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, 2021

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)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	MNKD	The Nasdaq Stock Market LLC

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of October 29, 2021, there were 251,256,353 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, 2021

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,740	$ 67,005
Restricted cash	—	158
Short-term investments	87,312	—
Accounts receivable, net	9,445	4,218
Inventory	7,482	4,973
Prepaid expenses and other current assets	3,227	3,122
Total current assets	159,206	79,476
Property and equipment, net	30,848	25,867
Long-term investments	42,059	—
Other assets	6,094	3,265
Total assets	$ 238,207	$ 108,608
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 9,528	$ 5,582
Accrued expenses and other current liabilities	20,829	19,707
PPP loan — current	—	4,061
Deferred revenue — current	14,016	33,275
Recognized loss on purchase commitments — current	5,660	11,080
Total current liabilities	50,033	73,705
Senior convertible notes	223,580	—
MidCap credit facility	38,723	49,335
Mann Group promissory notes	18,425	63,027
Accrued interest — Mann Group promissory notes	286	4,150
PPP loan — long term	—	812
2024 convertible notes	—	5,000
Recognized loss on purchase commitments — long term	79,653	84,208
Operating lease liability	798	1,202
Deferred revenue — long term	1,552	1,662
Milestone rights liability	4,838	5,926
Deposits from customer	5,007	—
Total liabilities	422,895	289,027
Commitments and contingencies (Note 12)		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.01 par value - 400,000,000 shares authorized, 250,245,831 and 242,117,089 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	2,502	2,421
Additional paid-in capital	2,914,818	2,866,303
Accumulated deficit	(3,102,008)	(3,049,143)
Total stockholders' deficit	(184,688)	(180,419)
Total liabilities and stockholders' deficit	$ 238,207	$ 108,608

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,	
	2021	2020	2021	2020
Revenues:				
Net revenue — commercial product sales	$ 9,753	$ 7,275	$ 27,828	$ 22,260
Revenue — collaborations and services	12,458	8,077	35,099	24,441
Total revenues	22,211	15,352	62,927	46,701
Expenses:				
Cost of goods sold	3,812	3,591	12,538	11,432
Cost of revenue — collaborations and services	6,075	1,581	14,885	6,926
Research and development	3,655	1,484	8,426	4,703
Selling, general and administrative	17,221	13,899	54,690	41,919
Asset impairment	106	—	106	1,889
(Gain) loss on foreign currency translation	(2,068)	3,927	(5,003)	3,998
Loss on purchase commitments	—	—	339	—
Total expenses	28,801	24,482	85,981	70,867
Loss from operations	(6,590)	(9,130)	(23,054)	(24,166)
Other (expense) income:				
Interest income	36	18	64	165
Interest expense on notes	(2,709)	(1,057)	(10,943)	(3,212)
Interest expense on Mann Group promissory notes	(94)	(1,318)	(1,492)	(3,858)
Gain (loss) on extinguishment of debt, net	4,930	—	(17,200)	—
Other income (expense)	1	14	(240)	24
Total other income (expense)	2,164	(2,343)	(29,811)	(6,881)
Loss before provision for income taxes	(4,426)	(11,473)	(52,865)	(31,047)
Provision for income taxes	—	218	—	218
Net loss	$ (4,426)	$ (11,255)	$ (52,865)	$ (30,829)
Net loss per share - basic and diluted	$ (0.02)	$ (0.05)	$ (0.21)	$ (0.14)
Shares used to compute net loss per share - basic and diluted	249,910	229,668	248,624	218,559

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,	
	2021	2020	2021	2020
Net loss	$ (4,426)	$ (11,255)	$ (52,865)	$ (30,829)
Other comprehensive loss:				
Cumulative translation loss	—	—	—	(19)
Comprehensive loss	$ (4,426)	$ (11,255)	$ (52,865)	$ (30,848)

