursuant to our At Market Issuance Sales Agreement with B. Riley FBR, Inc. (f/k/a FBR Capital Markets & Co.), dated as of April 26, 2016 (the “FBR Agreement”). On February 27, 2018, we terminated the FBR Agreement and no further sales will be made under such agreement.

On February 27, 2018 we entered into a Controlled Equity Offering^{SM} Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor Fitzgerald”), as sales agent, pursuant to which we may offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an aggregate offering price of up to $50.0 million or such other amount as may be permitted by the Sales Agreement. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an “at the market offering” as defined in Rule 415 under the Securities Act of 1933, as amended.

On April 5, 2018, we entered into securities purchase agreements with certain institutional investors. Pursuant to the terms of the Purchase Agreements, we sold to the purchasers in a registered offering an aggregate of 14,000,000 shares of our common stock and warrants to purchase up to an aggregate of 14,000,000 shares of our common stock at a combined purchase price of $2.00 per share and accompanying warrant. The shares of common stock and the warrants were immediately separable. The warrants became exercisable at a price of $2.38 per share beginning on October 9, 2018 and will expire April 9, 2019. The net proceeds to us from the offering were approximately $26.4 million. The offering closed on April 9, 2018.

For the quarter ended September 30, 2018, we sold an aggregate of 100,000 shares of our common stock for an aggregate proceeds of approximately $0.2 million pursuant to our Sales Agreement with Cantor Fitzgerald. For the nine months ended September 30, 2018, we sold an aggregate of 325,088 shares of our common stock for aggregate gross proceeds of approximately $0.8 million pursuant to our Sales Agreement with Cantor Fitzgerald.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the 2021 notes, Facility Financing Obligation, or the Mann Group Loan Arrangement when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2021 notes, or certain Major Transactions as defined in the Facility Agreement with respect to the Facility Financing Obligation, the holders of the respective debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. The 2021 note and Facility Financing Obligation are partially convertible and the Mann Group Loan Arrangement is fully convertible at any time prior to maturity as further disclosed in Note 6 – Related Party Arrangements and Note 7 – Borrowings.

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 2021 notes and the Facility Financing Obligation or if we fail to repay or repurchase the 2021 notes, Facility Financing Obligation, or borrowings under The Mann Group Loan Arrangement, we will be in default under the applicable instrument for such indebtedness, 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.

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, of which $75.0 million remain payable, upon the occurrence of specified strategic and sales milestones, including the achievement of specified net sales figures. In addition, the Facility Agreement includes customary representations, warranties and covenants, including, a restriction on the incurrence of additional indebtedness, and a financial covenant which requires our cash and cash equivalents to be at least $20.0 million as of October 31, 2018 and December 31, 2018 and $25.0 million as of the end of each fiscal quarter after December 31, 2018. We have met the required conditions as of the specified dates. See Note 12 — Commitments and Contingencies and Note 7 — Borrowings for further information related to the Facility Agreement.

On July 31, 2014, we entered into the Insulin Supply Agreement, pursuant to which we agreed to purchase certain annual minimum quantities of insulin. See Note 12 — Commitments and Contingencies for further information related to the Insulin Supply Agreement.

These factors raise substantial doubt about our ability to continue as a going concern. Our financial statements and related notes thereto included elsewhere in this Report, do not include adjustments that might result from any unfavorable outcome of this uncertainty.

During the nine months ended September 30, 2018, we used $62.7 million of cash for our operating activities as a result of our net loss of $77.2 million, which was offset by a net increase in operating assets and liabilities of $3.4 million and non-cash charges of $11.0 million. The increase in operating asset and liabilities was primarily a result of an increase in deferred payments from collaborations of $12.0 million. This was offset by a decrease in recognized loss on purchase commitments of $6.2 million, a decrease in inventory of $1.9 million and a decrease in accounts payable of $1.2 million. The non-cash charges included $5.7 million of stock-based compensation expense, $3.3 million of interest accrued on notes payable to the related party, a $3.1 million foreign currency translation gain, $2.5 million of depreciation, amortization and accretion, a $1.8 million inventory write-off and a $0.8 million loss on extinguishment of debt.

There was a minimal amount of cash provided from investing activities for the nine months ended September 30, 2018 compared to cash provided by investing activities of $16.7 million for the nine months ended September 30, 2017. The cash provided for the nine months ended September 30, 2017 was primarily related to net proceeds of $16.7 million received from the sales of certain parcels of real estate owned by us in Valencia, California and certain related improvements, personal property, equipment, supplies and fixtures.

Cash provided by financing activities was $25.3 million for the nine months ended September 30, 2018 compared to $15.3 million for the nine months ended September 30, 2017. The cash provided for the nine months ended September 30, 2018 was primarily related to $26.4 million in net proceeds related to a registered direct offering of common stock in April 2018. For the nine months ended September 30, 2017, cash provided by financing activities included $19.4 million related to borrowings on the note payable to related party. This was offset by $4.0 million in principal payments on Facility Financing Obligations.

Future Liquidity Needs.

As of September 30, 2018, we had $10.4 million in cash and cash equivalents and $0.5 million in restricted cash. Our cash position, together with our short-term debt obligations and anticipated operating expenses, raises substantial doubt about our ability to continue as a going concern. We expect to expend our capital resources for the manufacturing, sales and marketing of Afrezza and to develop our product candidates. We also intend to use our capital resources for general corporate purposes. We will need to raise additional capital before we exhaust our current cash resources in order to continue to fund our research and development, support continued product growth and commercialization efforts, and to fund operations, generally. We will seek to raise additional funds through various potential sources, such as equity and debt financings, or through collaboration and licensing agreements.

If we enter into strategic business collaborations with respect to our product candidates or Afrezza for commercialization outside of the United States, we may, as part of the transaction, receive additional capital. In addition, we expect to pursue the sale of equity and/or debt securities, 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 collaborations, 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 when needed or on acceptable terms, 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 plan to continue to fund our operating losses and capital funding needs through public or private equity or debt financings, strategic collaborations, licensing agreements or other arrangements. 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 through equity or debt financing or entering business collaborations, 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 will continue to be substantial doubt about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

As of September 30, 2018, we did not have any off-balance sheet arrangements.

Contractual Obligations

Material changes to our contractual obligations from December 31, 2017 to September 30, 2018, including our Facility Financing Obligation and Note Payable to Related Party are more fully described above under “Liquidity and Capital Resources”, as well as in Note 6 – Related Party Arrangements, Note 7 – Borrowings, Note 10 – Fair Value of Financial Instruments and Note 12 – Commitments and Contingencies.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Due to the fixed interest rates of our debt, we currently do not have exposure to changes in our interest expense as a result of changes in interest rates. See Note 6 – Related Party Arrangements, Note 7 – Borrowings and Note 15 – Subsequent Events in the Notes to the condensed consolidated financial statements included in Part I – Financial Statements (Unaudited) for information about the principal amount of outstanding debt.

The interest rate on amounts borrowed under The Mann Group Loan Arrangement is fixed at 5.84%. As of September 30, 2018, we also have debt related to the 2021 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%.

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, 2018 were to have occurred, this change would not have had a material effect on the value of our short-term investment portfolio.

Foreign Currency Exchange Risk

We incur and will continue to incur significant expenditures for insulin supply obligations under our supply agreement with Amphastar. Such obligations are denominated in Euros. At the end of each reporting period, the recognized loss on purchase commitment is 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. On October 1, 2018 we entered into a short-term (90 days) foreign currency hedging transaction to mitigate our exposure to foreign currency exchange risks in connection with our remaining purchase commitment. Exchange rate fluctuations may adversely affect our expenses, results of operations, financial position and cash flows. If a change in the U.S. dollar to Euro exchange rate equal to 10% of the U.S. dollar to Euro exchange rate on September 30, 2018 were to occur, this change would have resulted in a foreign currency impact to our pre-tax income (losses) of approximately a $9.9 million.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our 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, 2018. 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 SEC’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, 2018, we have concluded, as of such date, that our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) of the Exchange Act. An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Following the public announcement of Sanofi's election to terminate the Sanofi License Agreement and the subsequent decline in our stock price, two motions were submitted to the district court at Tel Aviv, Economic Department for the certification of a class action against MannKind and certain of our officers and directors. In general, the complaints alleged that MannKind and certain of our officers and directors violated Israeli and U.S. securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary damages. In November 2016, the district court dismissed one of the actions without prejudice. In the remaining action, the district court ruled in October 2017 that U.S. law will apply to this case. The plaintiff appealed this ruling to the Supreme Court of Israel, which upheld the ruling of the lower court. We will vigorously defend against the claims advanced.

We are also subject to legal proceedings and claims which arise in the ordinary course of our business. As of the date hereof, we believe that the final disposition of such matters will not have a material adverse effect on our financial position, results of operations or cash flows. We maintain liability insurance coverage to protect our assets from losses arising out of or involving activities associated with ongoing and normal business operations.

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 marked with an asterisk (*) did not appear as separate risk factors in, or contain changes to the similarly titled risk factors included in, Item 1A of the 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 will need to raise additional capital to fund our operations, and there is substantial doubt about our ability to continue as a going concern.*

This report includes disclosures stating that our existing cash resources and our accumulated stockholders' deficit raise substantial doubt about our ability to continue as a going concern. We will 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, including the commercialization of Afrezza and the development of our product candidates independently or with our collaboration partners, and to avoid defaulting under the financial covenant in our Facility Agreement with Deerfield, which requires us to maintain at least $20.0 million in cash and cash equivalents as of October 31, 2018 and December 31, 2018 and $25.0 million in cash and cash equivalents as of the end of each fiscal quarter after December 31, 2018. It may be difficult for us to raise additional funds on favorable terms, or at all. As of September 30, 2018, we had cash and cash equivalents of $10.4 million, $0.5 million in restricted cash and a stockholders' deficit of $205.4 million. Our cash position, together with our short-term debt obligations and anticipated operating losses due to increased effort on commercialization and research and development projects raises substantial doubt about our ability to continue as a going concern. The extent of our additional funding requirements will depend on a number of factors, including:

- The degree to which Afrezza is commercially successful;
- The degree to which we are able to generate revenue from our Technosphere drug delivery platform;
- The costs of developing and commercializing Afrezza on our own in the United States, including the costs of expanding our commercialization capabilities;
- The costs of finding regional collaboration partners for the development and commercialization of Afrezza in foreign jurisdictions;
- The demand by any or all of the holders of our debt instruments to require us to repay or repurchase such debt securities if and when required;
- Our ability to repay or refinance existing indebtedness, and the extent to which our notes with conversion options or any other convertible debt securities we may issue are converted into or exchanged for 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 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;
- Actions taken by the FDA and other regulatory authorities affecting Afrezza and our product candidates and competitive products;
- 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 and we may in the future pursue the sale of additional equity and/or debt securities, 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 in the future on acceptable terms, or at all. Issuances of additional debt or equity securities or the issuance of common stock upon conversion of outstanding convertible debt securities or upon 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 will 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 will need 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 collaboration, 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.

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. Moreover, if we do not obtain such additional funds, there will continue to be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and up to total loss of investment to our stockholders and other security holders. 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, holders of our common stock or other securities may lose the entire value of their investment.

We cannot provide assurances that changed or unexpected circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. There can be no assurances that we will be able to raise additional capital in sufficient amounts or on favorable terms, or at all. If we are unable to raise adequate additional capital when required or in sufficient amounts or on terms acceptable to us, we may have to delay, scale back or discontinue one or more product development programs, curtail our commercialization activities, significantly reduce expenses, sell assets (potentially at a loss), enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop or commercialize independently, cease operations altogether, pursue an acquisition of our company at a price that may result in up to a total loss on investment for our stockholders, file for bankruptcy or seek other protection from creditors, or liquidate all of our assets. In addition, if we default under the Facility Agreement, Deerfield could foreclose on substantially all of our assets.

Our prospects are heavily dependent on the successful commercialization of our only approved product, Afrezza. The continued commercialization and development of Afrezza will require substantial capital that we may not be able to obtain.*

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 prospects and ability to generate significant revenues will heavily depend on our ability to successfully commercialize Afrezza in the United States. In addition, we anticipate that revenues from our existing or future licensing arrangements for our Technosphere platform technology that involve license, milestone, royalty or other payments to us will depend on our ability to achieve the performance obligations specified in such arrangements.

Successful commercialization of Afrezza is subject to many risks and there are many factors that could cause the commercialization of Afrezza to be unsuccessful, including a number of factors that are outside our control. We ultimately may be unable to gain market acceptance of Afrezza for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, relative pricing compared with alternative products, the availability of alternative treatments and lack of coverage or adequate reimbursement.

We have never, as an organization, launched or commercialized a product other than Afrezza, and there is no guarantee that we will be able to successfully do so with Afrezza. There are numerous examples of unsuccessful product launches, second launches that underperform original expectations and other failures to fully exploit the market potential of drug products, including by pharmaceutical companies with more experience and resources than us. We will need to maintain and continue to build our commercialization capabilities in order to successfully commercialize Afrezza in the United States, and we may not have sufficient resources to do so. The market for skilled commercial personnel is highly competitive, and we may not be able to retain and find and hire all of the personnel we need on a timely basis or retain them for a sufficient period. In addition, Afrezza is a novel insulin therapy with a distinct time-action profile and non-injectable administration, and we are therefore required to expend significant time and resources to train our sales force to be credible, persuasive and compliant with applicable laws in marketing Afrezza for the treatment diabetes to physicians and to ensure that a consistent and appropriate message about Afrezza is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of Afrezza and its proper administration, our efforts to successfully commercialize Afrezza could be put in jeopardy, which would negatively impact our ability to generate product revenues.

If we are unable to maintain coverage of, and adequate payment levels for Afrezza, physicians may limit how much or under what circumstances they will prescribe or administer Afrezza. As a result, patients may decline to purchase Afrezza, which would have an adverse effect on our ability to generate revenues.

We are responsible for the NDA for Afrezza and its maintenance. Prior to the termination of the Sanofi License Agreement in April 2016, we had no experience with the maintenance of an NDA and may fail to comply with maintenance requirements, including timely submitting required reports. Furthermore, we are responsible for the conduct of the remaining required post-approval trials of Afrezza. Our financial and other resource constraints may result in delays or adversely impact the reliability and completion of these trials.

Maintaining and further building the internal infrastructure to further develop and commercialize Afrezza is costly and time-consuming, and we may not be successful in our efforts or successful in obtaining financing to support those efforts.

If we fail to successfully commercialize Afrezza in the United States, our business, financial condition and results of operations will be materially and adversely affected.

We expect that our results of operations will fluctuate for the foreseeable future, which may make it difficult to predict our future performance from period to period.

Our operating results have fluctuated in the past and are likely to do so in future periods. Some of the factors that could cause our operating results to fluctuate from period to period include the factors that will affect our funding requirements described above under “Risk Factors — We will need to raise additional capital to fund our operations, and there is substantial doubt about our ability to continue as a going concern.”

We believe that comparisons from period to period of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

If we do not obtain regulatory approval of Afrezza in foreign jurisdictions, we will not be able to market Afrezza in any jurisdiction outside of the United States, which could limit our commercial revenues. We may not be successful in establishing regional partnerships or other arrangements with third parties for the commercialization of Afrezza outside of the United States.*

While Afrezza has been approved in the United States by the FDA for glycemic control in adult patients with diabetes, we have not yet obtained approval in any other jurisdiction. In order to market Afrezza outside of the United States, we must obtain regulatory approval in each applicable foreign jurisdiction, and we may never be able to obtain such approvals. The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, and distribution of pharmaceutical products outside the United States are subject to extensive regulation by foreign regulatory authorities, whose regulations differ from country to country. We will be required to comply with different regulations and policies of the jurisdictions where we seek approval for Afrezza, and we have not yet identified all of the requirements that we will need to satisfy to submit Afrezza for approval for other jurisdictions. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work for other jurisdictions beyond the work that we have conducted to support the NDA for Afrezza.

Our current strategy for the future commercialization of Afrezza outside of the United States, subject to receipt of the necessary regulatory approvals, is to seek and establish regional partnerships in foreign jurisdictions where there are appropriate commercial opportunities. It may be difficult to find or maintain collaboration partners that are able and willing to devote the time and resources necessary to successfully commercialize Afrezza. Collaborations with third parties may require us to relinquish material rights, including revenue from commercialization, agree to unfavorable terms or assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We may also face significant competition in seeking collaboration partners, especially in the current market, and may not be able to find a suitable collaboration partner in a timely manner on acceptable terms, or at all. Any of these factors could cause delay or prevent the successful commercialization of Afrezza in foreign jurisdictions and could have a material and adverse impact on our business, financial condition and results of operations and the market price of our common stock and other securities could decline.

We may not be successful in our efforts to develop and commercialize our product candidates.

We have sought to develop our product candidates through our internal research programs. 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. Further research and development on these programs will require significant financial resources. Given our limited financial resources and our focus on development and commercialization of Afrezza, we will not be able to advance these programs unless we are able to enter into collaborations with third parties to fund these programs or to obtain funding to enable us to continue these programs.

A significant portion of the research that we have conducted involves new 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 develop and commercialize our product candidates, or if we are significantly delayed in doing so, our ability to generate product revenues will be limited to the revenues we can generate from Afrezza.

We have a history of operating losses, we expect to incur losses in the future and we may not generate positive cash flow from operations in the future.*

The Company is not currently profitable and has rarely generated positive net cash flow from operations. As of September 30, 2018, we had an accumulated deficit of $2.9 billion. The accumulated deficit has resulted principally from costs incurred in our research and development programs, the write-off of goodwill, inventory and property, plant and equipment, and general operating expenses. We expect to make substantial expenditures and to incur increasing operating losses in the future in order to continue the commercialization of Afrezza. In addition, under the amended Insulin Supply Agreement with Amphastar, we agreed to purchase certain annual minimum quantities of insulin for calendar years 2018 through 2023 for an aggregate total remaining purchase price of €85.8 million at September 30, 2018. We may not have the necessary capital resources on hand in order to service this contractual commitment.

Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Our ability to achieve and sustain positive cash flow from operations and profitability depends heavily upon successfully commercializing Afrezza, and we cannot be sure when, if ever, we will generate positive cash flow from operations or become profitable.

We have a substantial amount of debt, and we may be unable to make required payments of interest and principal as they become due.*

As of September 30, 2018, we had $104.7 million principal amount of outstanding debt, consisting of:

- $18.7 million principal amount of 2021 notes bearing interest at 5.75% per annum, with interest payable in cash semiannually in arrears on February 15 and August 15 of each year, and maturing on October 23, 2021;
- $12.0 million principal amount of 2019 notes bearing interest at 9.75% per annum. Interest is payable in cash quarterly in arrears in the last business day of March, June, September and December of each year. As of September 30, 2018, the principal amounts due and payable were as follows: $3.0 million in July 2018 (but deferred until the earlier of October 31, 2018 or the first business day following the date the Company receives an upfront payment of $45 million under the UT License Agreement – See Note 7 – Borrowings, and subsequently paid on October 18, 2018 – See Note 15 – Subsequent Events), and $9.0 million in July 2019;

- $2.5 million of Tranche B notes due and payable in May 2019 and bearing interest at 8.75% per annum. Interest is payable in cash quarterly in arrears on the last business day of March, June, September and December of each year; and
- $71.5 million principal amount of indebtedness under The Mann Group Loan Arrangement maturing on January 5, 2020, bearing interest at a fixed rate of 5.84% per annum compound quarterly payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, except that the lender has agreed to defer interest payments until July 1, 2018 unless otherwise permitted under the subordination agreement with Deerfield, and such interest payments are subject to additional deferral beyond July 1, 2018 until our payment obligations to Deerfield have been satisfied in full.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the terms of our indebtedness when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2021 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 debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. 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 2021 notes, 2019 notes, or Tranche B notes, or if we fail to repay or repurchase the 2021 notes, 2019 notes, Tranche B notes, or the loans under The Mann Group Loan Arrangement when required, we will be in default under the instrument for such debt securities 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.

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 obligations under the Facility Agreement, including any indebtedness under the 2019 notes and the Tranche B notes, and the Milestone Agreement are 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. 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 Facility Financing Obligation; 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 falling below $20.0 million as of October 31, 2018 and December 31, 2018 or $25.0 million as of the end of each fiscal quarter after December, 31, 2018. There have been no events of default under the Facility Financing Obligation. If we fail to timely pay accrued interest under The Mann Group Loan Arrangement when required, we will be in default under The Mann Group Loan Arrangement. If one or more events of default under the Facility Agreement occurs and continues beyond any applicable cure period, the holders of the Facility Financing Obligation may declare all or any portion of the Facility Financing Obligation 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.

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 Facility Financing Obligation would demand repayment of the outstanding balance of the Facility Financing Obligation as applicable 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 and the holders of our other securities. 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 2021 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 2021 notes and Facility Financing Obligation may accelerate all of our repayment obligations, and, with respect to the Facility Financing Obligation, 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. 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 secured debt would be senior to the rights of the holders of our unsecured debt and our common stock to receive any proceeds from the liquidation.

If we do not achieve our projected development goals in the timeframes we expect, our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities 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 preclinical 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 expect (or within the timeframes expected by analysts or investors), our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities may decline.

Afrezza or our product candidates may be rendered obsolete by rapid technological change.

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 or Afrezza less competitive, uneconomical or obsolete. Our future success will depend on our ability to develop and improve our approved product and product candidates 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 or any future marketing partner’s 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.

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, financial condition and results of operations and the market price of our common stock and other securities may decline.

If our suppliers fail to deliver materials and services needed for the production of Afrezza in a timely and sufficient manner or fail to comply with applicable regulations, and if we fail to timely identify and qualify alternative suppliers, our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities could decline.

For the commercial manufacture of Afrezza, we need access to sufficient, reliable and affordable supplies of insulin, our Afrezza inhaler, the related cartridges and other materials. Currently, the only approved source of insulin for Afrezza is manufactured by Amphastar. We must rely on our suppliers, including Amphastar, to comply with relevant regulatory and other legal requirements, including the production of insulin and FDKP in accordance with the FDA's cGMP for drug products, and the production of the Afrezza inhaler and related cartridges in accordance with 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. Likewise, if Amphastar ceases to manufacture or is otherwise unable to deliver insulin for Afrezza, we will need to locate an alternative source of supply and the production of Afrezza may be delayed. If any of our suppliers is unwilling or unable to meet its supply obligations and we are unable to secure an alternative supply source in a timely manner and on favorable terms, our business, financial condition, and results of operations may be harmed and the market price of our common stock and other securities may decline.

If we fail as an effective manufacturing organization or fail 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 utilize a contract packager to assemble the final kits of foil-pouched blisters containing cartridges along with 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 obtain sufficient quantities for the commercialization of Afrezza at the costs that we currently anticipate. 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, sustainable compliance 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.

If Afrezza or any other 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 other products that we may develop in the future, 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 other products that we may develop in the future depends on many factors, including the:

- Approved labeling claims;
- Effectiveness of efforts by us or any future marketing partner 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 develop 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 government and other 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 have been several congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion, and members of Congress and the Trump administration have stated that they will address such costs through new legislative and administrative measures. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that there will continue to be a number of federal and state proposals to implement similar and/or additional 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 and reimbursement reform proposals or legislation. Such reforms may limit our ability to generate revenues from sales of Afrezza or other products that we may develop in the future and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of any future marketing partner for Afrezza, 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 coverage and adequate 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 may 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 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.

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 European Union 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 or any future marketing partner is 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 any future 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. For example, in March 2010, 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 certain drug-device combination products, which has been suspended for calendar years 2016 through 2019;
- An increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- A licensure framework for follow-on biological products;
- 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% (and 70% commencing January 1, 2019) 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 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 annually to the Centers for Medicare & Medicaid Services ("CMS") 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;

- A new requirement to annually report drug samples that certain manufacturers and authorized 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.

Some of the provisions of the PPACA have yet to be fully implemented, while certain provisions have been subject to judicial and congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, and also increases in 2019 the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent under current law to 70 percent. We continue to evaluate the potential effect of the possible repeal and replacement of the PPACA may have on our business.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. For example, 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 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, and, following passage of the BBA, will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (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. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. These new laws and initiatives 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 any future marketing partner fails 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, including those pertaining to fraud and abuse and patients' rights are and will be applicable to our business. For example, 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, among others:

- The federal Anti-Kickback Statute (as amended by PPACA, which modified the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the Statute or specific intent to violate it to have committed a violation), which constrains our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities by prohibiting, among other things, knowingly and willfully 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, including without limitation the civil False Claims Act, and civil monetary penalties 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 federal healthcare programs that are false or fraudulent, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government, and under PPACA, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal false claims laws;
- HIPAA, which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or falsifying, concealing, or covering up a material fact in connection with the delivery of or payment for health care benefits;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information. In addition, the European Union, or EU, has established its own data security and privacy legal framework, including but not limited to Directive 95/46/EC, or the Data Protection Directive. The Data Protection Directive was replaced in May 2018 with the European General Data Protection Regulation, or GDPR, which contains provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We anticipate that over time we may expand our business operations to include additional operations in the EU, including potentially conducting preclinical and clinical trials. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR.
- 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.
- 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; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; and state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities.

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, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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 we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.*

We participate in the Medicaid Drug Rebate Program, as administered by CMS, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries/recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition.

In addition, the Office of Inspector General of the Department of Health and Human Services and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price (“AMP”) and best price (“BP”) for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payors. We may also be subject to civil penalties for failure to submit monthly/quarterly AMP and BP data on a timely basis, which penalties could be up to $18,107 per day for each day the submission is late beyond the due date . Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that the CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

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 any clinical testing of our 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 product liability insurance in the amount of $10.0 million. Our insurance coverage may not 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 seek to obtain, or be able to obtain if desired, sufficient additional coverage. If losses from such claims exceed our liability insurance coverage, we may incur substantial liabilities that we may not have the resources to pay. If we are required to pay a product liability claim our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities 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 and sales and marketing. 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 internal controls over financial reporting are not considered effective, our business, financial condition and market price of our common stock and other securities 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.

Our management, including our Chief Executive Officer and our 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. A material weakness in our internal controls has been identified in the past, and 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, financial condition and the market price of our common stock and other securities.

Changes or modifications in financial accounting standards, including those related to revenue recognition, may harm our results of operations. *

From time to time, the Financial Accounting Standards Board ("FASB"), either alone or jointly with other organizations, promulgates new accounting principles that could have an adverse impact on our financial position, results of operations or reported cash flows. In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The standard requires a company to recognize revenue to depict the transfer of goods or services when transferred to customers in the amount that reflects the consideration it expects to be entitled to receive in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued additional ASUs which clarified certain aspects of the new guidance. We adopted the new standard for the year beginning January 1, 2018. We had the option to either apply the new standard retrospectively for all prior reporting periods presented (full retrospective) or retrospectively with the cumulative effect of initially applying the new standard recognized at the date of initial application (modified retrospective). We have elected to apply the new standard using the modified retrospective approach with the cumulative effect of initial application recognized as of January 1, 2018. Based on the impact of adopting the new standard, the cumulative effect adjustment was approximately a $1.9 million decrease to the opening balance of accumulated deficit. Any difficulties in implementing this standard, or in adopting or implementing any other new accounting standard, and to update or modify our internal controls as needed on a timely basis, could result in our failure to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us. Finally, if we were to change our critical accounting estimates, including those related to the recognition of collaboration revenue and other revenue sources, our operating results could be significantly affected.

***Our ability to use net operating losses to offset future taxable income may be subject to limitations. **

As of December 31, 2017, we had federal and state net operating loss carryforwards of $2.0 billion and $2.2 billion, respectively. The federal and state net operating loss carryforwards began to expire in the prior year. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. As a result of our initial public offering, an ownership change within the meaning of Section 382 occurred in August 2004. As a result, federal net operating loss and credit carry forwards of approximately $216.0 million are subject to an annual use limitation of approximately $13.0 million. The annual limitation is cumulative and therefore, if not fully utilized in a year can be utilized in future years in addition to the Section 382 limitation for those years. The federal net operating losses generated subsequent to our initial public offering in August 2004 are currently not subject to any such limitation as there have been no ownership changes since August 2004 within the meaning of Section 382 of the Code. We may however experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

We may undertake internal restructuring activities in the future that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition.

From time to time we may undertake internal restructuring activities as we continue to evaluate and attempt to optimize our cost and operating structure in light of developments in our business strategy and long-term operating plans. These activities may result in write-offs or other restructuring charges. There can be no assurance that any restructuring activities that we undertake will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. Restructuring activities may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. In addition, internal restructurings can require a significant amount of time and focus from management and other employees, which may divert attention from commercial operations. If we undertake any internal restructuring activities and fail to achieve some or all of the expected benefits therefrom, our business, results of operations and financial condition could be materially and adversely affected.

***We and certain of our executive officers and directors have been named as defendants in ongoing securities lawsuits that could result in substantial costs and divert management's attention.**

Following the public announcement of Sanofi's election to terminate the Sanofi License Agreement and the subsequent decline in our stock price, two motions were submitted to the District Court at Tel Aviv, Economic Department for the certification of a class action against MannKind and certain of our officers and directors. The complaints alleged that MannKind and certain of our officers and directors violated Israeli and U.S. securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of MannKind's common stock. The plaintiffs are seeking monetary damages. In November 2016, the court in Israel dismissed one of the actions without prejudice. In the remaining action, the district court ruled in October 2017 that U.S. law will apply to this case. The plaintiff appealed this ruling to the Supreme Court of Israel, which upheld the ruling of the lower court. We intend to vigorously defend against these claims. If we are not successful in our defense, we could be forced to make significant payments to or other settlements with our stockholders and their lawyers, and such payments or settlement arrangements could have a material adverse effect on our business, operating results or financial condition. Even if such claims are not successful, the litigation could result in substantial costs and significant adverse impact on our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results and financial condition.

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. 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 or cause interruptions in our commercialization of Afrezza.

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 and commercialization of Afrezza 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 $20.0 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, which is not completed. The responsible party 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, financial condition and results of operations may be harmed.

We are increasingly dependent on information technology systems, infrastructure and data security.

We are increasingly dependent upon information technology systems, infrastructure and data security. Our business requires manipulating, analyzing and storing large amounts of data. In addition, we rely on an enterprise software system to operate and manage our business. Our business therefore depends on the continuous, effective, reliable and secure operation of our computer hardware, software, networks, Internet servers and related infrastructure. The multitude and complexity of our computer systems and the potential value of our data make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data including intellectual property, trade secrets or personal information belonging to us or our customers or other business partners may be exposed to unauthorized persons or to the public. Our systems are also potentially subject to cyber-attacks, which can be highly sophisticated and may be difficult to detect. Such attacks are often carried out by motivated, well-resourced, skilled and persistent actors including nation states, organized crime groups and “hacktivists.” Cyber-attacks could include the deployment of harmful malware and key loggers, a denial-of-service attack, a malicious website, the use of social engineering and other means to affect the confidentiality, integrity and availability of our information technology systems, infrastructure and data. Our key business partners face similar risks and any security breach of their systems could adversely affect our security status. While we continue to invest in the protection of our critical or sensitive data and information technology, there can be no assurance that our efforts will prevent or detect service interruptions or breaches in our systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us.

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.

The FDA and other regulatory authorities impose significant restrictions on approved products through regulations on advertising, promotional and distribution activities. This oversight encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving the Internet. Regulatory authorities may also review industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. The FDA and other regulatory authorities may take enforcement action against a company for promoting unapproved uses of a product (such as off-label uses) or for other violations of its advertising and labeling laws and regulations. Enforcement action may include product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Enforcement action may also result in exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs. Failure to comply with such regulations also can result in adverse publicity or increased scrutiny of company activities by the U.S. Congress or other legislators. Certain states have also adopted regulations and reporting requirements surrounding the promotion of pharmaceuticals. Failure to comply with state requirements may affect our ability to promote or sell our products in certain states.

If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined or forced to remove a product from the market, subject to criminal prosecution, 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, as part of the approval of Afrezza, the FDA required that we complete a clinical trial to evaluate the potential risk of pulmonary malignancy with Afrezza. To date, we have not enrolled any subjects in this trial.

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, financial condition and results of operations will be harmed and the market price of our common stock and other securities 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. For example, stability failure of Afrezza could lead to product recall or other sanctions.

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, financial condition and results of operations.

FDA and comparable foreign regulatory authorities subject Afrezza and any approved drug product to extensive and ongoing regulatory requirements concerning the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- Restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- Fines, warning letters or holds on clinical trials;
- Refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- Product seizure or detention, or refusal to permit the import or export of our product candidates; and
- Injunctions or the imposition of civil or criminal penalties.

We are required to comply with FDA regulations concerning the advertising and promotion of Afrezza. Failure to comply with these regulations can result in the receipt of warning letters and further liability if off-label promotion is involved. In October 2018, we received a warning letter from the FDA's Office of Prescription Drug Promotion related to a particular post on our Afrezza Facebook page. The warning letter stated that the post in question failed to adequately disclose the risks associated with the use of Afrezza. As a result, we inactivated all Afrezza social media accounts (including Facebook, Instagram and Twitter) and commenced a review to determine whether any additional postings may contain content similar to the post in question. We submitted our response plan on October 19th and will continue to work with the FDA to address their concerns. In the meantime, we have not determined whether, and to what extent, we will continue to promote Afrezza actively on social media platforms.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Our suppliers are 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 and is subject to inspection by the FDA. Although we conduct our own inspections and review and/or approve investigations of each supplier, there can be no assurance that the FDA, upon inspection, 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.

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 any other products we may develop.

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, financial condition and results of operations and cause the market price of our common stock and other securities 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 potentially competitive with, our 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, financial condition and results of operations and cause the market price of our common stock and other securities 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.

For example, the coverage claimed in a patent application can be significantly reduced before a patent is issued, either in the United States or abroad. Statutory differences in patentable subject matter may limit the protection we can obtain on some of our inventions outside of the United States. For example, methods of treating humans are not patentable in many countries outside of the United States. These and other issues may limit the patent protection we are able to secure internationally. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subjected to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated.

In addition, in certain countries, including the United States, applications are generally published 18 months after the application's priority date. In any event, because publication of discoveries in scientific or patent literature often trails behind actual discoveries, we cannot be certain that we were the first inventor of the subject matter covered by our pending patent applications or that we were the first to file patent applications on such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act ("AIA"), or the Leahy-Smith Act, the United States moved to a first inventor to file system. In general, 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, 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 Afrezza inhalation powder have terms extending into 2020, 2026, 2028, 2029, and 2030. 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, 2029, 2030 and 2031. 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.

An issued patent is presumed valid unless it is declared otherwise by a court of competent jurisdiction. However, 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 post grant proceedings, including, oppositions, 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.

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. These agreements provide that all inventions developed by the individual on behalf of us must be assigned to us and that the individual will cooperate with us in connection with securing patent protection on the invention if we wish to pursue such protection. We also execute confidentiality agreements with outside collaborators. There can be no assurance, however, that our inventions and assignment agreements and our confidentiality 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.

Interference proceedings brought by the USPTO, may be necessary to determine the priority of inventions with respect to our pre-AIA 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. In particular Inter Partes Review (“IPR”), available against any issued United States patent (pre-and post-AIA), has resulted in a higher rate of claim invalidation, due in part to the much reduced opportunity to repair claims by amendment as compared to re-examination, as well as the lower standard of proof used at the USPTO as compared to the federal courts. With the passage of time an increasing number of patents related to successful pharmaceutical products are being subjected to IPR. Moreover, the filing of IPR petitions has been used by short-sellers as a tool to help drive down stock prices. We may not prevail in any litigation, post-grant review, or interference proceedings in which we are involved and, even if we are successful, these proceedings may result in substantial costs and be a distraction to our management. Further, 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.

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 and other securities 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 and financial condition.

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) (a "337 action") with the International Trade Commission (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 that may trigger an allegation of infringement in connection with the commercial manufacture and sale of Afrezza. We do not believe that Afrezza infringes on any patents. However, 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 are 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, financial condition and results of operations would be harmed and our profitability could be materially and adversely impacted.

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 and other securities 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, financial condition and results of operations and cause the market price of our common stock and other securities 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 in our pipeline; therefore, we have not filed trademark registrations for such potential trade names for our product candidates, nor can we assure that we will be granted registration of any potential trade names for which we do file. 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

We may not be able to generate sufficient cash to service all of our indebtedness. We may be forced to take other actions to satisfy our obligations under our indebtedness or we may experience a financial failure.

Our ability to make scheduled payments on or to refinance our debt obligations will depend on our financial and operating performance, which is subject to the commercial success of Afrezza, the extent to which we are able to successfully develop and commercialize our Technosphere drug delivery platform and any other product candidates that we develop, prevailing economic and competitive conditions, and to certain financial, business and other factors beyond our control. We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, that these actions would be successful and permit us to meet our scheduled debt service obligations or that these actions would be permitted under the terms of our future debt agreements. In the absence of sufficient operating results and resources, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. We may not be able to consummate those dispositions or obtain sufficient proceeds from those dispositions to meet our debt service and other obligations when due.

Future sales of shares of our common stock in the public market, or the perception that such sales may occur, may depress our stock price and adversely impact the market price of our common stock and other securities.

If our existing stockholders or their distributees sell substantial amounts of our common stock in the public market, the market price of our common stock could decrease significantly. The perception in the public market that our existing stockholders might sell shares of common stock could also depress the market price of our common stock and the market price of our other securities. Any such sales of our common stock in the public market may affect the price of our common stock or the market price of our other securities.

In the future, we may sell additional shares of our common stock to raise capital. In addition, a substantial number of shares of our common stock is reserved for: issuance upon the exercise of stock options, and the vesting of restricted stock unit awards; the purchase of shares of common stock under our employee stock purchase program; and the issuance of shares upon exchange or conversion of the 2021 notes or any other convertible debt we may issue. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance or sale of substantial amounts of common stock, or the perception that such issuances or sales may occur, could adversely affect the market price of our common stock and other securities.

Our stock price is volatile and may affect the market price of our common stock and other securities.*

Between January 1, 2014 and September 30, 2018, our closing stock price as reported on The Nasdaq Global Market has ranged from $0.71 to $54.80, adjusted for the reverse stock split that occurred during this period. The trading price of our common stock is likely to continue to be 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:

- Our ability to obtain marketing approval for Afrezza outside of the United States and to find collaboration partners for the commercialization of Afrezza in foreign jurisdictions;
- Our future estimates of Afrezza sales, prescriptions or other operating metrics;
- Our ability to successful commercialize our Technosphere drug delivery platform;
- The progress of preclinical and clinical studies of our product candidates and of post-approval studies of Afrezza required by the FDA;
- The results of preclinical and clinical studies of our product candidates;
- General economic, political or stock market conditions, especially for emerging growth and pharmaceutical market sectors;
- 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 relationship with any of our current or future collaborators or third party manufacturers;
- 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;
- Sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- Our ability, or the perception of investors of our ability, to continue to meet all applicable requirements for continued listing of our common stock on The Nasdaq Stock Market, and the possible delisting of our common stock if we are unable to do so;
- The status of any legal proceedings or regulatory matters against or involving us or any of our executive officers and directors; 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 value of our common stock and other securities to decline.

If we fail to continue to meet all applicable listing requirements, our common stock may be delisted from The Nasdaq Global Market, which could have an adverse impact on the liquidity and market price of our common stock.

Our common stock is currently listed on The Nasdaq Global Market, which has qualitative and quantitative listing criteria. If we are unable to meet any of the Nasdaq listing requirements in the future, such as the corporate governance requirements, the minimum closing bid price requirement, or the minimum market value of listed securities requirement, Nasdaq could determine to delist our common stock. A delisting of our common stock could adversely affect the market liquidity of our common stock, decrease the market price of our common stock, adversely affect our ability to obtain financing for the continuation of our operations and result in the loss of confidence in our company. In 2016, we received a notice of non-compliance from the Listing Qualifications Department of the Nasdaq Stock Market with respect to the $1.00 minimum closing bid price requirement. Although we regained compliance with the minimum closing bid price requirement after effecting a reverse stock split in March 2017 there can be no assurance that we will be able to meet the minimum closing bid price requirement or other listing requirements in the future.

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

Public companies in general, including companies listed on The Nasdaq Global Market, have experienced 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 and other securities 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.

The future sale of our common stock or the exchange or conversion of our convertible debt into, or exercise of our outstanding warrants for, common stock could negatively affect the market price of our common stock and other securities.*

As of September 30, 2018, we had 159,497,573 shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations. 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 and other securities may decline. Likewise the issuance of additional shares of our common stock upon the exchange or conversion of some or all of our 2021 notes, 2019 notes, Tranche B notes, or the Mann Group Loan Arrangement, or upon issuance of our outstanding warrants, could adversely affect the market price of our common stock and other securities. In addition, the existence of these notes may encourage short selling of our common stock by market participants, which could adversely affect the market price of our common stock and other securities.

In addition, we will need to raise substantial additional capital in the future to fund our operations. If we raise additional funds by issuing equity securities or additional convertible debt, the market price of our common stock and other securities may decline.

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 or the holders of our other securities. 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 any investment in our common stock.

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. Pursuant to the Facility Agreement, we are subject to contractual restrictions on the payment of dividends. There is no guarantee that our common stock will appreciate or maintain its current price. You could lose the entire value of any investment in our common stock.

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

On August 14, 2018, we issued 475,520 shares of our common stock to the holders of our 2021 notes in satisfaction of our obligation to pay such holders $0.4 million of accrued interest due and payable on August 15, 2018. We relied on Section 4(a)(2) of the Securities Act of 1933, as amended with respect to such issuance.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2016).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of MannKind Corporation (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 March 2, 2017).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of MannKind Corporation (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 13, 2017).
3.4	Amended and Restated Bylaws (incorporated by reference to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on November 19, 2007).
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
4.2	Form of common stock certificate (incorporated by reference to Exhibit 4.2 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2017).
4.3	Form of 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.4	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).
4.5	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. 000-50856), filed with the SEC on May 12, 2014).
4.6	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).
4.7	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).
4.8	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 MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.9	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 10.39 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
4.10	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. (incorporated by reference to Exhibit 4.14 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 10, 2014).
4.11	Exchange and Third Amendment to Facility Agreement, dated June 29, 2017 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 June 29, 2017).
4.12	Fourth Amendment to Facility Agreement, dated October 23, 2017 by and among MannKind, MannKind LLC, 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 October 23, 2017).

Exhibit Number	Description of Document
4.13	Fifth Amendment to Facility Agreement, dated January 15, 2018 by and among MannKind, MannKind LLC, 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 January 18, 2018.
4.14	Sixth Amendment to Facility Agreement, dated January 18, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., and Deerfield Private Design International II, L.P. (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 January 18, 2018.
4.15	Exchange and Seventh Amendment to Facility Agreement, dated June 8, 2018 by and among MannKind, MannKind LLC, 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 June 11, 2018).
4.16	Exchange and Eighth Amendment to Facility Agreement, dated July 12, 2018 by and among MannKind, MannKind LLC, 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 13, 2018).
4.17	Ninth Amendment to Facility Agreement, dated September 5, 2018 by and among MannKind, MannKind LLC, 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 September 5, 2018).
4.18	Tenth Amendment to Facility Agreement, dated September 26, 2018 by and among MannKind, MannKind LLC, 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 September 27, 2018).
4.19	Indenture, by and between MannKind and U.S. Bank (dated October 30, 2017 (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 October 30, 2017).
4.20	Form of 5.75% Convertible Senior Subordinated Exchange Note due 2021 (incorporated by reference to Exhibit A of Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on October 30, 2017).
4.21	Form of Warrant to Purchase Common Stock issued November 16, 2015 (incorporated by reference to Exhibit 4.17 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 15, 2016).
4.22	Amended and Restated Promissory Note made by MannKind in favor of The Mann Group LLC, dated March 11, 2018 (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 March 12, 2018).
4.23	Form of Common Stock Purchase Warrant issued April 9, 2018 (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 April 6, 2018).
10.1*	MannKind Corporation 2018 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to MannKind's registration statement Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).
10.2*	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the MannKind 2018 Equity Incentive Plan (incorporated by reference to Exhibit 99.2 to MannKind's registration statement on Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).
10.3*	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the MannKind 2018 Equity Incentive Plan (incorporated by reference to Exhibit 99.3 to MannKind's registration statement on Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).
10.4*	MannKind Corporation 2004 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 99.4 to MannKind's registration statement Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).
10.5	Exchange and Eighth Amendment to Facility Agreement, dated July 12, 2018 by and among MannKind, MannKind LLC, 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 13, 2018).