See notes to condensed consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(Unaudited)
(In thousands)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Loss	Deficit	Total
BALANCE, JANUARY 1, 2020	211,788	$ 2,118	$ 2,799,278	$ (19)	$ (2,991,903)	$ (190,526)
Issuance of common stock under Employee Stock Purchase Plan	334	3	315	—	—	318
Stock-based compensation expense	—	—	1,128	—	—	1,128
Issuance of common stock associated with debt interest payment	99	1	143	—	—	144
Net issuance of common stock associated with stock options and restricted stock units	504	5	(322)	—	—	(317)
Issuance of common stock in at-the-market offering	413	4	518	—	—	522
Issuance cost associated with at-the-market offering	—	—	(16)	—	—	(16)
Write-off of cumulative translation loss	—	—	—	19	—	19
Net loss	—	—	—	—	(9,322)	(9,322)
BALANCE, MARCH 31, 2020	213,138	$ 2,131	$ 2,801,044	$ —	$ (3,001,225)	$ (198,050)
Stock-based compensation expense	—	—	2,185	—	—	2,185
Issuance of common stock from the exercise of warrants	7,250	73	11,527	—	—	11,600
Issuance of common stock pursuant to conversion of the June 2020 note	1,235	12	2,618	—	—	2,630
Net issuance of common stock associated with stock options and restricted stock units	297	3	114	—	—	117
Issuance of common stock in at-the-market offering	7,459	75	12,291	—	—	12,366
Issuance cost associated with at-the-market offering	—	—	(320)	—	—	(320)
Issuance of common stock from market price stock purchase	10	—	14	—	—	14
Adjustment of common stock in association with restricted stock units	(461)	(5)	5	—	—	—
Net loss	—	—	—	—	(10,252)	(10,252)
BALANCE, JUNE 30, 2020	228,928	$ 2,289	$ 2,829,478	$ —	$ (3,011,477)	$ (179,710)
Stock-based compensation expense	—	—	1,294	—	—	1,294
Issuance of common stock associated with debt interest payment	89	1	143	—	—	144
Net issuance of common stock associated with stock options and restricted stock units	82	1	100	—	—	101
Issuance of common stock in at the market offering	1,531	15	2,664	—	—	2,679
Issuance cost associated with at the market offering	—	—	(39)	—	—	(39)
Issuance of common stock under Employee Stock Purchase Plan	293	3	363	—	—	366
Net loss	—	—	—	—	(11,255)	(11,255)
BALANCE, SEPTEMBER 30, 2020	230,923	$ 2,309	$ 2,834,003	$ —	$ (3,022,732)	$ (186,420)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Loss	Deficit	Total
BALANCE, JANUARY 1, 2021	242,118	$ 2,421	$ 2,866,303	$ —	$ (3,049,143)	$ (180,419)
Net issuance of common stock associated with stock options and restricted stock units	390	4	393	—	—	397
Issuance of common stock under Employee Stock Purchase Plan	293	3	387	—	—	390
Stock-based compensation expense	—	—	1,935	—	—	1,935
Issuance of common stock pursuant to conversion of the Mann Group convertible note	3,830	38	9,535	—	—	9,573
Issuance of common stock pursuant to conversion of the Mann Group convertible note interest	170	2	425	—	—	427
Issuance of common stock pursuant to conversion of the 2024 convertible notes	1,667	17	4,983	—	—	5,000
Issuance of common stock pursuant to payoff of the 2024 convertible note interest	27	—	143	—	—	143
Issuance of common stock in at-the-market offering	578	6	1,880	—	—	1,886
Issuance cost associated with at-the-market offering	—	—	(38)	—	—	(38)
Net loss	—	—	—	—	(12,916)	(12,916)
BALANCE, MARCH 31, 2021	249,073	$ 2,491	$ 2,885,946	$ —	$ (3,062,059)	$ (173,622)
Net issuance of common stock associated with stock options and restricted stock units	520	5	(550)	—	—	(545)
Stock-based compensation expense	—	—	3,926	—	—	3,926
Premium on Mann Group convertible note	—	—	22,107	—	—	22,107
Issuance of common stock from market price stock purchase	25	—	106	—	—	106
Net loss	—	—	—	—	(35,523)	(35,523)
BALANCE, JUNE 30, 2021	249,618	$ 2,496	$ 2,911,535	$ —	$ (3,097,582)	$ (183,551)
Net issuance of common stock associated with stock options and restricted stock units	394	4	(594)	—	—	(590)
Issuance of common stock under Employee Stock Purchase Plan	234	2	698	—	—	700
Stock-based compensation expense	—	—	3,179	—	—	3,179
Net loss	—	—	—	—	(4,426)	(4,426)
BALANCE, SEPTEMBER 30, 2021	250,246	$ 2,502	$ 2,914,818	$ —	$ (3,102,008)	$ (184,688)