Exhibit Number	Description of Document
10.6	Ninth Amendment to Facility Agreement, dated September 5, 2018 by and among MannKind, MannKind LLC, 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 September 5, 2018).
10.7	Tenth Amendment to Facility Agreement, dated September 26, 2018 by and among MannKind, MannKind LLC, 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 September 27, 2018).
10.8**	License and Collaboration Agreement, dated September 3, 2018 by and between MannKind and United Therapeutics Corporation.
10.9**	Research Agreement, dated September 3, 2018 by and between MannKind and United Therapeutics Corporation.
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.
32.1	Certification of the Chief Executive 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).
32.2	Certification of the 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.

* Indicates management contract or compensatory plan.

** 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 1, 2018

MANNKIND CORPORATION

By: /s/ MICHAEL E. CASTAGNA
Michael E. Castagna
Chief Executive Officer
(on behalf of the registrant and as the registrant's Principal Executive Officer)

By: /s/ STEVEN B. BINDER
Steven B. Binder
Chief Financial Officer
(on behalf of the registrant and as the registrant's Principal Financial and Accounting Officer)

Exhibit 10.8

*****Text Omitted and Filed Separately**
with the Securities and Exchange Commission.
Confidential Treatment Requested
Under 17 C.F.R. Sections 200.80(c) and Rule 24b-2

LICENSE AND COLLABORATION AGREEMENT

This **License and Collaboration Agreement** (the "***Agreement***") is entered into as of September 3, 2018 (the "***Execution Date***") between **MannKind Corporation**, a Delaware corporation ("***MannKind***"), having a principal place of business at 30930 Russell Ranch Road, Suite 301, Westlake Village, California 91362, and **United Therapeutics Corporation**, a Delaware corporation ("***United Therapeutics***"), having a principal place of business at 1040 Spring Street, Silver Spring, Maryland 20910.

RECITALS

Whereas, MannKind is developing Product (as defined below) in the Territory (as defined below) for the treatment of pulmonary arterial hypertension and owns or controls certain patents, know-how and other intellectual property related to Product;

Whereas, United Therapeutics is engaged in the development and commercialization of pharmaceutical products; and

Whereas, United Therapeutics desires to obtain from MannKind, and MannKind desires to grant to United Therapeutics, certain exclusive rights and licenses to develop Product in the Territory in collaboration with MannKind and to 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, MannKind and United Therapeutics 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 "***Accessory Apparatus***" shall mean an interactive apparatus that contains one or more sensors for real-time profiling ([…***…]*, etc.) through a Device, such as the Bluhale® apparatus.

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

1.3 "***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.

1.4 "***API***" shall mean treprostinil.

1.5 "***Applicable Laws***" shall mean the applicable provisions of any and all national, supranational, regional, territorial, provincial, 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.

1.6 "***Approved Suppliers***" shall have the meaning provided in Section 4.6.

1.7 "***Auditor***" shall have the meaning set forth in Section 7.6.

1.8 "***Bankruptcy Laws***" shall have the meaning set forth in Section 13.4.

1.9 "***Budget***" shall mean with respect to a particular Development Plan, the budget included in such Development Plan setting forth the maximum amount of reimbursement that MannKind is eligible to receive with respect to the Development Expenses it has incurred in performance of the various activities it is required to perform under such Development Plan and for which United Therapeutics has expressly agreed to provide reimbursement under such Development Plan.

1.10 "***Bulk FDKP***" means fumaryl diketopiperazine in bulk form.

1.11 "***Business Day***" shall mean a day other than a Saturday or Sunday or any public holiday in the United States.

1.12 "***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.

1.13 "***Calendar Year***" shall mean a period of 12 consecutive months beginning on and including January 1st.

1.14 "***Change of Control***" means, with respect to a Party: (a) completion of a merger, reorganization, amalgamation, arrangement, share exchange, consolidation, tender or exchange offer, private purchase, business combination, recapitalization or other transaction involving the Party as a result of which either (1) the stockholders of the Party immediately preceding such transaction hold less than 50% of the outstanding shares, or less than 50% of the outstanding voting

power, respectively, of the ultimate company or entity resulting from such transaction immediately after consummation thereof (including a company or entity which as a result of such transaction owns the then-outstanding securities of the Party or all or substantially all of the Party's assets, including Party's assets related to Product, either directly or through one or more subsidiaries), or (2) any single Third Party person or group (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect, referred to as a "***Group***") holds 50% or more of the outstanding shares or voting power of the ultimate company or entity resulting from such transaction immediately after the consummation thereof (including a company or entity which as a result of such transaction owns the then outstanding securities of the Party or all or substantially all of the Party's assets either directly or through one or more subsidiaries); or (b) the direct or indirect acquisition (including by means of a tender offer or an exchange offer) by any Third Party person or Group of beneficial ownership (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect), or the right to acquire beneficial ownership, or formation of any Third Party Group which beneficially owns or has the right to acquire beneficial ownership, of 50% or more of either the outstanding voting power or the then-outstanding shares of the Party, in each case on a fully diluted basis.

1.15 "***CMC***" shall mean chemistry, manufacturing and controls.

1.16 "***Commercialization Plan***" shall have the meaning set forth in Section 5.1(b).

1.17 "***Commercially Reasonable Efforts***" shall mean, with respect to the efforts to be expended by a Party with respect to any objective, those reasonable, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances. With respect to United Therapeutics' efforts with respect to the development of, or obtaining Marketing Approval for, the Product, "Commercially Reasonable Efforts" means the carrying out of such activities using the efforts and resources that a similarly situated company in the pharmaceutical industry would use for its own pharmaceutical product with similar market potential at a similar stage of its development, taking into consideration all scientific, commercial, and other factors that a similarly situated company within the pharmaceutical industry would reasonably take into account including issues of safety and efficacy, expected and actual cost and time to develop, expected and actual or potential competitiveness of alternative products (including alternative products being developed or commercialized by or on behalf of United Therapeutics and its Affiliates), the nature, breadth, duration and extent of their expected and actual market exclusivity (including patent coverage and regulatory exclusivity), expected likelihood of regulatory approval, their expected and actual likelihood of reimbursement, expected and actual pricing, expected and actual profitability, including royalties and other payments required to be made, the expected and actual amounts of marketing and promotional expenditures required with respect to such product and all other relevant factors, including comparative technical, legal, scientific and/or medical factors. Further, to the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, the impact of such other Party's failure to perform will be taken into account in determining whether the initial Party has used Commercially Reasonable Efforts with respect to the performance of such affected obligations. For clarity, "Commercially Reasonable Efforts" does not require United Therapeutics to disadvantage any currently marketed products (such as Remodulin®, Tyvaso® or Orenitram®) or products currently under development or which may in the future enter development (including without limitation RemoPro™, RemUnity™, esuberaprost, the Implantable System for Remodulin® and Trevyent™ and any additional delivery devices and formulations for the administration of treprostinil), the success of any of which may substantially diminish efforts and resources devoted to the development of Product.

1.18 "***Commercial Strategy***" shall have the meaning set forth in Section 5.1(a).

1.19 "***Competing Product***" shall mean a product other than Product that (a) contains a Prostacyclin as an active ingredient or (b) contains an active ingredient other than a Prostacyclin and that is indicated for use (or being developed for use) in the treatment of Pulmonary Hypertension (or is being developed with the objective of seeking approval for the treatment of Pulmonary Hypertension).

1.20 […***…]*.

1.21 "***Component Parts***" means injection-molded component parts for the Device (including cartridges).

1.22 "***Confidential Information***" shall have the meaning set forth in Section 8.1.

1.23 "***Confidentiality Agreement***" shall mean that certain confidentiality agreement, dated July 27, 2018, between MannKind and United Therapeutics.

1.24 "***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 or right to use under this Agreement, without violating the terms of an agreement with a Third Party.

1.25 "***Data***" shall mean any and all raw scientific, technical or test data pertaining to Product that is generated by or on behalf of a Party, its Affiliates (and to the extent Controlled by a Party or its Affiliates, the licensees or sublicensees of a Party or its Affiliates), 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 and all data in publications, presentations or submissions made in association with a Regulatory Filing with respect to Product. Data presented in graphical format should be accompanied by the tables used to generate such graphics. All Data should be accompanied by the methodology used to derive such Data.

1.26 ***"Deerfield***" shall mean Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P. and Horizon Santé FLML, SARL.

1.27 "***Development Expenses***" shall mean out-of-pocket costs incurred by MannKind or any of its Affiliates in conducting or performing its activities under a Development Plan. For clarity, Development Expenses shall not include labor costs incurred by MannKind in performing its obligations under the Initial Development Plan, which costs shall be the sole responsibility of MannKind.

1.28 "***Development Plan***" shall mean the Initial Development Plan, as the same may be subsequently amended from time to time in accordance with this Agreement, as well as any additional written plan mutually agreed by the Parties setting forth studies and other activities outside the scope of the Initial Development Plan that United Therapeutics requests that MannKind undertake in connection with United Therapeutics' development of Products other than the Initial Product in the Field in the Territory (each such plan, an "***Additional Development Plan***"). For example, in the event that United Therapeutics elects to develop a Product configuration that utilizes a Cricket inhaler and desires MannKind's assistance in such undertaking, the Parties would need to prepare an Additional Development Plan that outlines the various development activities with respect to which MannKind's assistance was needed and establishes a mutually agreeable budget for such activities. Once the Parties have agreed on an Additional Development Plan, any changes to such Development Plan shall require the written approval of the ESC.

1.29 "***Development Term***" shall mean the period during which MannKind is conducting activities under the Development Plan, commencing on the Effective Date and ending upon the completion of all activities specified in the Development Plan or earlier termination of this Agreement.

1.30 "***Device***" shall mean any device Controlled by MannKind through which a Formulation may be administered by inhalation, such as the Dreamboat® inhaler and Cricket® inhaler.

1.31 "***Disclosing Party***" shall have the meaning set forth in Section 8.1.

1.32 "***DMF***" shall mean the Drug Master File 028677 (including any amendments thereto) and any other drug master file filed by MannKind with the FDA to provide confidential detailed information about facilities, processes, analytical methods, or articles used in the manufacturing, processing, packaging and storing of one or more human drugs, or design and manufacture of any devices, including Product and/or Device. The term "DMF" shall also include within its meaning throughout this agreement any device master file or MAF filed by MannKind for the same purpose.

1.33 "***Effective Date***" shall have the meaning set forth in Section 15.16.

1.34 "***ESC***" shall have the meaning set forth in Section 3.1(a).

1.35 "***Export Control Laws***" shall mean all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury 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).

1.36 "***FCPA***" shall mean the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.) as amended.

1.37 "***FDA***" shall mean the United States Food and Drug Administration, or any agency that is responsible for approving the sale of medical devices and/or pharmaceutical products in the United States.

1.38 "***Field***" shall mean, with respect to a Prostacyclin, the administration to human beings for the prevention or treatment of diseases and other conditions in all indications and, with respect to any Other Agent, the administration to human beings for the prevention or treatment of Pulmonary Hypertension.

1.39 "***Filings***" shall have the meaning set forth in Section 15.16.

1.40 "***First Commercial Sale***" shall mean the first *bona fide*, arm's length sale of Product in a country following receipt of Marketing Approval in such country. Sales of Product for registration samples, compassionate use, named patient use and inter-company transfers to Affiliates of a Party will not constitute a First Commercial Sale.

1.41 "***Formulation***" shall mean a formulation of an active pharmaceutical ingredient suitable for pulmonary administration based upon or incorporating the drug delivery technology Controlled by MannKind involving diketopiperazine as a carrier.

1.42 "***GAAP***" shall mean generally accepted accounting principles in the United States, or internationally, as appropriate, consistently applied.

1.43 "***Governing Body***" shall mean the ESC or any working group of the ESC.

1.44 "***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).

1.45 "***Government Health Care Program***" shall mean the Medicare program (Title XVIII of the Social Security Act), 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.

1.46 "***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).

1.47 "***HIPAA***" shall have the meaning set forth in Section 16.4.

1.48 "***HSR Act***" shall have the meaning set forth in Section 15.16.

1.49 "***HSR Filing Date***" shall have the meaning set forth in Section 15.16.

1.50 "***IND***" shall mean the Investigational New Drug Application 134582 (including any amendments thereto) filed by MannKind with the FDA before commencement of clinical trials of Product.

1.51 "***Indemnitee***" shall have the meaning set forth in Section 11.3.

1.52 "***Indemnitor***" shall have the meaning set forth in Section 11.3.

1.53 "***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, discoveries, inventions, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, prototypes, specifications, 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, in each case (whether or not confidential, proprietary, patented or patentable, of commercial advantage or not) in written, electronic or any other form now known or hereafter developed.

1.54 "***Initial Device***" shall mean the reusable Dreamboat® inhaler and associated cartridges that is intended to be the utilized in the Initial Product.

1.55 "***Initial Development Plan***" shall mean the written plan attached to a separate letter delivered by MannKind to United Therapeutics and agreed to in writing by United Therapeutics on the Execution Date setting forth the activities to be performed by MannKind (or by the Parties jointly) with respect to the CMC development of the Initial Product and the Accessory Apparatus as well as the transfer to United Therapeutics of the manufacturing technology required to manufacture the Initial Product. The Initial Development Plan shall be subject to the terms and conditions of this Agreement. To the extent any terms or provisions of the Initial Development Plan conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement shall control.

1.56 "***Initial Product***" shall mean the Product (which shall utilize the Initial Device) that is intended to be the subject of the initial Regulatory Approval of Product.

1.57 "***Intervening Event***" shall have the meaning set forth in Section 15.1.

1.58 "***Inventions***" shall have the meaning set forth in Section 9.1(b).

1.59 "***Joint Inventions***" shall have the meaning set forth in Section 9.1(b).

1.60 "***Joint Patents***" shall mean all Patents claiming any Joint Invention.

1.61 "***Loss of Market Exclusivity***" shall mean with respect to a specified country in the Territory, the reduction by […***…]%*or more in any 12-month period in Net Sales of Product due to the sale in such country of any interchangeable pharmaceutical product containing a fumaryl diketopiperazine-based formulation of the same active ingredient as Product, which are marketed by any entity or entities other than United Therapeutics or any of its Affiliates or sublicensees in such country, as compared with the 12-month period immediately prior to the 12-month period in which the sale of any such pharmaceutical product first occurred (as measured by reputable published data, e.g. by reference to market share data collected by IMS).

1.62 "***Losses***" shall have the meaning set forth in Section 11.1.

1.63 "***Major Market Country***" shall mean each of […***…].

1.64 "***MannKind Indemnitees***" shall have the meaning set forth in Section 11.1.

1.65 "***MannKind Know-How***" shall mean all Information not included in the MannKind Patents that is Controlled by MannKind or any of its Affiliates (subject to Section 15.9) as of the Effective Date or during the Term that is necessary or reasonably useful for the development, manufacture, use, import, offer for sale or sale 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.

1.66 "***MannKind Patents***" shall mean all Patents Controlled by MannKind or any of its Affiliates (subject to Section 15.9) as of the Effective Date or during the Term that claim or disclose Product or its components, or are necessary or reasonably useful for the development, manufacture, use, import, offer for sale, or sale 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.

1.67 "***MannKind Technology***" shall mean all MannKind Know-How, MannKind Patents and MannKind's or its Affiliate's interest in Joint Patents and Joint Inventions.

1.68 "***Manufacturing Information***" shall mean all Information within the MannKind Know-How and MannKind Patents that is necessary or useful for the manufacture, assembly, test, operation and service of Product, including (a) such Information contained in the CMC section of any applicable Regulatory Filing, (b) any Information that MannKind has provided to its Approved Suppliers in relation to the Component Parts and Bulk FDKP supplied by them, (c) all processes and procedures for the manufacture of the Processed FDKP, and all necessary or useful specifications for any specialized equipment used in MannKind's facility to so manufacture the Processed FDKP, (d) all assembly procedures for Devices and all necessary or useful specifications for any specialized equipment used in the Danbury facility to assemble Devices, and (e) all batch record procedures for manufacture of Product.

1.69 "***Marketing Approval***" shall mean all clearances, approvals, licenses, registrations or authorizations of Regulatory Authorities in a country necessary for the manufacture, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of a pharmaceutical product and/or medical device in such country. For countries where governmental approval is required for pricing or reimbursement for a pharmaceutical 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.

1.70 "***NDC***" shall have the meaning set forth in Section 13.2(c).

1.71 "***Net Sales***" shall mean the net sales recorded by United Therapeutics or its Affiliates or sublicensees for the sale or disposition of Product to Third Parties (other than sublicensees) in *bona fide* arm's length transactions, as determined in accordance with GAAP and as reported in United Therapeutics' audited financial statements. The recorded net sales shall be equal to gross sales minus appropriate deductions, each to the extent actually incurred, allowed, taken or paid and not otherwise recovered, which shall be booked on an accrual basis by United Therapeutics and its Affiliates and sublicensees under GAAP, such as:

(a) trade, quantity and cash discounts;

(b) rebates, chargebacks, reimbursements, fees or similar payments to wholesalers and other distributors, pharmacies and other retailers, buying groups (including group purchasing organizations), health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, Governmental Authorities, or other institutions or health care organizations, including Medicare, Medicaid, Managed Healthcare and similar types of rebates;

(c) amounts repaid or credited by reasons of defects, rejections, recalls or returns of Product;

(d) amounts provided or credited to customers through coupons and other discount programs;

(e) costs of freight, insurance, import/export, and other transportation charges directly related to the distribution of Product, to the extent included in gross sales;

(f) that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) and reasonably allocable to sales of the Product;

(g) bad debts and uncollectable invoiced amounts, provided that any such amounts subsequently collected will be included in Net Sales;

(h) taxes, duties or other governmental charges (including any tax such as a value added or similar tax or government charge other than an income tax) levied on or measured by the billing amount for Product, as adjusted for rebates and refunds;

(i) delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates; and

(j) any other customary deductions that are consistent with GAAP, but which may not be duplicative of the deductions specified in (a) – (i) above.

In no event will any particular amount identified above be deducted more than once in calculating Net Sales (i.e., no "double counting" of reductions). Sales of Product between United Therapeutics and its Affiliates and sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Product to a Third Party (other than a sublicensee) shall be included within the computation of Net Sales. Neither United Therapeutics nor any of its Affiliates or sublicensees shall sell any Product for any non-monetary consideration. Notwithstanding anything to the contrary herein, disposal or use of Product for, marketing, regulatory or development purposes, such as clinical trials, compassionate use or indigent patient programs, without direct or indirect consideration, shall not be deemed a sale for purposes of this Net Sales definition.

1.72 "***Option***" shall have the meaning set forth in Section 2.6(a).

1.73 "***Optioned Agent***" shall mean (a) […***…]* or (b) any Other Agent that is indicated for use (or being developed for use) in the treatment of Pulmonary Hypertension or is being developed with the objective of seeking approval for the treatment of Pulmonary Hypertension.

1.74 "***Option Exercise Fee***" shall mean, with respect to each Optioned Agent, a non-refundable, non-creditable fee of $[…***…].

1.75 "***Other Agent***" shall mean an active pharmaceutical ingredient that is not a Prostacyclin, a […***…] or an […***…].

1.76 "***Party***" shall mean MannKind or United Therapeutics individually, and "***Parties***" shall mean MannKind and United Therapeutics collectively.

1.77 "***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.

1.78 "***Person***" shall mean any individual, corporation, partnership, limited liability company, trust, governmental entity, or other legal entity of any nature whatsoever.

1.79 "***Processed FDKP***" means a suspension or dried preparation of fumaryl diketopiperazine that is a component of a Formulation.

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1.80 "***Product***" shall mean a product in a form suitable for human applications consisting of (a) a Formulation that contains API for use in an inhalation device or 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), (c) both a Device and such a Formulation described in clause (a) for use together, or (d) an Accessory Apparatus for use with the Product configuration described in (c), in each case, including all improvements incorporated therein. 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 API unless such active pharmaceutical ingredient is an Optioned Agent that has been added to this Agreement pursuant to Section 2.6.

1.81 "***Prostacyclin***" shall mean a prostacyclin, a prostacyclin analog and a prostacyclin receptor agonist. For clarity, the API is a Prostacyclin.

1.82 "***Public Official or Entity***" shall mean (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), 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.

1.83 "***Pulmonary Hypertension***" a medical condition that encompasses all WHO classifications of pulmonary hypertension identified in the Nice 2013 Revised Classification system, including pulmonary arterial hypertension.

1.84 "***Receiving Party***" shall have the meaning set forth in Section 8.1.

1.85 "***Regulatory Authority***" shall mean any Governmental Authority whose review or approval is necessary for the development, design, manufacture, packaging, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of Product. 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.

1.86 "***Regulatory Exclusivity***" shall mean the ability to exclude any other Person from manufacturing or commercializing a product that could compete with Product in a specified country in the Territory, either through data exclusivity rights, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country.

1.87 "***Regulatory Filing***" shall mean all approvals, clearances, licenses, registrations, submissions and authorizations made to or received from a Regulatory Authority necessary for the development, manufacture or commercialization of a medical device and/or pharmaceutical product, including any investigational new drug applications, clinical trial applications, drug master files, device master files and Marketing Approvals.

1.88 "***Royalty Report***" shall have the meaning set forth in Section 7.1.

1.89 "***SEC***" shall mean the U.S. Securities and Exchange Commission, or any successor agency.

1.90 "***Segregate***" shall mean with respect to a product or program, to use Commercially Reasonable Efforts to segregate the development and commercialization activities relating to such product or program from development and commercialization with respect to Product under this Agreement, including using Commercially Reasonable Efforts to ensure that: (i) no personnel involved in performing the development or commercialization of such product or program have access to non-public plans or information relating to the development or commercialization of Product (provided that management personnel may review and evaluate plans and information regarding the development and commercialization of Product in connection with portfolio decision-making or other company-wide responsibilities); and (ii) no personnel involved in performing the development or commercialization of Product have access to non-public plans or information relating to the development or commercialization of such product or program (provided that management personnel may review and evaluate plans and information regarding the development and commercialization of such product or program in connection with portfolio decision-making or other company-wide responsibilities).

1.91 "***Specified Matters***" shall mean the subject matter described in the separate letter delivered by MannKind to United Therapeutics and confirmed in writing by United Therapeutics on the Execution Date.

1.92 ***"Term***" shall have the meaning set forth in Section 12.1.

1.93 "***Territory***" shall mean everywhere.

1.94 "***Third Party***" shall mean any Person other than MannKind, United Therapeutics and their respective Affiliates.

1.95 "***Third Party Claims***" shall have the meaning set forth in Section 11.1.

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

1.97 "***United Therapeutics Indemnitees***" shall have the meaning set forth in Section 11.2.

1.98 "***United Therapeutics Know-How***" shall mean all Information that (a) is Controlled by United Therapeutics or any of its Affiliates as of the Effective Date or during the Term and (b) is necessary for the development, manufacture, use, import, offer for sale or sale of Product in the Field.

1.99 "***United Therapeutics Patents***" shall mean all Patents Controlled by United Therapeutics or any of its Affiliates as of the Effective Date or during the Term that are necessary for the development, manufacture, use, import, offer for sale, or sale of Product in the Field, but excluding any Joint Patents.

1.100 ***"United Therapeutics Technology***" shall mean all United Therapeutics Know-How, United Therapeutics Patents and United Therapeutics' or its Affiliate's interest in Joint Patents and Joint Inventions.

1.101 "***Valid Claim***" shall mean a claim of an issued and unexpired Patent included within the MannKind Patents or Joint Patents in the Territory that (a) has not been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and (b) has not been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

1.102 "***Wind-down Period***" shall mean any period after the date of termination of this Agreement during which, pursuant to Section 13.2(a), United Therapeutics is required to continue to perform certain activities.

ARTICLE 2

GRANT OF LICENSE

2.1 Development Licenses. Subject to the terms and conditions of this Agreement, (a) MannKind hereby grants to United Therapeutics an exclusive (except as to MannKind which shall retain during the Development Term such rights as are necessary to fulfil its obligations under the Development Plan), royalty-free license, with the right to grant sublicenses as provided in Section 2.3, under the MannKind Technology to develop and seek Marketing Approval for Product (including to conduct non-clinical research and clinical studies, and to make and have made Product for purposes thereof) in the Field in the Territory, and (b) United Therapeutics hereby grants to MannKind a non-exclusive, worldwide, royalty-free license, with the right to grant sublicenses to Affiliates, under United Therapeutics Technology as is necessary for MannKind to perform activities to be performed by MannKind under the Development Plan, solely to perform such activities during the Development Term.

2.2 License to United Therapeutics. Subject to the terms and conditions of this Agreement, MannKind hereby grants to United Therapeutics an exclusive, royalty-bearing license, with the right to grant sublicenses as provided in Section 2.3, under the MannKind Technology to make and have made, use, sell, offer for sale, have sold and import Product in the Field in the Territory. The license granted in this Section 2.2 shall be exclusive even as to MannKind, subject to Section 5.2 and the rights reserved by MannKind pursuant to Section 2.4.

2.3 Sublicenses. United Therapeutics shall have the right to grant sublicenses through one or more tiers within the scope of the rights granted to it under Sections 2.1 and 2.2. Any sublicense shall be in writing and shall be consistent with the terms and conditions of this Agreement. Within 10 days after execution or receipt thereof, as applicable, United Therapeutics shall provide MannKind with a full and complete copy of each sublicense granted to any sublicensee (provided that United Therapeutics may redact any confidential information contained therein that is not necessary to disclose to ensure compliance with this Agreement). United Therapeutics shall be responsible for the acts or omissions of its sublicensees in exercising rights under the sublicense that would constitute a breach hereunder. For the avoidance of doubt, any sublicense issued by United Therapeutics during the Term will survive expiration or termination of this Agreement excluding any termination of this Agreement by MannKind pursuant to Section 12.5 or pursuant to Section 12.2(b) if the material breach was due to the actions or inactions of such sublicensee, or any termination of this Agreement by United Therapeutics pursuant to Section 12.3(a).

2.4 Reserved Rights; No Implied Licenses. Except for the rights and licenses expressly granted in this Agreement, MannKind retains all rights under its intellectual property, including the MannKind Technology, and United Therapeutics retains all rights under its intellectual property, including the United Therapeutics Technology, and no rights shall be deemed granted by one Party to the other Party by implication, estoppel or otherwise. United Therapeutics agrees, on behalf of itself and its Affiliates, not to practice MannKind Technology except pursuant to the licenses expressly granted to United Therapeutics in this Agreement or any other written agreement between the Parties. MannKind agrees, on behalf of itself and its Affiliates and sublicensees, not to practice United Therapeutics Technology except pursuant to the licenses expressly granted to MannKind in this Agreement or any other written agreement between the Parties.

2.5 Exclusivity.

(a) MannKind. During the Term, neither MannKind nor any of its Affiliates (subject to Section 15.9) shall develop, manufacture or commercialize, or authorize any Third Party to develop, manufacture or commercialize a Competing Product, provided that the foregoing shall not prevent MannKind from fulfilling its development obligations under the Development Plan or its manufacturing and supply obligations or performing any activities under any other written agreement between MannKind and United Therapeutics.

(b) United Therapeutics. During the Term, neither United Therapeutics nor any of its Affiliates (subject to Section 15.10) shall develop, manufacture or commercialize, or authorize any Third Party to develop, manufacture or commercialize any product (other than Product) containing or comprising any dry powder formulation of API that is or is intended to be primarily administered in or through the lungs.

2.6 Option to Add Additional Products.

(a) Option. Subject to the terms and conditions set forth in this Agreement, MannKind hereby grants to United Therapeutics an option (the "***Option***") to include as an "API" for purposes of this Agreement an Optioned Agent (with any Product containing such Optioned Agent, an "***Optioned Product***"). The Option may be exercised by United Therapeutics pursuant to the procedures set forth in this Section 2.6 at any time during the Term ("***Option Period***").

(b) Exercise of Option. To exercise the Option with respect to a particular Optioned Agent, United Therapeutics shall give MannKind written notice during the Option Period identifying the applicable Optioned Agent and stating that United Therapeutics desires that Optioned Product containing such Optioned Agent be included as "Product" under this Agreement (the "***Exercise Notice***"). United Therapeutics' exercise of the Option shall be effective upon timely receipt by MannKind of the Exercise Notice and of an Option Exercise Fee, whereupon the Optioned Product containing the Optioned Agent identified in such Exercise Notice shall be deemed a "Product" for purposes of this Agreement.

(c) Amendment of Agreement. As soon as practicable (and within ten (10) days) after United Therapeutics' exercise of the Option with respect to a particular Optioned Agent in accordance with Section 2.6(b) above, United Therapeutics and MannKind shall amend the definition of "API" in this Agreement to include the Optioned Agent. In the event additional development work is requested of MannKind in connection with the Optioned Agent, the Parties will negotiate the scope of such efforts (and the financial responsibility of the Parties therefor) as an additional Development Plan to be executed by both Parties as soon as practicable thereafter.

ARTICLE 3

GOVERNANCE

3.1 Executive Steering Committee.

(a) Establishment. Within 30 days following the Effective Date, MannKind and United Therapeutics shall establish an Executive Steering Committee (the "***ESC***") to oversee the activities of the Parties under this Agreement.

(b) Membership. The ESC shall be composed of six members, three of whom shall be nominated by MannKind and three of whom shall be nominated by United Therapeutics, 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 issues within the jurisdiction of the ESC. MannKind and United Therapeutics shall designate their respective initial members of the ESC within 30 days after the Effective Date. Each Party may change its ESC members at any time by written notice to the other Party. United Therapeutics shall have the right to designate the chair of the ESC.

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

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

(i) reviewing and approving any material changes to a Development Plan;

(ii) providing a forum for the Parties to exchange Data and information and to coordinate their respective activities with respect to development, regulatory and manufacturing matters pertaining to Product;

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

(iv) providing a forum for the Parties to discuss and coordinate regarding the forecasting, manufacture and supply of Product, and any regulatory activities with respect thereto;

(v) 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;

(vi) resolving all disputes referred to the ESC by working groups responsible for the sub-plans of the Development Plan; and

(e) Decision-Making and Dispute Resolution. For clarity, the ESC is intended primarily to be a consultative body with its decision making authority limited to the approval of material changes to the Development Plan (including the constituent development sub-plans). All decisions within the authority of the ESC shall be made by unanimous vote or written consent, with the MannKind members of the ESC collectively having one vote and the United Therapeutics members of the ESC collectively having one vote in all decisions of the ESC. The members of the ESC shall use reasonable efforts to reach agreement on all matters. If, despite such efforts, agreement on a particular matter cannot be reached by the ESC within 10 days after the ESC 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 Chief Executive Officer of MannKind and, on behalf of United Therapeutics, the Chief Executive Officer of United Therapeutics. 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 chair of the ESC shall have the right to make the final decision with regard to the disputed matter following good faith consideration of MannKind's comments, provided that the chair of the ESC shall not have power to resolve a dispute: (i) in a manner that would require MannKind to perform activities which materially exceed the scope of, or are materially different in nature with respect to, the activities MannKind has agreed to perform under the Development Plan or has otherwise agreed in writing to perform; (ii) by overriding MannKind's rights under this Agreement; or (iii) by unilaterally determining that it has fulfilled any diligence obligations hereunder. For all purposes under this Agreement, any decision made pursuant to this Section 3.1(e) shall be deemed to be the decision of the ESC.

(f) Working Groups of the ESC. Promptly following its establishment, the ESC shall establish two working groups, one to oversee the performance of the CMC development activities ("***CMC Working Group***") and one to oversee the performance of the manufacturing technology transfer ("***Mfg Technology Transfer Working Group***"). These working groups shall periodically review their applicable activities within the Initial Development Plan and develop detailed and specific sub-plan updates as needed, which shall be submitted to the ESC for review and approval. In addition, each Party may submit requested modifications to such sub-plans to the ESC, which the ESC will reasonably consider. From time to time, the ESC may establish additional working groups as necessary to oversee particular projects or activities added to the Development Plan, as it deems necessary or advisable. Each working group shall consist of such number of representatives of each Party as the ESC determines is appropriate from time to time and shall meet with such frequency as the ESC 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 United Therapeutics 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 ESC, which shall resolve such matter in accordance with Section 3.1(e).

3.2 Scope of Governance. Notwithstanding the creation of the ESC, each Party shall retain the rights, powers and discretion granted to it hereunder, and the ESC 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 ESC shall not have the power to amend or modify this Agreement, and no decision of the ESC 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 ESC are only those specific issues that are expressly provided in this Agreement to be decided by the ESC. Notwithstanding anything to the contrary in Sections 3.1(e), 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.

ARTICLE 4

DEVELOPMENT AND REGULATORY ACTIVITIES

4.1 Development Activities.

(a) United Therapeutics' Obligations.

(i) General. Except as provided in Section 4.1(b) below, as between the Parties, United Therapeutics shall be solely responsible for the development of Product(s), including the conduct of clinical trials, and shall bear all of the costs and expenses that it (or its Affiliates or sublicensees) incur in the course of such activities.

(ii) United Therapeutics Diligence. United Therapeutics shall use Commercially Reasonable Efforts to: (A) carry out such development activities with respect to the Initial Product as may be necessary to support filing for Marketing Approval for the Initial Product in the United States, and (B) upon successful completion of such development activities, to file for, and obtain Marketing Approval for, the Initial Product in the United States. Notwithstanding the foregoing: (1) in the event that United Therapeutics has expended at least […***…]* U.S. Dollars (USD $[…***…]) on the development of the Initial Product in any Calendar Year (at least $[…***…] of which shall be out-of-pocket expenditures), such expenditure shall constitute conclusive evidence of United Therapeutics having used Commercially Reasonable Efforts with respect to the development of the Initial Product in such Calendar Year, and (2) United Therapeutics' receipt of Marketing Approval for the Initial Product in the United States shall constitute conclusive evidence that United Therapeutics has fulfilled in full its diligence obligations under this Section 4.1(a)(ii).

(iii) Reports. Up until the First Commercial Sale of the Initial Product, United Therapeutics shall provide MannKind with annual written summary reports detailing the progress and results of development activities with respect to the Initial Product. After the First Commercial Sale of the Initial Product, United Therapeutics shall provide MannKind with royalty reports as provided in Section 7.1 below.

(b) MannKind's Obligations.

(i) General. MannKind shall be responsible for performing those tasks with respect to the development of the Initial Product that are set forth in the Initial Development Plan and those tasks with respect to the development of any additional Product(s) that are set forth in any Additional Development Plans mutually agreed by the Parties. Except as provided in Section 6.4, MannKind shall be responsible for the costs associated with the performance of its obligations under the Development Plan. Notwithstanding the foregoing, in the event that MannKind is required to have its personnel visit United Therapeutics' facilities in connection with the manufacturing technology transfer activities contemplated in the Initial Development Plan, United Therapeutics agrees to reimburse MannKind for the reasonable travel and lodging expenses incurred in connection therewith.

(ii) MannKind Diligence. MannKind shall use Commercially Reasonable Efforts to conduct and complete the activities assigned to it in the Development Plan in accordance with the timelines specified therein. Without limiting the foregoing, MannKind shall proceed diligently and in a timely manner with the activities assigned to it under the Development Plan by using its good faith efforts to allocate sufficient time, effort, equipment and facilities to such development activities and to use personnel with sufficient skills and experience as are required to accomplish such activities in accordance with the terms of the Development Plan and this Agreement.

(c) Mutual Obligations.

(i) Compliance with Development Plan and Applicable Laws. Each Party shall conduct the development activities assigned to it under the Development Plan in accordance with the terms of the Development Plan and the other provisions of this Agreement and in compliance in all material respects with all Applicable Laws and in accordance with generally accepted scientific standards and good clinical practices, applicable under the Applicable Laws of the country in which such activities are conducted or of the country in which a Regulatory Filing is made.

(ii) Information Regarding Development Activities Under the Development Plan. 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 the activities assigned to it under the Development Plan. MannKind shall keep the ESC appropriately informed of the status of its activities conducted under the Development Plan. Upon request by the ESC, without limiting the foregoing, each Party shall promptly provide the ESC with summaries in reasonable detail of all Data and results generated or obtained in the course of such Party's performance of its activities under the Development Plan.

4.2 Regulatory Activities.

(a) Regulatory Strategy. United Therapeutics shall develop and be solely responsible for the regulatory strategy for Product in the Field in the Territory.

(b) Regulatory Submissions and Marketing Approvals. At its sole expense, United Therapeutics or its Affiliates shall be responsible for filing and attempting to obtain Marketing Approval for the Product in the Field in the Territory and as between the Parties, shall own, all Regulatory Filings for the Product in the Territory, including all investigational new drug applications, investigational device exemptions and filings for Marketing Approvals.

(c) Assignment of IND. As soon as practicable, but in any event within 30 days after the Effective Date, MannKind will transfer the IND to United Therapeutics. Following the Effective Date, MannKind shall not initiate any interaction with any Regulatory Authority regarding the Product, nor engage in any correspondence with any Regulatory Authority regarding the Product, in each case except at the direction of United Therapeutics. In the event that MannKind receives any communications from a Regulatory Authority with respect to the Product, MannKind will promptly notify United Therapeutics and collaborate with United Therapeutics in drafting such response as United Therapeutics may reasonably deem appropriate. For clarity, commencing on the Effective Date, United Therapeutics shall have ultimate decision-making authority with respect to any communications with any competent Governmental Authority, Regulatory Authority or other administrative body with respect to the Product, including without limitation, the FDA. MannKind shall promptly provide to United Therapeutics copies of all Regulatory Filings for the Product made by or on behalf of MannKind or its Affiliates, together with copies of any correspondence with Regulatory Authorities or other government agencies relating to such Regulatory Filings and/or Product. Without limiting the foregoing, MannKind will ensure that it has transferred to United Therapeutics all Information that MannKind was required by Applicable Laws to maintain as the holder of the IND or that is necessary or useful to prepare and defend any inquiries from Regulatory Authorities.

(d) Cooperation. Upon request by United Therapeutics, MannKind shall provide reasonable assistance to United Therapeutics in relation to the regulatory activities described in this Section 4.2, including without limitation assisting United Therapeutics in the preparation of Regulatory Filings for Product in the Territory.

4.3 Right of Reference.

(a) By MannKind. MannKind shall grant to United Therapeutics: (a) a right of reference with respect to the DMF as well as to all other Regulatory Filings (including Data contained therein) of MannKind or its Affiliates related to Product, and (b) the right to access such Regulatory Filings and any data therein and use such data in connection with the performance of its obligations and exercise of its rights under this Agreement, including inclusion of such data in its own Regulatory Filings for Product, which rights United Therapeutics may extend to its Affiliates and sublicensees of such Products. Upon request from United Therapeutics, MannKind shall provide a signed statement to this effect, if United Therapeutics, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in any country or region or otherwise provide appropriate notification of such right of United Therapeutics to the applicable Regulatory Authority. MannKind will provide, and cause its Affiliates to provide, cooperation to United Therapeutics to effect the foregoing.

(b) By United Therapeutics. United Therapeutics shall grant to MannKind: (a) a right of reference with respect to Regulatory Filings (including Data contained therein) of United Therapeutics or its Affiliates related to Product, and (b) the right to access such Regulatory Filings and any data therein and use such data in connection with its own Regulatory Filings for products other than Product, which rights MannKind may extend to its Affiliates and licensees of such products. Upon request from MannKind, United Therapeutics shall provide a signed statement to this effect, if MannKind, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in any country or region or otherwise provide appropriate notification of such right of MannKind to the applicable Regulatory Authority. United Therapeutics will provide, and cause its Affiliates to provide, cooperation to MannKind to effect the foregoing

4.4 Provision of Know-How. Promptly following the Effective Date, at no additional cost or expense to United Therapeutics, MannKind will transfer to United Therapeutics Data generated by or on behalf of MannKind or its Affiliates, including all pre-clinical and clinical records generated by or on behalf of MannKind with respect to the Initial Product, and provide to United Therapeutics the MannKind Know-How that exists as of the Effective Date. During the Term, MannKind shall provide to United Therapeutics, at no additional cost or expense to United Therapeutics, all MannKind Know-How that has not previously been provided hereunder promptly upon such MannKind Know-How being obtained or generated by MannKind. MannKind further agrees to make its employees (or the employees of its applicable Affiliate) reasonably available and without charge to answer questions with respect to: (a) the MannKind Know-How (including Data generated by or on behalf of MannKind or its Affiliates), (b) MannKind's Regulatory Filings and related regulatory Information provided or required to be provided under Section 4.2(c), and (c) the Manufacturing Information provided or required to be provided under Section 5.2(c). For clarity, MannKind's transfer obligations under this Section 4.4, the transfer of which are specifically addressed elsewhere (e.g., transfer of Regulatory Filings under Section 4.2(c) and transfer of Manufacturing Information under Section 5.2(c)) shall remain subject to the terms and conditions in such other Sections. During the Term, United Therapeutics shall provide to MannKind, at no additional cost or expense to MannKind, all United Therapeutics Know-How as is necessary for MannKind to perform studies and activities to be performed by MannKind under the Development Plan that has not previously been provided hereunder and is reasonably requested by MannKind.

4.5 Regulatory Updates. United Therapeutics agrees to keep MannKind reasonably informed as to the regulatory strategy and regulatory activities carried out by or on behalf of United Therapeutics, its Affiliates and sublicensees relating to Product, including its material correspondence and meetings with Regulatory Authorities, by way of updates to the ESC at its meetings and as otherwise reasonably requested by MannKind.

4.6 Use of Subcontractors. MannKind shall not assign, delegate, or subcontract to a Third Party any of the development or regulatory activities assigned to it under the Development Plan without the prior written approval of United Therapeutics, provided that the Parties agree that the subcontractors listed in the Initial Development Plan ("***Approved Suppliers***") shall be deemed pre-approved for the tasks indicated therein. United Therapeutics shall be free to perform its development or regulatory activities under this Agreement through one or more subcontractors. In the event that either Party elects to use subcontractors as permitted in this Section 4.6, such Party shall ensure that (a) none of the other Party's rights hereunder are diminished or otherwise adversely affected as a result of such subcontracting, and (b) the subcontractor 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 a Party performs any of its development or regulatory activities hereunder through a subcontractor, then such Party will at all times be fully responsible for the performance and payment of such subcontractor.