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,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (52,865)	$ (30,829)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on extinguishment of debt, net	17,200	—
Stock-based compensation expense	9,040	4,607
Interest on milestone payment	3,663	—
(Gain) loss on foreign currency translation	(5,003)	3,998
Depreciation, amortization and accretion	2,995	1,639
Interest expense on Mann Group promissory notes	1,480	3,852
Amortization of right-of-use assets	505	879
Asset impairment	106	1,889
Write-off of inventory	—	496
Other, net	—	19
Changes in operating assets and liabilities:		
Accounts receivable, net	(5,227)	(622)
Inventory	(2,509)	(1,222)
Prepaid expenses and other current assets	(105)	(1,306)
Other assets	(439)	191
Accounts payable	3,946	1,008
Accrued expenses and other current liabilities	3,471	641
Deferred revenue	(19,369)	(10,281)
Operating lease liabilities	(1,367)	(2,087)
Recognized loss on purchase commitments	(4,972)	(1,235)
Deposits from customer	5,007	—
Accrued interest on Mann Group promissory notes	(4,919)	—
Net cash used in operating activities	(49,362)	(28,363)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of debt securities	105,724	—
Purchase of debt securities	(235,406)	—
Purchase of available-for-sale securities	(3,000)	—
Purchase of property and equipment	(6,276)	(304)
Proceeds from sale of treasury bills	—	20,000
Net cash (used in) provided by investing activities	(138,958)	19,696
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the Senior convertible notes	230,000	—
Issuance costs associated with Senior convertible notes	(7,268)	—
Principal payments on Mann Group promissory notes	(35,051)	—
Payment of MidCap credit facility	(10,000)	—
Payment of MidCap credit facility prepayment penalty	(1,000)	—
Milestone payment	(5,000)	—
Proceeds from at-the-market offering	1,886	15,139
Issuance costs associated with at-the-market offering	(38)	(368)
Payment of employment taxes related to vested restricted stock units and exercise of stock options	(738)	(99)
Proceeds from market price stock purchase	106	14
Issuance of common stock from the exercise of warrants	—	11,600
Proceeds from PPP loan	—	4,873
Net cash provided by financing activities	172,897	31,159
NET INCREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(15,423)	22,492
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	67,163	30,222
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 51,740	$ 52,714
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash, net of amounts capitalized	10,535	2,861
Addition of right-of-use asset	605	—
Right-of-use asset modification	(139)	—
Addition of operating lease liability	(605)	—
Operating lease liability modification	139	—
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Premium on Mann Group convertible note	22,107	—
Payment on Mann Group convertible note through issuance of common stock	9,575	—
Payment of 2024 convertible notes through issuance of common stock	5,000	—
Forgiveness of PPP loan	(4,873)	—
Non-cash construction in progress and property and equipment	154	—
Reclassification of investments from long-term to current	20,747	—
Payment of Mann Group convertible note interest through issuance of common stock	427	—
Issuance of common stock under Employee Stock Purchase Plan	1,090	684
Payment of interest on 2024 convertible notes through issuance of common stock	143	288
Payment of principal on Senior convertible notes through issuance of common stock	—	2,630
Receivable from at-the-market offering	—	574

See notes to condensed consolidated financial statements.

1. Description of Business and Significant Accounting Policies

The 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, 2020 filed with the SEC on February 25, 2021 (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, 2021 may not be indicative of the results that may be expected for the full year.

Financial Statement Estimates — 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 and the COVID-19 pandemic has increased the level of judgment used by management in developing these estimates and assumptions. The COVID-19 pandemic continues to rapidly evolve and the ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. These effects could have a material impact on the estimates and assumptions used in the preparation of the condensed consolidated financial statements. The more significant estimates include revenue recognition, including gross-to-net adjustments, stand-alone selling price considerations, assessing long-lived assets for impairment, clinical trial expenses, inventory costing and recoverability, recognized loss on purchase commitment, 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 patients with endocrine and orphan lung diseases. The Company's lead product is Afrezza (insulin human) Inhalation Powder, an ultra rapid-acting inhaled insulin indicated to improve glycemic control in adults with diabetes, which was approved by the U.S. Food and Drug Administration ("FDA") in June 2014. Since September 2018, the Company has been collaborating with United Therapeutics Corporation ("United Therapeutics" or "UT") to develop an inhaled formulation of treprostinil, known as Tyvaso DPI. In April 2021, United Therapeutics submitted a new drug application ("NDA") to the FDA seeking approval of Tyvaso DPI for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). In October 2021, the FDA issued a complete response letter to United Therapeutics pursuant to which the FDA declined to approve the NDA at this time, noting one deficiency related to an open inspection issue at a third-party analytical testing center for treprostinil. The complete response letter did not pertain to MannKind, and no issues were cited by the FDA as it relates to MannKind's facility in Connecticut for manufacturing, testing and packaging of finished Tyvaso DPI, including its associated device. On October 18, 2021, UT stated that it believes that the single deficiency identified in the complete response will be resolved quickly and that Tyvaso DPI can receive approval by the summer of 2022, if not earlier.

Basis of Presentation — The condensed consolidated financial statements have been prepared in accordance with GAAP.

The Company is not currently profitable and has rarely generated positive net cash flow from operations. In addition, the Company expects to continue to incur significant expenditures for the foreseeable future in support of its manufacturing operations, sales and marketing costs for Afrezza, and development of other product candidates in the Company's pipeline. As of September 30, 2021, the Company had capital resources of $51.7 million in cash and cash equivalents, $87.3 million in short-term investments, $42.1 million in long-term investments, an accumulated deficit of $3.1 billion and total principal amount of outstanding borrowings of $288.4 million.