4.7 DMF. The Parties acknowledge that MannKind has included certain CMC Information required to be included in an application for Marketing Approval of the Initial Product in a drug master file filed with the FDA and referred to as the DMF. MannKind agrees to file additional drug master file(s) and/or device master file(s) with other Regulatory Authority(ies) as reasonably requested by United Therapeutics, and provide the appropriate authorizations to such Regulatory Authority(ies) allowing the right to review and reference such drug master file(s) and/or device master file(s) in support of applications for Marketing Approval for Product submitted by United Therapeutics (or its permitted designee). To the extent practicable, MannKind shall file such drug master file(s) and/or device master file(s) in coordination with United Therapeutics' efforts to file and prosecute the applicable Regulatory Filings to such Regulatory Authority and shall be responsible, at its sole expense or as otherwise specified in the Development Plan, for providing the applicable Regulatory Authorities with such additional data as they may request (provided, however, that any additional studies that must be conducted to provide such additional data shall be at United Therapeutics' expense under Section 6.4 to the extent such studies relate solely or substantially to Product), and for correcting any deficiencies of such drug master file(s) and/or device master file(s) identified by such Regulatory Authority, in each case in a reasonably prompt and efficient manner so as to prevent any delay in obtaining Marketing Approvals based on such drug master file(s) and/or device master file(s). MannKind shall be responsible for maintaining the drug master file(s) (including without limitation the DMF) and/or device master file(s) in accordance with applicable laws and ensuring that all CMC Information and other MannKind Know-How incorporated therein is accurate and up to date as necessary to support filing and prosecuting the applicable Regulatory Filing(s) and obtaining and maintaining the applicable regulatory approval(s) (including without limitation investigational new drug applications and Marketing Approvals) hereunder. MannKind shall provide United Therapeutics with true and complete copies of such drug master file(s) and/or device master file(s) (including for clarity, copies of the "closed" portion of such file(s)).

4.8 Pharmacovigilance. Upon United Therapeutics' request, the Parties shall negotiate in good faith and enter into a mutually agreeable safety data exchange agreement ("***Pharmacovigilance Agreement***"). Each Party shall comply or procure compliance with the terms and conditions of such Pharmacovigilance Agreement once it has been agreed and executed between the Parties. In the absence of a Pharmacovigilance Agreement, the following terms shall govern with respect to Adverse Events (as defined below).

(a) Each Party shall, and shall require its respective Affiliates to:

(i) notify the other Party promptly of all information coming into its possession concerning any untoward medical occurrence, whether or not considered Product-related, associated with clinical or commercial uses of a Product or any component thereof (including the Device or Processed FDKP utilized in a Product) (an "***Adverse Event***");

(ii) provide to the other Party a copy of any written submission made by such Party to a Regulatory Authority regarding Adverse Events no later than five (5) days following finalization of such written submission (and, to the extent permissible under time constraints and reporting requirements, in advance of submission to the applicable Regulatory Authority); and

(iii) adhere to all requirements of Applicable Laws that relate to the reporting and investigation of Adverse Events.

(b) If a Party contracts with a Third Party for research to be performed by such Third Party on the Product, that Party shall require such Third Party to report to the contracting Party the information set forth above; and both Parties shall be furnished a copy of said report.

4.9 Information Sharing. The Parties acknowledge that development and registration of a Device in one country has the potential to impact the development and registration of a similar Device in the same country as well as in other countries. Similarly the development of a Formulation for pulmonary administration of a particular active pharmaceutical ingredient in one country has the potential to impact the development and registration of the same Formulation for pulmonary administration of a different active pharmaceutical ingredient in the same country as well as in other countries. Accordingly, each Party shall provide the other Party with the following information in the disclosing Party's possession (and subject to any confidentiality obligations) relating to (i) any drug device combination utilizing the Dreamboat® inhaler or any other Device that is the same or substantially similar to the Device employed in a Product, and (ii) any drug device combination in which the applicable active pharmaceutical ingredient is formulated for pulmonary delivery using Processed FDKP:

(a) Regulatory Actions. All material information pertaining to actions taken by Regulatory Authorities with respect to products described in (i) and (ii) above, including without limitation, any notice, audit notice, notice of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning such products, notice of violation letter (i.e., untitled letter), warning letter, service of process or other inquiry, but only to the extent in each case that such action pertains specifically to the Device component or the Processed FDKP component of the applicable product;

(b) Regulatory Non-Compliance. All material information pertaining to notices from Regulatory Authorities of non-compliance with Applicable Laws in connection with products described in (i) and (ii) above, including without limitation, receipt of a warning letter or other notice of alleged non-compliance from any Regulatory Authority relating to such products, but only to the extent in each case that such non-compliance pertains specifically to the Device component or the Processed FDKP component of the applicable product;

(c) Safety Data. Any information relating to products of the type described in (i) and (ii) above, including any information learned by the Party from its licensees or sublicensees, as applicable, that suggests a hazard, contraindication, side effect or precaution or other potential safety issue with such products, but only to the extent in each case that such hazard, contraindication, side effect or precaution or other potential safety issue is attributable to the Device component or the Processed FDKP component of the applicable product.

ARTICLE 5

COMMERCIALIZATION; MANUFACTURE AND SUPPLY

5.1 Commercialization of Product.

(a) United Therapeutics Responsibilities. United Therapeutics shall have the exclusive right to commercialize Product in the Territory during the Term, subject to the terms and conditions of this Agreement. Without limiting the foregoing, during the Term, United Therapeutics will have the exclusive right and responsibility, at United Therapeutics' sole expense, for the following with respect to Product 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 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).

(b) Commercialization Plan. At least six (6) months prior to anticipated launch of Product, United Therapeutics shall prepare a three-year, non-binding high-level plan for the marketing, promotion and pricing of Product in the Field in the United States as well as a more detailed, non-binding one-year plan that shall contain the commercialization objectives to be achieved during the applicable Calendar Year, the launch, promotion, distribution, detailing and marketing activities to be performed in pursuit of such objectives in such Calendar Year, and a budget setting out the amounts anticipated to be expended in the performance of such activities during such Calendar Year (such three-year high level plan and more detailed one-year plan, collectively the "***Commercialization Plan***"). Thereafter, United Therapeutics shall provide an updated Commercialization Plan to MannKind on an annual basis and shall additionally modify each such Commercialization Plan throughout the Calendar Year as it deems necessary in its sole discretion to accurately reflect United Therapeutics' then current plans for the Product, provided that any material amendments to the Commercialization Plan shall be promptly provided to MannKind. Without limiting the provisions of this Section 5.1, at MannKind's reasonable request, United Therapeutics shall periodically consult with and provide updates to MannKind regarding the Commercial Strategy and commercialization of Product in the Territory.

(c) United Therapeutics Obligations. United Therapeutics shall endeavor in good faith to market, promote and commercialize Product in the Field in the Territory in accordance with the provisions of this Agreement and the then-current Commercialization Plan. It is acknowledged that the intent of Sections 5.1(b) and Section 5.1(c) is to provide MannKind with an accurate understanding of United Therapeutics plans for the commercialization of the Product in the Territory and that so long as United Therapeutics (i) has endeavored in good faith to ensure that the Commercialization Plan accurately reflects United Therapeutics' plans for the commercialization of the Product and (ii) attempts in good faith to carry out the activities described in the current Commercialization Plan, it shall have complied with its obligations under this Section 5.1. Failure to comply in any material respect with the obligations of this Section 5.1(c) as described in the preceding sentence shall be deemed a material breach of this Agreement, subject to all of the terms and conditions applicable to a material breach.

(d) Commercialization Outside the United States. In the event that United Therapeutics determines that it will make no commercialization efforts with respect to Product in one or more Major Market Countries outside of the United States, either through its own endeavors or through those of its Affiliates and sublicensees, MannKind shall have the option, exercisable by written notice to United Therapeutics during the Term, to exclude one or more of such Major Market Countries (the "***Excluded Countries***") from the Territory. Such exercise shall be effective only if MannKind provides a written plan reasonably satisfactory to United Therapeutics demonstrating that MannKind or its Affiliates will establish the necessary infrastructure and commercial capabilities to commercialize Product in the Excluded Countries in coordination with United Therapeutics' efforts in the Territory. In the event that MannKind exercises its option to reduce the Territory as described in this Section 5.1(d), the Parties shall negotiate in good faith an amendment to this Agreement setting forth the terms and conditions of such commercialization of Product by MannKind or its Affiliates in the Excluded Countries, which amendment shall include the payment by MannKind to United Therapeutics of royalties on the net sales of Product in the Excluded Countries equal to the amount of royalties specified in Section 6.3 of this Agreement.

5.2 Manufacture and Supply.

(a) Initial Clinical Supply and Clinical Supply for Pivotal Study and Product Launch. The Parties shall establish as soon as practicable following the Effective Date procedures for the supply of Initial Product to United Therapeutics for use by United Therapeutics in continuing the development of the Initial Product, and the Parties shall enter into a clinical supply agreement within three (3) months of the Effective Date pursuant to which MannKind shall supply United Therapeutics with (i) finished Initial Product suitable for use by United Therapeutics in clinical trials, and (ii) semi-finished Product (unkitted, unlabeled Devices and packaged cartridges for Initial Product) for use in the planned pivotal trial for the Initial Product and for subsequent commercial launch, the key terms of which agreement are set forth on an exhibit attached to a separate letter delivered by MannKind to United Therapeutics and agreed to in writing by United Therapeutics as of the Execution Date.

(b) Long Term Commercial Supply. At United Therapeutics' request, the Parties shall enter into long term commercial supply agreement pursuant to which MannKind shall supply United Therapeutics with assembled Devices (unfilled), unassembled cartridges (lids and cups) and Processed FDKP, which United Therapeutics would then use to manufacture fully packaged, kitted and labeled Initial Product, the key terms of which agreement are set forth on an exhibit attached to a separate letter delivered by MannKind to United Therapeutics and agreed to in writing by United Therapeutics as of the Execution Date. If desired by the Parties, the supply of Accessory Apparatuses may also be included in the long-term commercial supply agreement.

(c) Manufacturing Information. On United Therapeutics request, MannKind shall deliver to United Therapeutics, at no additional cost or expense to United Therapeutics, all Manufacturing Information that exists as of the Effective Date. Upon United Therapeutics' request at any time, MannKind shall also deliver to United Therapeutics, at no additional cost or expense to United Therapeutics, all Manufacturing Information that has not previously been provided under this Agreement, promptly upon such Manufacturing Information being obtained or generated by MannKind. The Manufacturing Information will be of sufficient detail to enable a reasonably experienced manufacturer to manufacture, assemble, test, operate, and service the Initial Product.

(d) Direct United Therapeutics Purchases. The Parties agree that United Therapeutics has the right under Section 2.2 to source all raw materials for the manufacture of Product from the suppliers of its choice. In the event that MannKind enters into a new supply agreement or amends an existing supply agreement with an Approved Supplier for Bulk FDKP or the Component Parts of the Device, MannKind shall take reasonable steps to ensure that United Therapeutics will be considered a third party beneficiary of such supply agreement or amendment. Without limiting the foregoing, at United Therapeutics' written request, MannKind will facilitate United Therapeutics entering into a direct supply arrangement with MannKind's Approved Supplier(s) for supply of Bulk FDKP or the Component Parts of the Device by providing United Therapeutics with letters of introduction to such Approved Supplier(s) and such other assistance as may be reasonably requested by United Therapeutics and providing to such Approved Supplier(s) any necessary authorizations or waivers under MannKind's contract(s) with such Approved Supplier(s) that would be necessary for such Approved Supplier(s) to supply United Therapeutics with FDKP or the Component Parts.

ARTICLE 6

CONSIDERATION

6.1 Initial Payment. In partial consideration for the licenses and rights granted to United Therapeutics hereunder, United Therapeutics shall pay to MannKind a non-refundable, non-creditable payment in the amount of $45,000,000 within 10 Business Days following the Effective Date.

6.2 Milestone Payments.

(a) Generally. In partial consideration for the licenses and rights granted to United Therapeutics hereunder, and on the terms and subject to the conditions set forth herein, United Therapeutics shall pay to MannKind the following non-refundable, non-creditable milestone payments set out below (the "***Milestone Payments***") following the achievement of the corresponding milestone events (each, a "***Milestone***"). Such payment shall be made within 10 Business Days of the achievement of the applicable milestone event by United Therapeutics.

Milestone Event	Milestone Payment
(A) […***…]*	$12,500,000
(B) […***…]	$12,500,000
(C) […***…]	$12,500,000
(D) […***…]*	$12,500,000
(E) […***…]	$15,000,000
(F) […***…]	$15,000,000

(b) Certain Additional Terms. For the avoidance of doubt, the following shall apply to Milestone Payments:

(i) Milestone Payments (A) through (D) above shall be made no more than once (and each only upon the first achievement of the corresponding milestone), irrespective of how many Products achieve the corresponding milestone. Milestone Payments (E) and (F) above may be paid more than once (i.e., if there are multiple Optioned Agents), but each shall be paid only once for the first Optioned Product for each Optioned Agent that reaches the corresponding milestone.

(ii) No unachieved Milestone Payments shall accrue and be due once notice has been given by United Therapeutics for termination of this Agreement in its entirety under Article 12.

6.3 Royalty Payments.

(a) Royalty Rate. Subject to the terms and conditions of this Agreement, in partial consideration for the licenses and rights granted to United Therapeutics under this Agreement, United Therapeutics shall pay to MannKind a royalty of […***…]% on aggregate Net Sales of Product in the Territory.

******Confidential Treatment Requested**
******Confidential Treatment Requested**

(b) Third Party Licenses. Without limiting MannKind's indemnification obligations to United Therapeutics under this Agreement, if, during the Term, United Therapeutics determines in good faith that it is necessary or useful to obtain a license from any Third Party to any Patent in connection with the practice of the MannKind Technology in order to manufacture, use, sell or offer for sale Product in the Field in the Territory, 100% of any royalties paid to such Third Party under the license for such Patent in respect of Product in the Territory may be deducted from royalties otherwise due to MannKind with respect to Product in the Territory under this Agreement; provided in no event shall such deduction reduce the royalties otherwise payable to MannKind in respect of such Product in such country by more than 50% in any Calendar Quarter; provided that any excess deduction shall be carried over and applied against royalties payable to MannKind in respect of Product in the Territory in subsequent periods of the Term until the full deduction is taken.

(c) Royalty Term. On a Product-by-Product and country-by-country basis, United Therapeutics will be obligated to make royalty payments pursuant to this Section 6.3 beginning upon the First Commercial Sale of Product in such country and continuing until the later of (i) the expiration of the last-to-expire Valid Claim covering Product (or the Formulation or Device included in Product) or its manufacture or use in such country and (ii) the expiration of Regulatory Exclusivity in such country. After the later date described in Section 6.3(c)(i) and (ii), in consideration of the continuing license of MannKind Know-How and Joint Inventions, royalties shall continue to be payable with respect to Net Sales of Product in such country, but the amount of periodic Net Sales shall be reduced by […***…]%* for purposes of calculating royalties payable in accordance with Section 6.3(a).

(d) Loss of Market Exclusivity. On a Product-by-Product and country-by-country basis, in the event of Loss of Market Exclusivity, the royalty payment due to United Therapeutics for Net Sales of Product in such country shall be reduced to […***…]%.

(e) Aggregate Floor for Royalty Reductions. Notwithstanding Sections 6.3(b), (c) and (d), the royalty payment to MannKind shall not be reduced in any Calendar Quarter to less than […***…]%.

6.4 Reimbursement of Development Expenses. Subject to the terms of this Section 6.4, (i) United Therapeutics shall reimburse MannKind for the Development Expenses it incurs in carrying out those obligations under a Development Plan which are expressly designated as being subject to reimbursement by United Therapeutics; *provided, however,* that United Therapeutics shall not be responsible for reimbursing MannKind for Development Expenses that exceed the amount budgeted for such activities in the applicable Budget by more than […***…]% unless otherwise approved by the ESC.

(a) Payment. Within 30 days after the end of each Calendar Quarter, MannKind will provide United Therapeutics a written report (each, a "***Quarterly Report***") setting forth in reasonable detail the Development Expenses for such Calendar Quarter that are reimbursable by United Therapeutics to MannKind in accordance with Section 6.4(a). United Therapeutics shall pay the amount due to MannKind as set forth in the applicable Quarterly Report within 30 days after receipt of such Quarterly Report.

******Confidential Treatment Requested**

(b) Audit. United Therapeutics shall have the right to cause an independent, certified public accounting firm reasonably acceptable to MannKind to audit MannKind's records relating to Development Expenses to confirm the amount of such expenses reflected in the Quarterly Reports. Such audit right may be exercised during normal business hours upon reasonable prior written notice to MannKind; provided that such audit right may be exercised no more than once in any 12 month period and no more than once with regard to any given Calendar Quarter. As appropriate, prompt adjustments to payments made pursuant to this Section 6.4 shall be made by the Parties to reflect the results of such audit. United Therapeutics shall bear the full cost of such audit unless such audit discloses an over-reporting by MannKind of more than 5% of the amount of Development Expenses for a given Calendar Quarter, in which case, MannKind shall bear the full cost of such audit.

ARTICLE 7

PAYMENTS, BOOKS AND RECORDS

7.1 Royalty Report and Payment. During the Term, within […***…]* days after the end of each Calendar Quarter, United Therapeutics shall deliver to MannKind a report setting forth the gross sales of Product and Net Sales in the relevant Calendar Quarter and a calculation of the payments due under Section 6.3 (a "***Royalty Report***"). Following receipt of any Royalty Report, MannKind shall issue an invoice for the amount stated by United Therapeutics to be payable to MannKind in such Royalty Report, and payment shall be due to MannKind by United Therapeutics within […***…] days of its receipt of such invoice.

7.2 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 designated in writing by MannKind. Payments hereunder will be considered to be made as of the day on which they are received by MannKind's designated bank.

7.3 Payment Currency. Unless otherwise expressly stated in this Agreement, all amounts specified to be payable under this Agreement are in United States Dollars and shall be paid in United States Dollars. Net Sales in the Territory invoiced in currency other than United States Dollars, as appropriate, shall be translated to United States Dollars using the exchange rate utilized by United Therapeutics in calculating its own revenues for financial reporting purposes.

7.4 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. For the avoidance of doubt, the Parties expect that only United Therapeutics shall be responsible for the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) as a result of the sale of Products.

(b) Payment of Tax. A Party receiving a payment shall pay any and all taxes levied on such payment. 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; and (iii) send evidence of the obligation together with proof of payment to the other Party within 60 days following that payment.

7.5 Records. United Therapeutics 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 to MannKind pursuant to this Agreement. Such books and records shall be kept for such period of time required by Applicable Laws, 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 7.6.

7.6 Audits. Upon not less than 60 days' prior written notice, United Therapeutics shall permit an independent, certified public accountant selected by MannKind and reasonably acceptable to United Therapeutics, which acceptance will not be unreasonably withheld or delayed (for the purposes of this Section 7.6, the "***Auditor***"), to audit or inspect those books or records of United Therapeutics and its Affiliates and sublicensees (to the extent United Therapeutics has the contractual right to audit and inspect the books and records of sublicensees) that relate to Net Sales and Royalty Reports for the sole purpose of verifying the: (a) royalties payable hereunder in respect of Net Sales; and (b) withholding taxes, if any, required by Applicable Laws to be deducted as a payment by United Therapeutics in respect of such Net Sales. The Auditor will disclose to MannKind 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 United Therapeutics at the same time it is sent to MannKind. Such inspections may be made no more than once each Calendar Year and during normal business hours. Such records for any particular Calendar Quarter shall be subject to no more than one inspection. The Auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection. Inspections conducted under this Section 7.6 shall be at the expense of MannKind, 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 United Therapeutics. The Parties will endeavor in such inspection to minimize disruption of United Therapeutics' normal business activities to the extent reasonably practicable.

7.7 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 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.

(a) General. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, 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 any confidential or proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which is disclosed 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 all United Therapeutics Technology shall be Confidential Information of United Therapeutics. The Receiving Party shall (i) 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 and (ii) limit access to and use of Confidential Information to its employees, agents, consultants and other representatives (and those of its Affiliates) with a need to know such 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) exercising its or its Affiliates' rights under this Agreement, including in the case of United Therapeutics, for the purpose of developing the Product, seeking, obtaining and maintaining Marketing Approvals of Product (including complying with the requirement of Regulatory Authorities with respect to filing for, obtaining and maintaining Marketing Approval of the Product) and manufacturing or commercializing Product;

(b) filing or prosecuting Patents as permitted by this Agreement;

(c) prosecuting or defending litigation as permitted by this Agreement;

(d) complying with Applicable Laws, including regulations promulgated by security exchanges (specifically recommendations and requests from NASDAQ stock exchange), court order or administrative subpoenas or orders or otherwise submitting information to tax or other Governmental Authorities;

(e) disclosure to Affiliates, contractors, employees, agents, consultants, licensees or sublicensees who need to know such information in connection with development, manufacturing, regulatory and commercialization activities with respect to Product as contemplated by this Agreement. provided that in each case the recipients of such Confidential Information are subject to confidentiality and non-use obligations consistent in scope with those set forth in this Article 8; and; and

(f) in communication with existing and potential investors, consultants, advisors (including financial advisors, lawyers and accountants) and others on a need to know basis in order to further the purposes of this Agreement; provided that in connection with such disclosure, the Disclosing Party shall inform each disclosee of the confidential nature of such Confidential Information and cause each disclosee to treat such Confidential Information as confidential.

In the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to Section 8.3(c) or (d), it shall promptly notify the other Party of such required disclosure and shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order or confidential treatment limiting or preventing the required disclosure, and disclose only the minimum information necessary for such disclosure; provided that such Confidential Information disclosed accordingly shall only lose its confidentiality protection for purposes of such disclosure.

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 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. Prior to a Party publishing, publicly presenting, and/or submitting for written or oral publication a manuscript, abstract or the like that includes Information or Data relating to any Product that has not been previously published, such Party shall provide to the other Party a draft copy thereof for its review at least thirty (30) days prior to the proposed date of submission or presentation (unless such Party is required by Applicable Laws to publish such information sooner, in which case such Party shall provide such draft copy to the other Party as much in advance of such publication as possible). The publishing or presenting Party shall consider in good faith any comments provided by the other Party during such 30-day period and any such publication shall be subject to the limitations of Sections 8.1, 8.2 and 8.3. In addition, the publishing Party shall, at the other Party's request, remove therefrom any Confidential Information of such other Party. The contribution of each Party shall be noted in all publications or presentations by acknowledgment or co-authorship, whichever is appropriate. Notwithstanding the foregoing, any publication, presentation or submission thereof by a Third Party clinical collaborator, clinical site or academic or government run non-clinical site, including investigators within such institutions, to which a Party delegates the performance of non-clinical, pre-clinical or clinical research, shall be subject to the terms and conditions of the delegating Party's agreement with such Third Party to the extent inconsistent with the terms and conditions of this Section 8.6.

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 without limitation 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. As between the Parties, all right, title and interest to inventions and other subject matter (together with all intellectual property rights therein) conceived or created or first reduced to practice (in the case of patentable inventions) or made or developed (in the case of non-patentable inventions) in the course of performing activities contemplated by this Agreement ("***Inventions***") (i) by or under the authority of United Therapeutics or its Affiliates, independently of MannKind and its Affiliates, shall be owned by United Therapeutics ("***United Therapeutics Inventions***"), (ii) by or under the authority of MannKind or its Affiliates, independently of United Therapeutics and its Affiliates, shall be owned by MannKind ("***MannKind Inventions***") and (iii) that is invented jointly by personnel of United Therapeutics or its Affiliates, on the one hand, and MannKind or its Affiliates, on the other hand, shall be jointly owned by United Therapeutics and MannKind ("***Joint Inventions***"). For purposes of determining questions of inventorship for Inventions, the Parties shall apply the laws of the United States. 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.

(c) Data. All Data generated in connection with development and regulatory activities performed by MannKind or United Therapeutics pursuant to this Agreement shall be owned by United Therapeutics. Notwithstanding the foregoing, 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 in accordance with Section 4.3(b).

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, oppositions, or reexaminations thereon and to request any reissues or patent term extensions thereof), at MannKind's sole expense.

(ii) Cooperation. MannKind shall keep United Therapeutics fully informed of progress with regard to the preparation, filing, prosecution and maintenance of the MannKind Patents in the Territory. MannKind shall:

(A) provide United Therapeutics with a copy of the final draft of any proposed application prior to filing the same in any patent office worldwide with sufficient time to review and comment, unless otherwise agreed by patent counsel for both parties, and MannKind shall consider in good faith any comments or revisions suggested by United Therapeutics or its counsel;

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

(C) promptly provide United Therapeutics with a copy of any action, communication, letter, or other correspondence issued by the relevant patent office, and MannKind shall consult with United Therapeutics regarding responding to the same and will consider in good faith any comments, strategies, and the like proposed by United Therapeutics.

(D) promptly provide United Therapeutics with a copy of any response, amendment, paper, or other correspondence filed with the relevant patent office upon MannKind's receipt of the as-filed document;

(E) promptly notify United Therapeutics of the allowance, grant, or issuance of such MannKind Patents; and

(F) consult with United Therapeutics regarding the countries where MannKind Patents are to be filed and maintained.

(iii) Option of United Therapeutics to Prosecute and Maintain. In the event that MannKind desires to abandon or cease prosecution or maintenance of any MannKind Patent in the Territory under which United Therapeutics then has a license under this Agreement, MannKind shall provide reasonable prior written notice to United Therapeutics 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 MannKind Patent in the relevant patent office). In such case, MannKind shall permit United Therapeutics, at United Therapeutics' sole discretion, to continue prosecution and maintenance of such MannKind Patent in the Territory, in MannKind's name and at United Therapeutics' own expense and United Therapeutics shall provide to MannKind the rights and information described in Sections 9.2(a)(ii)(A) through (F) with respect to such MannKind Patents.

(b) United Therapeutics Patents. United Therapeutics shall be responsible, in its discretion, for the preparation, filing, prosecution and maintenance of United Therapeutics Patents (including the right to conduct any interferences, oppositions, or reexaminations thereon and to request any reissues or patent term extensions thereof), at United Therapeutics' sole expense.

(c) Joint Patents.

(i) Initial Responsibility. With regard to Joint Patents worldwide, (A) MannKind shall be responsible, in its discretion, for the preparation, filing, prosecution and maintenance of Joint Patents that primarily claim or cover a Formulation or Device, where (1) the Formulation so covered or claimed is generally applicable to any Formulation and is neither specific nor primarily related to the Formulation contained or used in a Product or any other Formulation of API (including as the definition of "API" may be expanded by operation of Section 2.6) and (2) the Device so covered or claimed is generally applicable to any Formulation and is neither specific nor primarily related to the Formulation contained or used in a Product or any other Formulation of API (including as the definition of "API" may be expanded by operation of Section 2.6) ("***General Joint Patents***") (including the right to conduct any interferences, oppositions, or reexaminations thereon and to request any reissues or patent term extensions thereof), subject to this Section 9.2(c) and at MannKind's sole expense; and (B) United Therapeutics shall be responsible, in its discretion, for the preparation, filing, prosecution and maintenance of Joint Patents other than General Joint Patents ("***Other Joint Patents***") (including the right to conduct any interferences, oppositions, or reexaminations thereon and to request any reissues or patent term extensions thereof), subject to this Section 9.2(c) and at United Therapeutics' sole expense. MannKind in its role as the Party responsible for General Joint Patents and United Therapeutics in its role as the Party responsible for Other Joint Patents shall be referred to as the "***Joint Patent Lead***".

(ii) Cooperation. For any Joint Patents for which it is the Joint Patent Lead, the Joint Patent Lead shall keep the other Party fully informed of progress with regard to the preparation, filing, prosecution and maintenance of the Joint Patents in the Territory. The Joint Patent Lead shall:

(A) provide the other Party with a copy of the final draft of any proposed application prior to filing the same in any patent office worldwide with sufficient time to review and comment, unless otherwise agreed by patent counsel for both Parties, and the Joint Patent Lead shall consider in good faith any comments or revisions suggested by the other Party or its counsel;

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

(C) promptly provide the other Party with a copy of any action, communication, letter, or other correspondence issued by the relevant patent office, and the Joint Patent Lead shall consult with the other Party regarding responding to the same and shall consider in good faith any comments, strategies, and the like proposed by the other Party;

(D) promptly provide the other Party with a copy of any response, amendment, paper, or other correspondence filed with the relevant patent office upon Joint Patent Lead's receipt of the as-filed document;

(E) promptly notify the other Party of the allowance, grant, or issuance of such Joint Patents; and

(F) consult with the other Party regarding the countries to be filed and maintained, the payment of annuities, taxes and maintenance fees for any such Joint Patents.

(iii) Option of Other Party to Prosecute, Maintain and Enforce. In the event that the Party that is the Joint Patent Lead desires to abandon or cease prosecution or maintenance of any Joint Patent for which it is responsible, such Party shall provide reasonable prior written notice to the other Party 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 and, in any case, shall be prior to abandonment). In such case, at the other Party's sole discretion, upon written notice from such other Party, such other Party may elect to continue prosecution and maintenance of any such Joint Patent at its own expense, and the Party that elected to abandon or cease prosecution or maintenance of such Joint Patent shall execute such documents and perform such acts, at its own expense, as may be reasonably necessary to effect an assignment of such Party's entire right, title, and interest in and to such Joint Patent to the other Party. Any such assignment shall be completed in a timely manner to allow such other Party to continue prosecution and maintenance of any such Joint Patent. Any Patents so assigned shall no longer be considered Joint Patents.

9.3 Infringement by Third Parties.

(a) Notice. In the event that either MannKind or United Therapeutics 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. Any such notice shall include evidence to support an allegation of infringement or threatened infringement by such Third Party.

(b) MannKind Patents and Joint Patents.

(i) Subject to this Section 9.3(b), MannKind shall have the right (but not the obligation), as between MannKind and United Therapeutics, to bring and control any action or proceeding with respect to infringement of any MannKind Patent or Joint Patent, at its own expense and by counsel of its own choice, to the extent the infringement does not include the manufacture, use, import, offer for sale or sale of a Product or any other product containing or comprising a dry powder formulation of API that is or is intended to be primarily administered in or through the lungs, in each case in the Territory ("***Competing Activity***").

(ii) Subject to this Section 9.3(b), United Therapeutics shall have the first right (but not the obligation), as between MannKind and United Therapeutics, to bring and control any action or proceeding with respect to infringement of any MannKind Patent or Joint Patent, at its own expense and by counsel of its own choice, to the extent the infringement includes Competing Activity in the Territory. MannKind shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and United Therapeutics and its counsel will reasonably cooperate with MannKind and its counsel in strategizing, preparing and presenting any such action or proceeding.

(iii) If United Therapeutics fails to bring an action or proceeding that it has the right to bring and control under pursuant to Section 9.3(b)(ii) with respect to infringement that is commercially significant Competing Activity in the Territory within (A) 90 days following the notice of alleged infringement or (B) 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 United Therapeutics shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(iv) Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any recovery or damages actually received 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, with any remaining compensatory damages relating to Product (including lost sales or lost profits with respect to Product) being retained by United Therapeutics (or if received by MannKind, paid to United Therapeutics) and deemed Net Sales subject to the royalty provisions of Section 6.3, and any punitive damages shall be shared equally by the Parties.

(c) United Therapeutics Patents. United Therapeutics shall have the right (but not the obligation) to bring and control any action or proceeding with respect to infringement of any United Therapeutics Patent worldwide, at its own expense and by counsel of its own choice.

(d) 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 named as a Party to such action.

9.4 Infringement of Third Party Rights. 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 infringes or may infringe the intellectual property rights of such Third Party. MannKind shall have the sole right (but not the obligation), as between MannKind and United Therapeutics, to bring and control any defense of any such claim involving alleged infringement of Third Party rights by MannKind's activities pursuant to this Agreement at its own expense and by counsel of its own choice, and United Therapeutics shall have the right, at its own expense, to be represented in any such defense by counsel of its own choice. United Therapeutics shall have the sole right (but not the obligation), as between United Therapeutics and MannKind, to bring and control any defense of any such claim involving alleged infringement of Third Party rights by United Therapeutics' activities pursuant to this Agreement at its own expense and by counsel of its own choice, and MannKind shall have the right, at its own expense, to be represented in any such defense by counsel of its own choice. Nothing in this Section 9.4 limits MannKind's indemnification obligations to United Therapeutics under this Agreement.

9.5 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, which consent shall not be unreasonably withheld.

9.6 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) concerning any MannKind Patent, Joint Patent or United Therapeutics 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 United Therapeutics Patent shall be brought and controlled as provided in Section 9.3(b) or 9.3(c) as applicable.

9.7 Patent Term Extension. MannKind shall cooperate with United Therapeutics to the extent reasonable requested by United Therapeutics to extend a MannKind Patent by way, for example, of a Patent Term Restoration and Supplementary Protection Certificate.

9.8 Orange Book Listing. After consultation with and consideration of input from MannKind, United Therapeutics shall have the sole authority and discretion to maintain with the applicable Regulatory Authorities during the Term listings of applicable MannKind Patents, Joint Patents or United Therapeutics Patents for Product then being commercialized by United Therapeutics in the Territory, including all Orange Book listings required under the Hatch-Waxman Act.

9.9 Trademarks. United Therapeutics shall own and be responsible for all trademarks, trade names, branding, or logos related to Product or commercialization thereof, and will be responsible for selecting, registering, defending, and maintaining the same.

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, violate or breach, or constitute a default or require any consent 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 (including under any agreements relating to MannKind indebtedness), 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 MannKind. MannKind represents and warrants to United Therapeutics that, as of the Execution Date and as of the Effective Date:

(a) Scope of License.

(i) MannKind has delivered to United Therapeutics a list of MannKind Patents existing as of such date under separate cover (the "***Existing Patents***"), which list (A) is a true and complete list of all Patents Controlled by MannKind or its Affiliates as of such date that that claim or disclose Product or its components, or are necessary or reasonably useful for the development, manufacture, use, import, offer for sale, or sale 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 (B) 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 such date.

(ii) MannKind is the sole and exclusive owner of the entire right, title and interest in the Existing Patents, free of any encumbrance, lien, or claim of ownership by any Third Party other than the liens held by Deerfield.

(iii) Each Person who has or has had any rights in or to any MannKind Patents or any MannKind Know-How, has assigned and has executed an agreement assigning its entire right, title, and interest in and to such MannKind Patents or any MannKind Know-How to MannKind or its Affiliates. To MannKind's knowledge, no current officer, employee, agent, or consultant of MannKind or any of its Affiliates is in violation of any term of any assignment or other agreement regarding the protection of Patents or Information that would constitute MannKind Know-How or of any provision regarding the assignment or protection of intellectual property or proprietary rights of MannKind in any employment contract or any other contractual obligation relating to the relationship of any such Person with MannKind.

(iv) Neither MannKind nor any of its Affiliates has previously entered into any agreement, whether written or oral, with respect to the assignment, transfer, license, conveyance or encumbrance of, or otherwise assigned, transferred, licensed, conveyed or encumbered its right, title, or interest in or to any Material Patent or Information (including by granting any covenant not to sue with respect thereto) that would otherwise be included in the MannKind Patents or MannKind Know-How but for such assignment, transfer, license, conveyance, or encumbrance. As used herein, "Material Patent or Information" means a Patent or item of Information which if not included in the MannKind Patents or MannKind Know-How, would be expected to have a material adverse effect on United Therapeutics' ability to develop or commercialize Product in the Field in the Territory in the manner currently conducted or proposed to be conducted.

(b) Patent 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; and (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.

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

(d) Third Party Claims. Neither MannKind nor any of its Affiliates has received any written notice from any Person, or has knowledge of, any claim or potential claim, whether or not asserted, that: (i) the MannKind Patents are invalid or unenforceable, (ii) the disclosing, copying, assigning, or licensing of the MannKind Patents, MannKind Know-How or the Regulatory Filings for the Product made by or on behalf of MannKind or its Affiliates, does or would be reasonably expected to violate, infringe or misappropriate the valid intellectual property rights of a Third Party, (iii) the use or practice of the MannKind Patents, MannKind Know-How or the Regulatory Filings for the Product made by or on behalf of MannKind or its Affiliates, does or would be reasonably expected to, based on the development or commercialization of Product in the Field as currently proposed to be conducted, violate, infringe or misappropriate the valid intellectual property rights of a Third Party, or (iv) the development or commercialization of any product utilizing a Device, a Formulation or an Accessory Apparatus as contemplated herein, including the Initial Product, does or would be reasonably expected to, based on the development or commercialization of Product in the Field as currently proposed to be conducted, violate, infringe, misappropriate or otherwise conflict or interfere with, the valid intellectual property rights of a Third Party.

(e) 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 MannKind or any of its 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 MannKind with respect to any MannKind Know-How, MannKind Patents or Product.

(f) No Governmental Funding. As of the Effective Date: (i) none of the inventions claimed in the MannKind Patents has been conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by any Governmental Authority, and (ii) the inventions claimed in the MannKind Patents are not a "subject invention" as that term is described in 35 U.S.C. Section 201(f).

(g) Compliance. As of the Effective Date, MannKind and its Affiliates and, to MannKind's knowledge, any contract research organization to which MannKind or its 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 MannKind nor any of its Affiliates nor, to MannKind's knowledge, any contract research organization to which MannKind or its 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.

(h) No Injunction. No Governmental Authority (including the FDA) has commenced or, to MannKind's knowledge, threatened to initiate any action to enjoin production of Product at any facility, nor has MannKind or any of its Affiliates or, to MannKind's knowledge, any of its subcontractors involved in production of Product, received any notice to such effect.

(i) Regulatory Information.

(i) MannKind and its Affiliates have generated, prepared, maintained, and retained all Regulatory Filings for the Product that are required to be maintained or retained pursuant to and in accordance with good laboratory and clinical practice and Applicable Laws, and all such information is true, complete and correct. Neither MannKind nor any of its Affiliates, nor any of its or their respective officers, employees, or agents has knowingly made an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the development of the Device, Formulation or Product, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to the Development of the Device, Formulation or Product, or committed an act, made a statement, or failed to make a statement with respect to the Development of the Device, Formulation or Product that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory.

(ii) MannKind has made available to United Therapeutics a true and correct copy, which is complete in all material respects, of (A) the IND associated with Product, (B) all data from nonclinical studies and clinical studies conducted under the IND for Product, (C) all material correspondence with the FDA regarding Product, and (D) all minutes of meetings and telephone conferences with the FDA with respect to the IND for Product. To MannKind's knowledge, MannKind has disclosed or otherwise provided United Therapeutics with all material information in MannKind's possession as of the Effective Date relating to (1) the MannKind Know-How or MannKind Patents, (2) the nonclinical and clinical development activities undertaken with respect to the Product, (3) the safety or efficacy of Product, and (4) the manufacture of Product, all of which information is true, complete in all material respects, and correct.

(j) During the time period between the Execution Date and the Effective Date, MannKind shall promptly inform United Therapeutics in writing if MannKind or any of its Affiliates becomes aware that the representations and warranties made by MannKind pursuant to Sections 10.1 and 10.2 as of the Execution Date are not true and correct in any material respects on and as of the Effective Date as though made on and as of the Effective Date.

10.3 Representations and Warranties of United Therapeutics. United Therapeutics represents and warrants to MannKind that there is no action, suit, proceeding or investigation pending or, to its knowledge, threatened before any court or administrative agency against United Therapeutics 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 United Therapeutics 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. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE EXPRESSLY EXCLUDED. WITHOUT LIMITING THE FOREGOING, AND WITHOUT LIMITING THE EXPRESS COVENANTS OF THE PARTIES SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION, WARRANTY OR COVENANT, EITHER EXPRESS OR IMPLIED, THAT (A) IT WILL SUCCESSFULLY DEVELOP, MANUFACTURE, COMMERCIALIZE OR CONTINUE TO DEVELOP, MANUFACTURE OR COMMERCIALIZE ANY PRODUCT IN ANY COUNTRY, OR (B) IF COMMERCIALIZED, ANY PRODUCT WILL ACHIEVE ANY PARTICULAR SALES LEVEL, WHETHER IN ANY INDIVIDUAL COUNTRY OR CUMULATIVELY THROUGHOUT THE TERRITORY.

ARTICLE 11

INDEMNIFICATION

11.1 Indemnification of MannKind. United Therapeutics 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 (a "***Third Party Claims***") incurred by any MannKind Indemnitee, arising from, or occurring as a result of: (a) the development, manufacture, use, handling, storage, sale, other disposition, marketing, promotion or commercialization of Product by United Therapeutics or its Affiliates as contemplated by this Agreement; (b) gross negligence or willful misconduct of United Therapeutics or its Affiliates and (c) any material breach of any representations, warranties or covenants by United Therapeutics under Article 10 or Section 4.9 of 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 United Therapeutics. MannKind shall indemnify and hold harmless each of United Therapeutics and its Affiliates and the directors, officers, shareholders and employees of such entities, and the successors and assigns of any of the foregoing (the "***United Therapeutics Indemnitees***"), from and against any and all Losses from any Third Party Claims incurred by any United Therapeutics Indemnitee, arising from, or occurring as a result of: (a) the development of Product by MannKind or its Affiliates prior to the Effective Date or during the Development Term as contemplated by this Agreement; (b) gross negligence or willful misconduct of MannKind or its Affiliates; (c) any material breach of any representations, warranties or covenants by MannKind under Article 10 or Section 4.9 of this Agreement; and (d) the Specified Matters, except to the extent such Third Party Claims (excluding Third Party Claims in relation to the Specified Matters) falls within the scope of the indemnification obligations of United Therapeutics set forth in Section 11.1.

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
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, 12.4 or 12.5 (the "***Term***").

12.2 Termination by the Parties. 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;

(b) upon written notice by a Party to the other Party if such other Party is in material breach of this Agreement and has not cured such breach within 90 days (10 days with respect to failure to pay any undisputed payment) after written notice from the terminating Party describing the breach and requesting that it be cured. Any such termination shall become effective at the end of such 90 day (10 day with respect to failure to pay any undisputed payment) period

unless (i) the breaching Party has cured any such breach or default prior to the end of such period, or (ii) the Party alleged to be in breach of this Agreement disputes such breach within such ninety (90) day period, in which case the non-breaching Party shall not have the right to terminate this Agreement unless it has been determined by a court of competent jurisdiction pursuant to Article 14 that this Agreement was materially breached, and the breaching Party fails to comply with its obligations hereunder within ninety (90) days after such determination; or

(c) upon the bankruptcy or insolvency, or the filing of an action to commence insolvency proceedings against the other Party, or the making or seeking to make or arrange an assignment for the benefit of creditors of the other Party, or the initiation of proceedings in voluntary or involuntary bankruptcy, or the appointment of a receiver or trustee of such Party's property that is not discharged within 90 days.

12.3 Additional United Therapeutics Termination Rights.

(a) United Therapeutics shall have the right to terminate this Agreement in its entirety or with respect to (i) a Development Plan or (ii) any particular Product, at any time for any reason or for no reason upon delivery of at least 90 days' prior written notice to MannKind.

(b) United Therapeutics shall have the right to terminate this Agreement prior to the Effective Date immediately upon notice to MannKind if any of MannKind's representations and warranties contained in Article 10 become untrue in any material respect or if MannKind fails to deliver the Closing Certificate to United Therapeutics as contemplated by Section 15.16.

12.4 Change of Control. If a Change of Control of United Therapeutics is publicly announced and is reasonably anticipated to result in (a) a material reduction in Net Sales of Product or (b) access to Manufacturing Information by a Third Party with very competitive products or pipelines to MannKind's products (each, a "***Subject Change of Control***"), then United Therapeutics agrees that, in order to minimize the adverse impact to MannKind caused by such Subject Change of Control, United Therapeutics shall promptly inform MannKind thereof and in good faith endeavor to agree with MannKind about how to continue the development, manufacturing and commercialization of Product and/or put reasonable measures in place to prevent access to Manufacturing Information. If United Therapeutics and MannKind cannot reach an agreement about how to continue the development, manufacturing and commercialization of Product according to this Agreement, then MannKind shall have the right, effective upon the Subject Change of Control of United Therapeutics, to terminate this Agreement; provided that there shall be no termination right under this Section 12.4 if both (i) reasonable measures are put in place to prevent access to Manufacturing Information and (ii) clause (a) above does not apply.

12.5 Additional MannKind Termination Right. MannKind shall have the right to terminate this Agreement immediately upon written notice to United Therapeutics if United Therapeutics or any of its Affiliates directly, or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any MannKind Patent.

ARTICLE 13

EFFECT OF TERMINATION

13.1 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.

13.2 Rights on Termination Other than Termination By United Therapeutics for Cause. This Section 13.2 shall apply upon the termination of this Agreement by agreement of the Parties under Section 12.2(a), by MannKind pursuant to Section 12.2(b) or (c), Section 12.4 or Section 12.5 or by United Therapeutics pursuant to Section 12.3(a). In the event of a termination by United Therapeutics pursuant to Section 12.3(a) for a particular Product, this Section 13.2 shall apply only to such terminated Product:

(a) Wind-down Period.

(i) Development. In the event there are any on-going clinical trials of Product in the Territory, at MannKind's request in writing, United Therapeutics agrees: (A) the Parties shall work together in good faith to adopt, and United Therapeutics shall have the final decision-making authority with respect to, a plan to wind-down any such clinical trials in an orderly fashion at United Therapeutics' expense, with due regard for patient safety and the rights of 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, or (B) to the extent so requested by MannKind, to promptly transition to MannKind or its designee such clinical trials then being conducted by United Therapeutics, or portions thereof, for MannKind or its designee to complete at their expense. If United Therapeutics shall continue to conduct any such clinical trials, it shall do so in accordance with the terms and conditions of this Agreement. If MannKind elects to have United Therapeutics transition the clinical trial(s) to MannKind or its designee, MannKind shall reimburse United Therapeutics for the out-of-pocket costs incurred by United Therapeutics in carrying out such transfer. Notwithstanding anything to the contrary in this Section 13.2(a)(i), in no case shall United Therapeutics be obligated to pursue or support the activities described in this Section 13.2(a)(i) for a period exceeding 6 months after the date of notice of such termination.

(ii) Commercialization. United Therapeutics and its Affiliates shall continue, to the extent that United Therapeutics and its Affiliates 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 effective date of termination. For clarity, United Therapeutics shall have no obligation to continue to market and promote the Product after the termination is effective. For Product sold by United Therapeutics after the effective date of a termination (i.e., after the expiration of the applicable termination notice period), United Therapeutics shall continue to pay royalties on Net Sales pursuant to Section 6.3. Notwithstanding the foregoing, United Therapeutics and its Affiliates 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 United Therapeutics requesting the cessation of activities pursuant to the provision of this Section, United Therapeutics shall notify MannKind of an estimate of the quantity of Product and its shelf life remaining in United Therapeutics' inventory and MannKind shall have the right to purchase any such quantities of Product from United Therapeutics at a price mutually agreed by the Parties. To the extent MannKind does not purchase such quantities, United Therapeutics 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 United Therapeutics, to the extent permitted under Applicable Laws, United Therapeutics shall assign or cause to be assigned to MannKind or its designee (or to the extent not so assignable, United Therapeutics shall take all reasonable actions to make available to MannKind or its designee the benefits of) all Regulatory Filings (including the Data incorporated therein and Marketing Approvals) for Product in the Territory, including any such Regulatory Filings made or owned by its Affiliates. MannKind shall notify United Therapeutics before the effective date of termination, whether the Regulatory Filings should be assigned to MannKind or its designee, and if the latter, identify the designee, and provide United Therapeutics with all necessary details to enable United Therapeutics to effect the assignment (or availability). If MannKind fails to provide such notification prior to the effective date of termination, United Therapeutics shall assign the Regulatory Filings to MannKind.

(c) Transition. The Parties shall negotiate in good faith a written transition agreement pursuant to which the Parties would effectuate this Section 13.2 to coordinate the transition of relevant obligations and rights to MannKind as necessary to develop, manufacture and commercialize Product in the Territory to ensure no interruption of therapy or coverage for patients, including promptly submitting all necessary filings with Governmental Authorities. United Therapeutics shall use its reasonable efforts to cooperate with MannKind or its designee to effect a smooth and orderly transition in the development, manufacturing, sale and marketing, promotion and commercialization of Product in the Territory during the notice and the Wind-down Period. Without limiting the foregoing, United Therapeutics shall use its reasonable efforts to conduct, in an expeditious manner, any activities to be conducted under this Section 13.2. 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 (including the Data incorporated therein 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, United Therapeutics shall use its reasonable efforts to (i) supply API to MannKind until MannKind can establish and qualify a new supplier of API and (ii) maintain its Government Health Care Program Contracts for the Product bearing the United Therapeutics National Drug Codes ("***NDCs***") during the Wind-down Period, provided that in no event shall United Therapeutics be obligated to supply API to MannKind for a period longer than six months from the date notice of termination was given. 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 United Therapeutics 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, United Therapeutics shall work with MannKind and the applicable Government Health Care

Programs to transition the Product from United Therapeutics' Government Health Care Program Contracts for the Product bearing the United Therapeutics 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, chargebacks, or Branded Prescription Drug Fees accrued with respect to Product sold or dispensed during the Wind-down Period (provided, however, that United Therapeutics shall remain solely liable for such payments as may be accrued, but not yet paid, as of the effective date of termination or expiration 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, United Therapeutics' 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 United Therapeutics and its Affiliates, in accordance with this Section 13.2 shall be subject to the applicable payment obligations under Article 6.

(f) Licenses. United Therapeutics hereby grants to MannKind, effective upon termination of this Agreement, an exclusive, worldwide, royalty-free, fully paid, perpetual, irrevocable, worldwide license (with rights to sublicense) to use all Information and Regulatory Filings generated by United Therapeutics or its Affiliates with respect to Product, then Controlled by United Therapeutics or any of its Affiliates as of the effective date of termination, to develop, make, have made, use, offer for sale, sell, have sold, and import Product. Any and all licenses granted by MannKind to United Therapeutics under this Agreement shall terminate, except as otherwise expressly provided herein.

13.3 Rights on Termination By United Therapeutics for Cause. This Section 13.3 shall apply upon the termination of this Agreement by United Therapeutics pursuant to Section 12.2(b) or (c) or Section 12.3(b):

(a) Winding-Down of Development Activities. In the event there are any on-going clinical trials of Product in the Territory:

(i) The Parties shall work together in good faith to adopt, and United Therapeutics 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 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. United Therapeutics 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, United Therapeutics shall work with MannKind and the applicable Government Health Care Programs to transition the Product from United Therapeutics' Government Health Care Program Contracts for the Product bearing the United Therapeutics 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, chargebacks, or Branded Prescription Drug Fees accrued with respect to Product sold or dispensed during the Wind-down Period (provided, however, that United Therapeutics 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);

(ii) Each Party shall perform its outstanding non-cancellable obligations under the Development Plan that existed or accrued prior to the notice date of termination; and

(iii) All costs and expenses incurred from the effective date of the termination notice in winding-down the development activities with respect to the applicable Product shall be borne by MannKind; *provided, however,* that in no case shall MannKind be obligated to pursue or support such activities for a period exceeding 6 months after the date of notice of such termination.

(b) Termination of Licenses. Any and all licenses granted by United Therapeutics to MannKind or by MannKind to United Therapeutics under this Agreement shall terminate, except as otherwise expressly provided herein.

(c) Regulatory Filings. Upon United Therapeutics' request and to the extent permitted by Applicable Laws, MannKind may purchase all Regulatory Filings (including Data incorporated therein and Marketing Approval) that are owned by United Therapeutics or any of its Affiliates for Product at a price mutually agreed by the Parties, and United Therapeutics shall assign or cause to be assigned to MannKind or its designees (or to the extent not so assignable, United Therapeutics shall take all reasonable actions to make available to MannKind or its designee the benefits of) such Regulatory Filings (including Data incorporated therein and Marketing Approval) for Product in the Territory that are so purchased, including any such Regulatory Filings made or owned by its Affiliates.

(d) Termination Assistance. United Therapeutics and its Affiliates may continue to sell its inventory of Product in the Territory for up to 12 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 United Therapeutics, as may be reasonably necessary or useful for United Therapeutics to terminate the development or commercialization of the applicable Product in the applicable countries of the Territory.

(e) Continuing Payment Obligations. Any Product sold or disposed of by United Therapeutics or its Affiliates, in accordance with this Section 13.3 shall be subject to the applicable payment obligations under Article 6.

13.4 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, without limitation, 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, without limitation, 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, without limitation, the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.

13.5 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.

13.6 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 2.3 (last sentence only); 6.4(b) (for a period of up to three (3) years from the end of the Calendar Quarter in which termination occurs, but in any event not more than (3) years from the end of the Calendar Quarter in which the last Quarterly Report was submitted); 7.6 (for a period of three (3) years from end of the Calendar Quarter in which termination or expiration occurs); 9.1; 9.3(b), 9.3(d) and 9.5 (in each case with respect to any infringement action being prosecuted as of the effective date of termination); 10.4; and 11.1 – 11.3, and Articles 1, 8, 12, 13 (and sections referenced therein), 14 and 15.

ARTICLE 14

DISPUTE RESOLUTION AND GOVERNING LAW

14.1 Disputes. Parties recognize that issues or disputes as to certain matters may arise from time-to-time during the Term relating to or under this Agreement. It is the objective of the Parties to seek to resolve any issues or disputes arising under this Agreement in good faith in an expedient manner and, if at all possible, without resort to litigation, and to that end the Parties agree to abide by the following procedures set forth in this Article 14 to resolve any such issues or disputes arising under or relating to this Agreement, including any Party's rights or obligations or performance under this Agreement (each, a ***"Dispute"***). The Parties initially shall attempt to settle any such Dispute through good faith negotiations in the spirit of mutual cooperation between business executives with authority to resolve the Dispute. Notwithstanding anything to the contrary set forth herein, any issue or dispute falling within the ESC's authority will be handled in accordance with Section 3.1(e), not this Article 14.

14.2 Escalation. Prior to taking action as provided in Section 14.3 below, and at the request of any Party if there is a Dispute, the Parties shall first submit such Dispute to their respective chief executive officers, or the representative designated by such individual (provided that such representative is a senior executive officer of such Party with authority to settle the applicable issue or dispute submitted for resolution under this Section 14.2) ("***Senior Executives***") for good faith discussion and attempted resolution. The Senior Executives to whom any Dispute is submitted shall attempt to resolve the dispute through good faith negotiations over a reasonable period, not to exceed ten (10) Business Days, unless the Senior Executives mutually agree in writing to extend such period of negotiation. Such ten (10) Business Day period shall be deemed to commence on the date the dispute was submitted by a Party to the Senior Executives. The Senior Executives shall, if mutually agreed by the Senior Executives, submit the dispute to voluntary mediation at such place and following such procedures as the Parties shall reasonably agree. All negotiations and discussions pursuant to this Section 14.2 shall be confidential, and the Parties agree that all information concerning or disclosed as part of such negotiations and discussions are and such shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.

14.3 Court Actions. If the Senior Executives of the Parties are unable to resolve a given Dispute within the time limits set forth in Section 14.2, either Party may file suit to resolve such matter (including bringing an action for injunctive relief (or any other provisional remedy)) as described below. Unless otherwise agreed, by the Parties, all actions and proceedings relating to this Agreement shall be heard and determined in any New York State or federal court sitting in the City of New York, County of Manhattan, and the Parties hereby irrevocably submit to exclusive jurisdiction of such courts in any such action or proceeding and irrevocably waive any defense of inconvenient forum to the maintenance of any such action or proceeding and waive any right to request transfer venue outside any New York State or federal court sitting in the City of New York, County of Manhattan.

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.

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, 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 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.

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 any letter delivering information referenced herein) constitutes 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. 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 MannKind:

MannKind Corporation
30930 Russell Ranch Road, Suite 301
Westlake Village, California 91362
Telephone: (818) 661-5000
Facsimile: (818) 661-2098
Attention: General Counsel

To United Therapeutics:

United Therapeutics Corporation
1040 Spring Street, Silver Spring, Maryland 20910
Attention: General Counsel

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:

Wilson Sonsini Goodrich & Rosati
1700 K Street, NW, Suite 500
Washington, DC 20006
Telephone: (202) 973-8830
Facsimile: (202) 973-8899
Attention: James G. Clessuras, Esq.

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 ESC.

15.9 MannKind Change of Control. In the event of the occurrence of a Change of Control of MannKind during the Term, the following provisions shall apply:

(a) Certain Terms Regarding MannKind Know-How and MannKind Patents. All MannKind Know-How and MannKind Patents Controlled by MannKind immediately prior to such Change of Control of MannKind shall continue to be MannKind Know-How and MannKind Patents for purposes of this Agreement. Patents and Information that are Controlled by the entity acquiring MannKind (the "***Acquirer***") or a direct or indirect parent holding company of MannKind or the Acquirer's Affiliates (excluding MannKind or any of its Affiliates existing prior to such Change of Control of MannKind) shall not be included within the MannKind Know-How and MannKind Patents, unless they are actually used by MannKind in the development or commercialization of Product, and would fit within the definition of MannKind Know-How or MannKind Patents if Controlled by MannKind.

(b) Effect on Exclusivity. In the event of a Change of Control of MannKind pursuant to which MannKind is acquired by an Acquirer developing, manufacturing or commercializing one or more Competing Products, then provided the Acquirer Segregates all information directly pertaining to Product from the Competing Product programs of the Acquirer and its Affiliates, the provisions of Section 2.5(a) shall not apply with respect to the Competing Products developed, manufactured or commercialized by the Acquirer before such Change of Control of MannKind (including as further developed, manufactured or commercialized after such Change of Control of MannKind).

15.10 United Therapeutics Change of Control. In the event of the occurrence of a Change of Control of United Therapeutics during the Term, the following provisions shall apply:

(a) All United Therapeutics Know-How and United Therapeutics Patents Controlled by United Therapeutics immediately prior to such Change of Control of United Therapeutics shall continue to be United Therapeutics Know-How and United Therapeutics Patents for purposes of this Agreement. Patents and Information that are Controlled by the Acquirer of United Therapeutics or a direct or indirect parent holding company of United Therapeutics or the Acquirer's Affiliates (excluding United Therapeutics or any of its Affiliates existing prior to such Change of Control of United Therapeutics) shall not be included within the United Therapeutics Know-How and United Therapeutics Patents.

(b) Effect on Exclusivity. In the event of a Change of Control of United Therapeutics pursuant to which United Therapeutics is acquired by an Acquirer developing, manufacturing or commercializing one or more products (other than Product) containing or comprising any dry powder formulation of API that is or is intended to be primarily administered in or through the lungs, then provided the Acquirer Segregates all information directly pertaining to Product from such product programs of the Acquirer and its Affiliates, the provisions of Section 2.5(b) shall not apply with respect to such products developed, manufactured or commercialized by the Acquirer before such Change of Control of United Therapeutics (including as further developed, manufactured or commercialized after such Change of Control of United Therapeutics).

15.11 Assignment. This Agreement shall not be assignable or otherwise transferred, nor may any right or obligations hereunder be assigned or transferred, by either Party to any Third Party without the prior written consent of the other Party; except either Party may assign or otherwise transfer this Agreement (including, for clarity, with respect to the Option) 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. In addition, either Party shall have the right to assign this Agreement to an Affiliate upon written notice to the non-assigning Party; *provided*, *however*, the assigning Party hereby guarantees the performance of this Agreement by such Affiliate. 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 15.11 shall be null and void.

15.12 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 United Therapeutics 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.

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 GAAP 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. Each of MannKind and United Therapeutics shall use its reasonable best efforts to (i) 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, (ii) submit promptly any additional information requested by any such Governmental Authority, and (iii) obtain termination or expiration of the waiting period under 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, and (iv) prevent the entry in any action brought by a Governmental Authority or any other Person that would prohibit, make unlawful or delay the making of the rights and obligations of this Agreement effective. Without limiting the generality of the foregoing, each of MannKind and United Therapeutics 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 15 Business Days after the Execution Date unless otherwise agreed to in writing by the parties (the "***HSR Filing Date***"). The Parties will notify each other promptly of any oral communication with, and provide copies of written communications with, any Governmental Authority in connection with any filings made pursuant to this Section 15.16. Each Party shall cooperate reasonably with the other Party in connection with any such filing (including, to the extent permitted by Applicable Laws, providing copies of all such documents to the non-filing Party prior to filing and considering all reasonable additions, deletions or changes suggested in connection therewith) and in connection with resolving any investigation or other inquiry of any Governmental Authority under any Antitrust Laws with respect to any such

filing. No Party hereto shall independently participate in any meeting, teleconference, or other written or oral communication with any Governmental Authority in respect of any such filing, investigation or other inquiry without giving the other Party prior notice of the meeting and, to the extent permitted by such Governmental Authority, the opportunity to attend and/or participate. To the extent permitted by Applicable Laws, and subject to all applicable privileges (including the attorney client privilege), each Party shall consult and cooperate reasonably with the other Party, and shall consider in good faith the views of each other, in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, opinions and proposals made or submitted by or on behalf of any Party hereto in connection with proceedings under or relating to the HSR Act or other Antitrust Laws. Each Party may, as it deems advisable and necessary, reasonably designate any competitively sensitive material provided to the other Parties under this paragraph as "outside counsel only." Such materials and the information contained therein shall be given only to the outside legal counsel of the recipient and will not be disclosed by such outside legal counsel to employees, officers, or directors of the recipient, unless express written permission is obtained in advance from the source of the materials. United Therapeutics 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 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 (the date of such termination or expiration shall be the "***Effective Date***" of this Agreement). On the Effective Date, MannKind shall deliver to United Therapeutics a written certification (the "***Closing Certificate***") from an officer of MannKind that MannKind's representations and warranties in Article 10 are accurate in all material respects as of the date of 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 any such clearance associated with the Filings is not obtained within […***…]* days after the Execution Date (or such later date as agreed in writing by the Parties), this Agreement may be terminated by either Party. Notwithstanding anything to the contrary contained in this Agreement and in this Section 15.16, nothing in this Agreement shall require United Therapeutics or its Subsidiaries to agree or propose to (i) sell, hold separate, license or otherwise dispose of any assets or conduct their business in a specified manner, (ii) permit or agree to the sale, holding separate, licensing or other disposition of, any assets of MannKind, or (iii) take or refrain from taking any action that would result in any modification, amendment, or change to this Agreement. Notwithstanding anything to the contrary contained in this Agreement, if the Effective Date does not occur United Therapeutics shall reimburse MannKind for […***…]* percent ([…***…]%) of all reasonable and documented out-of-pocket fees, costs, and expenses incurred by MannKind in connection with this Section 15.16 after the Execution Date, up to a maximum reimbursement amount of $[…***…] in the aggregate.

******Confidential Treatment Requested**
******Confidential Treatment Requested**

ARTICLE 16

COMPLIANCE WITH LAW

16.1 Export Laws. Notwithstanding anything to the contrary contained herein, all obligations of MannKind and United Therapeutics 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. MannKind and United Therapeutics 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 Certain Payments. Each of the Parties acknowledges that it is aware that the United States and other countries have stringent laws which prohibit persons directly or indirectly to make unlawful payments to, and for the benefit of, government officials and related parties to secure approvals or permission for their activities. Each Party agrees that it will make no such prohibited payments, it will not indirectly make or have made such payments and it will make its Affiliates, employees and agents aware of the existence of such laws and their need to comply with such laws.

16.4 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 generally accepted scientific standards, good clinical and manufacturing practices and applicable industry ethical codes, applicable under the laws and regulations of the country in which such activities are conducted or of the country in which a Regulatory Filing is made. Without limiting the foregoing, each Party agrees as follows:

(a) In the performance of its obligations under this Agreement, such Party 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.

(b) Such Party and, to its knowledge, 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).

(c) Such Party and its Affiliates, and their respective employees and contractors, in connection with the performance of their respective obligations under this Agreement, shall not violate, and shall not cause the other Party or such other Party's Indemnitees to be in violation of the FCPA, Export Control Laws, the federal health care program anti-kickback statute, the public contracts anti-kickback act, any state anti-kickback law, the Health Insurance Portability and Accountability Act ("***HIPAA***"), set forth at 42 U.S.C. sec. 1320d-2, the federal civil False Claims Act (or any state equivalent), federal or state "sunshine"/aggregate spend reporting laws, government price reporting laws, consumer protection and unfair trade practices laws, or any other Applicable Laws, rules or regulations or otherwise cause any reputational harm to such other Party.

(d) Such Party shall immediately notify the other Party if such Party has any information or suspicion that there may be a violation of the FCPA, Export Control Laws, the federal health care program anti-kickback statute, the public contracts anti-kickback act, any state anti-kickback law, HIPAA, the federal civil False Claims Act (or any state equivalent), federal or state "sunshine"/aggregate spend reporting laws, government price reporting laws, consumer protection and unfair trade practices laws, or any other Applicable Laws in connection with the performance of this Agreement or the development, manufacture or commercialization of Product.

(e) In connection with the performance of its obligations under this Agreement, such Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with such Party's own anti-corruption and anti-bribery policy, a copy of which has been provided or made available to the other Party.

(f) The other Party will have the right, upon reasonable prior written notice and during such Party's regular business hours and without undue interference with business operations, to audit such Party's books and records in the event that a reasonably suspected violation of any of the representations, warranties or covenants in this Section 16.4 needs to be investigated (including without limitation, any Governmental Authority-identified deficiency.

(g) Each Party agrees that, in connection with any inspection or audit by a Governmental Authority relating to any activities contemplated under this Agreement, such Party shall: (i) respond promptly and courteously to the inspectors/auditors; (ii) use its reasonable best efforts to notify the other Party of such inspection/audit with sufficient time to permit the other Party to obtain a protective or similar order with respect to such Party's Confidential Information; (iii) use its reasonable best efforts to disclose the minimum of the other Party's Confidential Information necessary to comply with the request whether a protective order is obtained; and (iv) assert any applicable protections (such as exemption from freedom of information act disclosure, as may be applicable) with respect to disclosed information.

(h) In the event that such Party has violated or been suspected of violating any of the representations, warranties or covenants in this Section 16.4, such Party will cause its or its Affiliates' personnel or others working under its direction or control to submit to periodic training that such Party will provide on anti-corruption and/or "fraud and abuse" law compliance.

(i) Such Party will, at the other Party's request, annually certify to such other Party in writing such party's compliance, in connection with the performance of such Party's obligations under this Agreement, with the representations, warranties or covenants in Section 16.4.

(j) Such Party shall have the right to suspend or terminate this Agreement in their entirety where there is a credible finding, after a reasonable investigation, that the other Party, in connection with performance of such other Party's obligations under this Agreement, has violated any Applicable Laws.

[SIGNATURE PAGE FOLLOWS]

In Witness Whereof, the Parties have executed this License and Collaboration Agreement as of the Execution Date.

MANNKIND CORPORATION		**UNITED THERAPEUTICS CORPORATION**	
By:	/s/ Michael Castagna	By:	/s/ Martine Rothblatt
Name:	Michael Castagna	Name:	Martine Rothblatt
Title:	Chief Executive Officer	Title:	Chief Executive Officer

Exhibit 10.9

*****Text Omitted and Filed Separately**
with the Securities and Exchange Commission.
Confidential Treatment Requested
Under 17 C.F.R. Sections 200.80(c) and Rule 24b-2

RESEARCH AGREEMENT

This **Research Agreement** (the "***Agreement***") is entered into as of September 3, 2018 (the "***Effective Date***") between **MannKind Corporation**, a Delaware corporation ("***MannKind***"), having a principal place of business at 30930 Russell Ranch Road, Suite 301, Westlake Village, California 91362, and **United Therapeutics Corporation**, a Delaware corporation ("***United Therapeutics***"), having a principal place of business at 1040 Spring Street, Silver Spring, Maryland 20910 (each of MannKind and United Therapeutics, a "***Party***" and together, the "***Parties***").

RECITALS

Whereas, MannKind possesses (i) certain proprietary technology focused on the pulmonary delivery of certain pharmaceuticals, and (ii) experience and expertise with Bluetooth and WiFi components of devices;

Whereas, United Therapeutics is engaged in the development and commercialization of pharmaceutical products;

Whereas, the Parties have entered into a License and Collaboration Agreement dated September 3, 2018 (the "***LCA***") pursuant to which MannKind has granted to United Therapeutics certain exclusive rights and licenses to develop a specified pharmaceutical product in collaboration with MannKind and to commercialize that product; and

Whereas, MannKind and United Therapeutics desire to enter into this Agreement to provide the terms and conditions upon which (i) the Parties will evaluate the feasibility of formulating a Prototype Formulation (as defined below), which may have the potential for further development and commercialization under the framework established by the LCA, and (ii) MannKind will assist United Therapeutics and its collaborators in developing the hardware, software and firmware for a Bluetooth and WiFi component for United Therapeutics product.

AGREEMENT

Now Therefore, in consideration for the 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.

Certain capitalized terms not otherwise defined in this Agreement shall have the meaning given to such terms in the LCA.

1.1 "***Accessory Apparatus***" shall mean an interactive apparatus that contains one or more sensors for real-time profiling of the ([…***…]*, etc.) through a Device, such as the Bluhale® apparatus.

1.2 ***"Compound***" shall mean any active pharmaceutical ingredient that is a […***…]*.

1.3 "***Developed Technology***" shall mean all data, results, information, materials, ideas, inventions, techniques and other technology, whether or not patentable, that are generated, developed or discovered by or on behalf of a Party in the course of performance of the Work Plans or in the assistance of the performance of such Work Plans.

1.4 "***Device***" shall mean any device Controlled by MannKind through which a Formulation may be administered by inhalation, such as the Dreamboat® inhaler and Cricket® inhaler.

1.5 "***Formulation***" shall mean a formulation of an active pharmaceutical ingredient suitable for pulmonary administration based upon or incorporating the drug delivery technology Controlled by MannKind involving diketopiperazine as a carrier.

1.6 ***"Intellectual Property Rights"*** shall mean 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, utility models, and registered and unregistered designs, including mask works, copyrights, trade secrets designated in writing at the time of disclosure, design history, manufacturing documentation, and any other form of protection afforded by law to inventions, models, designs, works of authorship, databases or technical information and applications and registrations with respect thereto.

1.7 "***Product***" shall mean a product in a form suitable for human applications consisting of (a) a Formulation that contains Compound for use in an inhalation device or 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), (c) both a Device and such a Formulation described in clause (a) for use together, or (d) an Accessory Apparatus for use with the Product configuration described in (c), in each case, including all improvements incorporated therein.

1.8 "***Option Deadline***" shall mean the date that is […***…] years after the Effective Date of this Agreement.

******Confidential Treatment Requested**
******Confidential Treatment Requested**

1.9 "***Prototype Formulation***" shall mean a Formulation of a Compound prepared in accordance with a Work Plan to evaluate a dosage form comprising a cartridge containing a dry powder Formulation of a Compound, which cartridge would be inserted into, or contained within, a pulmonary delivery device (including a Device) for administration *in vivo*.

1.10 "***Work Plan***" means any written work plan(s) mutually agreed by MannKind to United Therapeutics in writing as of the Effective Date or during the term of this Agreement, which set(s) forth the activities to be conducted under this Agreement, as may be amended in accordance with Section 2.4, including the work plans set forth as exhibits attached to a separate letter delivered by MannKind to United Therapeutics and agreed to in writing by United Therapeutics as of the Effective Date.

2. STUDY OBLIGATIONS

2.1 Feasibility Activities.

2.1.1 Performance. MannKind agrees to use commercially reasonable efforts to (i) undertake the responsibilities assigned to it in the Work Plans, (ii) perform its obligations under the Work Plans in good faith in a commercially reasonable and workmanlike manner; (iii) as appropriate, make available to United Therapeutics those resources set forth in the Work Plans; and (iv) carry out all work done in the course of the Work Plans in material compliance with all Applicable Laws.

2.1.2 Records. MannKind shall keep complete and accurate records of the results of the Work Plans under this Agreement. These records, including any electronic files where such information may also be contained, shall fully and properly reflect all work done and results achieved in the performance of the Work Plans in sufficient detail and in good scientific manner appropriate for patent, compliance and regulatory purposes. During the term of this Agreement, United Therapeutics shall have the right to review and copy such records maintained by MannKind at reasonable times and upon reasonable notice.

(a) Report. Within 30 days of the completion of the Work Plans, MannKind shall submit to United Therapeutics a comprehensive written report of MannKind's activities thereunder.

2.2 Project Liaison.

2.2.1 Formation; Composition. The Parties shall designate one individual ("**Project Liaison**") to serve as the primary point of contact between the Parties with regard to activities contemplated by this Agreement. The United Therapeutics Project Liaison shall have the requisite skills in the discipline(s) necessary to provide such reasonable assistance to MannKind as may be required for MannKind to conduct the Work Plans. The MannKind Project Liaison shall provide the United Therapeutics Project Liaison with regular updates as necessary.

2.2.2 Meetings. The Project Liaisons shall meet at such times and locations, either in person or through video or telephone communications, as are necessary to accomplish the Work Plans. As necessary written minutes shall be kept of all material decisions made at such meetings.

2.3 Regular Communication. Each Party shall be available for a reasonable number of telephone and written consultations regarding activities contemplated by this Agreement on a schedule to be determined by mutual arrangement between the Parties.

2.4 Decision-Making. The Project Liaisons shall discuss in good faith any issues that arise with regard to activities conducted during the course of this Agreement. Any changes to a Work Plan shall require the mutual written approval of the Parties' Project Liaisons. In the event of a dispute on any matter within the responsibilities of the Project Liaisons, then the matter shall be referred to the Parties' Senior Executives as provided in Section 11.8.

3. OWNERSHIP RIGHTS

3.1 Ownership Rights. This Agreement does not convey any ownership or other rights in any Prototype Formulation or MannKind Intellectual Property Rights embodied therein by implication, estoppel or otherwise except for the rights expressly granted in Article 4. MannKind shall retain ownership and control of the Prototype Formulation and all of MannKind's Intellectual Property Rights therein that were in existence as of the Effective Date or are later generated by MannKind whether inside or outside of scope of the performance by MannKind of its obligations under this Agreement. Similarly, this Agreement does not convey any ownership or other rights in any Intellectual Property Rights of United Therapeutics by implication, estoppel or otherwise. United Therapeutics shall retain ownership and control of United Therapeutics' Intellectual Property Rights that were in existence as of the Effective Date or are later generated by United Therapeutics whether inside or outside of scope of the performance by United Therapeutics of its obligations under this Agreement.

3.2 Results of Work Plans. All Developed Technology and all associated Intellectual Property Rights, that are generated, developed or discovered by or on behalf of MannKind shall be deemed MannKind Intellectual Property Rights. All Developed Technology and all associated Intellectual Property Rights, that are generated, developed or discovered by or on behalf of United Therapeutics shall be deemed United Therapeutics Intellectual Property Rights.

3.3 Developed […***…**]***.

3.3.1 Notwithstanding the foregoing provisions of this Article 3, as between the parties, United Therapeutics owns all right, title, and interest in any and all Developed Technology that MannKind develops in the course of performing under this Agreement that constitutes or relates […***…] for United Therapeutics' products, and all Intellectual Property Rights therein (collectively, […***…]), but excluding Developed IP of General Application. MannKind hereby assigns, and shall continue to assign to United Therapeutics, all of its right, title and interest in any […***…] that is not Developed IP of General Application.

3.3.2 "***Developed IP of General Application***" means Developed Technology that MannKind develops in the course of performing under this Agreement that (i) consists of subject matter of general applicability; and (ii) is reasonably necessary or useful for MannKind's use in its products, and all Intellectual Property Rights therein.

3.3.3 MannKind hereby grants to United Therapeutics a non-exclusive, fully paid-up, irrevocable license, with the right to grant and authorize sublicenses, under all […***…] that is Developed IP of General Application, to make, have made, use, sell, have sold, offer for sale, import and distribute any and all products, components and services for any and all applications.

3.4 Reservation of Rights. Except for the rights expressly provided in this Agreement or any other written agreement of the Parties, 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.

4. RESEARCH AGREEMENT OPTION

4.1 Option. Subject to the terms and conditions of this Agreement, including payment of the amount set forth in Article 5, MannKind hereby grants to United Therapeutics an exclusive option (the ***"Research Agreement Option"***) to obtain from MannKind exclusive rights and licenses to develop Products in collaboration with MannKind and to commercialize Products, all on terms substantially the same as those provided in the LCA.

4.2 Option Exercise. In order to exercise the Research Agreement Option, United Therapeutics must deliver to MannKind a written exercise notice no later than 5:00 p.m. (Pacific Time) on the Option Deadline. In its notice to MannKind, United Therapeutics shall specify the particular Compound for which it wishes to exercise the Research Agreement Option (the "***Specified Compound***"). In the event that the Research Agreement Option is not timely exercised, this Agreement shall terminate and United Therapeutics shall have no further rights under this Article 4 with respect to the Compounds.

4.3 Effect of Option Exercise. As soon as practicable (and in any event within 30 days) of the timely exercise of the Research Agreement Option in accordance with Section 4.2, United Therapeutics and MannKind shall use best efforts to agree upon and execute a new royalty-bearing license and collaboration agreement (additional to and separate from the existing LCA) ("**Second LCA**") on substantially the same terms and the existing LCA (including, for clarity the additional option to add additional Products as provided in Section 2.6 of the LCA), except that:

4.3.1 As used in the Second LCA, the following terms shall have the following meanings and not the meanings provided in the LCA:

(a) "***API***" shall mean the Specified Compound (as defined above in Section 4.2 of this Agreement).

(b) "***Field***" shall mean the administration of Compounds to human beings for the prevention or treatment of Pulmonary Hypertension.

(c) "***Milestones***" and "***Milestone Payments***" shall refer to the following:

Milestone Event	Milestone Payment
(A) […***…]*	$15,000,000
(B) […***…]	$15,000,000
(C) […***…]	$15,000,000
(D) […***…]	$15,000,000

(d) "***Optioned Agent***" shall mean any Compound (as defined above in Section 1.1 of this Agreement), other than API.

(e) "***Other Agent***" shall be deleted.

4.3.2 All provisions of the LCA that are specific to the Initial Device, Initial Development Plan and Initial Product (as defined in the LCA) shall be deleted or amended as appropriate to effect the intent of the Research Agreement Option with respect to Product based on the Specified Compound for which the Research Agreement Option is exercised.

4.3.3 Corresponding changes from the LCA shall be made in the Second LCA, *mutatis mutandis*, as appropriate to effect the intent of the Research Agreement Option.

For clarity, no Option Exercise Fee shall be payable pursuant to this Agreement, the LCA or the Second LCA in order to exercise the Research Agreement Option or effect the Second LCA or the rights of United Therapeutics with respect to Product based on the Specified Compound for which the Research Agreement Option is exercised. In addition, the Parties shall discuss and agree on a Development Plan for such Product, allocating operational and financial responsibilities to each Party as appropriate for the different indications and therapeutic areas being pursued by each Party for such Product.

4.4 If the Parties are unable to agree on the terms of the Second LCA (a "***Negotiation Dispute***") either Party may submit the matter for resolution by a transactional lawyer (the "***Neutral Lawyer***") with at least fifteen years of experience and a background in biotechnology or agreements of the development, licensing and commercialization of pharmaceuticals. The Neutral Lawyer shall be selected by mutual agreement of the Parties; provided, however, that if the Parties cannot agree on a Neutral Lawyer within five days of a party's request for a Neutral Lawyer under this provision, the Neutral Lawyer shall be selected by the American Arbitration Association in Washington, D.C. Each Party shall submit its position as to the Negotiation Dispute to the Neutral Lawyer, who shall resolve the dispute by agreeing to one of the submitted positions of the Parties without any changes to such position. The Parties agree that the position agreed to by the Neutral Lawyer shall be reflected in the Second LCA. The costs of the Neutral Lawyer shall be shared equally by the Parties. The decision of the Neutral Lawyer shall be final and binding on the Parties. The Parties shall cooperate in all respects to resolve any Negotiation Dispute promptly.

5. Financial Obligations

As consideration for the activities to be performed by MannKind under the Work Plans and for other rights granted to United Therapeutics under this Agreement, United Therapeutics shall pay to MannKind a one-time, non-refundable fee of $10,000,000 within five business days of the Effective Date via wire transfer as instructed by MannKind. Except as otherwise set forth herein, each Party shall bear its own costs and expenses in connection with performance of this Agreement and the Work Plans.

6. Representations And Warranties; Covenants

6.1 General Representations and Warranties. Each Party represents and warrants:

6.1.1 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

6.1.2 Binding Agreement. This Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms; and

6.1.3 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, 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

6.1.4 Resources. It has adequate resources, both financial and otherwise, to perform its duties hereunder.

6.2 Warranty. MannKind represents and warrants to United Therapeutics that it has and shall at all times throughout the term of this Agreement maintain, whether by ownership, by license or otherwise, the Intellectual Property Rights that are required to use, manufacture, market, offer to sell, sell, import and export the Prototype Formulation.

6.3 Disclaimer. Except as expressly set forth in this Agreement, MannKind makes no representations nor extends any warranties of any kind, either express or implied, and 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 the Prototype Formulation. Except as expressly stated in this Agreement, all representations and warranties, whether arising by operation of law or otherwise, are expressly excluded.

7. 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 Losses from any Third Party Claims incurred by the Indemnified Parties arising from, or occurring as a result of any breach of any representation, warranty, covenant, or obligation of the Indemnifying Party under this Agreement or any intentional misconduct or 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 negligence of any of the Indemnified Parties.

8. Insurance Protection

Each Party shall obtain and maintain during the term of this Agreement insurance to support its obligations under this Agreement, which may include self-insurance.

9. Term; Termination

9.1 Term. This Agreement shall begin on the Effective Date and, unless terminated sooner as provided in Section 9.2, shall terminate (a) at 5:00 p.m. (Pacific Time) on the Option Deadline if the Research Agreement Option is not exercised prior to that time in accordance with Section 4.2, or (b) if the Research Agreement Option is timely exercised in accordance with Section 4.2, upon execution by the Parties of the Second LCA as contemplated by Section 4.3.

9.2 Termination Events

(a) Without Cause. United Therapeutics shall have the right to terminate this Agreement without cause upon 30 days' written notice to MannKind.

(b) 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.

9.3 Effects of Termination. Upon the expiration or earlier termination of this Agreement, 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 unless the Research Option is timely exercised in accordance with Section 4.2, in which case the terms of the Second LCA shall apply to such information. 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.

9.4 Survival. Sections 3, 6.3, 7, 9.3, 9.4, 10 and 11 shall survive the expiration or termination of this Agreement.

10. Confidential Information

All confidential or proprietary information of a Party disclosed to the other Party or generated in the course of this Agreement, including the identity of Compound, shall be deemed to be Confidential Information as such term is used in the LCA and shall be subject to the secrecy and non-use terms for such information set forth in the LCA.

11. MISCELLANEOUS

11.1 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 (including, for clarity, with respect to the Research Agreement Option) 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, or (b) to any Affiliate. Notwithstanding the foregoing, any such assignment to an Affiliate shall not relieve the assigning Party of its responsibilities for performance of its obligations under this Agreement. 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.

11.2 Relationship of the Parties. It is expressly agreed that United Therapeutics 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.

11.3 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 representatives of both Parties.

11.4 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.

11.5 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.

11.6 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
30930 Russell Ranch Road, Suite 301
Westlake Village, California 91362
Telephone: (818) 661-5000
Facsimile: (818) 661-5098
Attention: General Counsel

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.

To United Therapeutics:
United Therapeutics Corporation
1040 Spring Street, Silver Spring, Maryland 20910
Attention: General Counsel

with a copy to:
Wilson Sonsini Goodrich & Rosati
1700 K Street, NW, Suite 500
Washington, DC 20006
Telephone: (202) 973-8830
Facsimile: (202) 973-8899
Attention: James G. Clessuras, Esq.

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.

11.7 Dispute Resolution. If a dispute arises under this Agreement, including a dispute between the Project Liaisons, then 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 Section 11.8, prior to exercising any remedies that may exist by commencing an action against the other Party.

11.8 Escalation. Prior to taking action as provided in Section 11.9 below, and at the request of any Party if there is a dispute, the Parties shall first submit such dispute to their respective chief executive officers, or the representative designated by such individual (provided that such representative is a senior executive officer of such Party with authority to settle the applicable issue or dispute submitted for resolution under this Section 11.8) ("***Senior Executives***") for good faith discussion and attempted resolution. The Senior Executives to whom any dispute is submitted shall attempt to resolve the dispute through good faith negotiations over a reasonable period, not to exceed 10 Business Days, unless the Senior Executives mutually agree in writing to extend such period of negotiation. Such 10 Business Day period shall be deemed to commence on the date the dispute was submitted by a Party to the Senior Executives. The Senior Executives shall, if mutually agreed by the Senior Executives, submit the dispute to voluntary mediation at such place and following such procedures as the Parties shall reasonably agree. All negotiations and discussions pursuant to this Section 11.8 shall be confidential, and the Parties agree that all information concerning or disclosed as part of such negotiations and discussions are and such shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.

11.9 Court Actions. If the Senior Executives of the Parties are unable to resolve a given dispute within the time limits set forth in Section 11.8, either Party may file suit to resolve such matter (including bringing an action for injunctive relief (or any other provisional remedy) as described below. Unless otherwise agreed, by the Parties, all actions and proceedings relating to this Agreement shall be heard and determined in any New York State or federal court sitting in the City of New York, County of Manhattan, and the Parties hereby irrevocably submit to exclusive jurisdiction of such courts in any such action or proceeding and irrevocably waive any defense of inconvenient forum to the maintenance of any such action or proceeding and waive any right to request transfer venue outside any New York State or federal court sitting in the City of New York, County of Manhattan.

11.10 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.

11.11 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 with respect to the formulation prototyping activities described in the Work Plans.

11.12 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.

11.13 Limitation of Liability. EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 10, 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 11.13 shall not be construed to limit either Party's indemnification obligations with respect to Third Party Claims under Article 7.

11.14 Separate Agreements. For the avoidance of any doubt, this Agreement and the Second LCA (if executed) are entirely separate from, and its effectiveness is not conditioned in any way on the effectiveness of, the LCA.

[SIGNATURE PAGE FOLLOWS]

In Witness Whereof, the Parties hereto have this day caused this Agreement to be executed by their duly authorized officers.

MANNKIND CORPORATION		**UNITED THERAPEUTICS CORPORATION**	
By:	/s/ Michael Castagna	By:	/s/ Martine Rothblatt
Name:	Michael Castagna	Name:	Martine Rothblatt
Title:	Chief Executive Officer	Title:	Chief Executive Officer

Exhibit 31.1

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, Michael Castagna, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended September 30, 2018 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 conclusion 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 1, 2018

/s/ MICHAEL CASTAGNA

Michael Castagna
Chief Executive Officer

Exhibit 31.2

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, Steven Binder, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended September 30, 2018 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 1, 2018

/s/ STEVEN BINDER
Steven Binder
Chief Financial Officer

Exhibit 32.1

CERTIFICATION OF
CHIEF EXECUTIVE 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, 2018, as filed with the Securities and Exchange Commission on or about the date hereof to which this certification is attached as Exhibit 32.1 (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), Michael Castagna, Chief Executive Officer of MannKind Corporation (the "Company"), 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 1, 2018

In Witness Whereof, the undersigned has set his hand hereto as of the 1st day of November 2018.

/s/ Michael Castagna
Michael Castagna
Chief Executive Officer

[1] 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.

Exhibit 32.2

CERTIFICATION OF
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, 2018, as filed with the Securities and Exchange Commission on or about the date hereof to which this certification is attached as Exhibit 32.2 (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), Steven Binder, Chief Financial Officer of MannKind Corporation (the "Company"), 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 1, 2018

In Witness Whereof, the undersigned has set his hand hereto as of the 1st day of November 2018.

/s/ Steven Binder
Steven Binder
Chief Financial Officer

[1] 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.