In August 2019, MannKind and its wholly owned subsidiary, MannKind LLC, entered into a credit and security agreement with MidCap Financial Trust (as amended, the "MidCap credit facility"). The MidCap Credit Facility currently provides a secured term loan facility with a potential aggregate principal amount of up to $100.0 million, with a balance of $40.0 million outstanding as of September 30, 2021. See Note 6 – *Borrowings*. In March 2021, the Company issued $230.0 million of 2.50% convertible senior notes due 2026 (the "Senior convertible notes") to provide additional operating capital and pay down higher cost debt. The cash received from this debt issuance has resolved the Company's significant risks and uncertainties regarding sources of liquidity, which previously raised substantial doubt about the Company's ability to continue as a going concern.

The Company believes its resources will be sufficient to fund its operations for the next twelve months from the date of issuance of these condensed consolidated financial statements. Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported condensed consolidated balance sheets or statements of operations. An adjustment has been made to the condensed consolidated statements of cash flows for the nine months ended September 30, 2020 to combine payment of employment taxes related to vested restricted stock units and exercise of stock options in

the cash flows from financing activities. These changes in classification do not affect previously reported cash flows from operating or investing activities.

Principles of Consolidation — The condensed 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 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.

To determine revenue recognition for arrangements that are within the scope of Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*, 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 two types of contracts with customers: (i) contracts for commercial product sales with wholesale distributors and specialty pharmacies and (ii) collaboration arrangements.

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"). Wholesale distributors subsequently resell the Company's products 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 payers that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products.

The Company recognizes revenue on product sales when the Customer obtains control of the Company's product, which occurs at delivery for wholesale distributors and generally at delivery for specialty pharmacies. Product revenues are recorded net of applicable reserves, including discounts, allowances, rebates, returns and other incentives. See Reserves for Variable Consideration below.

Free Goods Program – From time to time, the Company offers programs to potential new patients that allow them to obtain free goods (prescription fills) from a pharmacy. The Company excludes such amounts related to these programs from both gross and net revenue. The cost of product associated with the free goods program is recognized as cost of goods sold in the condensed consolidated statements of operations.

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, payer rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its Customers, payers, and other indirect customers relating to the Company's sale of its products. These reserves, as further 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. Significant judgments are required in making these estimates.

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 analysis also contemplates 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, 2021 and, therefore, the transaction price was not reduced further during the nine months ended September 30, 2021. 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.

Significant judgment is required in estimating gross-to-net adjustments considering legal interpretations of applicable laws and regulations, historical experience, payer channel mix, current contract prices under applicable programs, unbilled claims, processing time lags and inventory levels in the distribution channel.

Trade Discounts and Allowances — The Company generally provides Customers with discounts which include incentives, 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 products to the Customer and, therefore, these payments have been recorded as a reduction of revenue and as 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 12 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 percentage is estimated to be in the single-digits. Adjustments to the returns reserve have been made in the past and may be necessary in the future based on revised estimates to the Company's assumptions.

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 that 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 Medicare and state Medicaid programs. 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 that is included in accrued expenses and other current liabilities. Estimates around Medicaid have historically required significant judgment due to timing lags in receiving invoices for claims from states. 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. The Company's estimates include consideration of historical claims experience, payer channel mix, current contract prices, unbilled claims, claim submission time lags and inventory in the distribution channel.

Payer Rebates — The Company contracts with certain private payer 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, including estimates for product that has been recognized as revenue, but which remains in the distribution channel, 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. The Company's estimates include consideration of historical claims experience, payer channel mix, current contract prices, unbilled claims, claim submission time lags and inventory in the distribution channel.

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 payers. 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 the 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 that is included in accrued expenses and other current liabilities.

Revenue Recognition — Revenue — Collaborations and Services — The Company enters into licensing, research or other agreements under which the Company licenses certain rights to its product candidates to third parties, conducts research or provides other services to third parties. The terms of these arrangements may include, but are not limited to payment to the Company of one or more of the following: up-front license fees; development, regulatory, and commercial milestone payments; payments for manufacturing commercial and clinical supply services the Company provides; and royalties on net sales of licensed products and sublicenses of the rights. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment such as determining the performance obligation in the contract and determining the stand-alone selling price for each performance obligation identified in the contract. If an arrangement has multiple performance obligations, the allocation of the transaction price is determined from observable market inputs, and the Company uses key assumptions to determine the stand-alone selling price, which may include development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success. Revenue is recognized based on the measurement of progress as the performance obligation is satisfied and consideration received that does not meet the requirements to satisfy the revenue recognition criteria is recorded as deferred revenue. Current deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months. Amounts that the Company expects will not be recognized within the next 12 months are classified as long-term deferred revenue. For further information see Note 7 – *Collaboration, Licensing and Other Arrangements*.

The Company recognizes upfront license payments as revenue upon delivery of the license only if the license is determined to be a separate unit of accounting from the other undelivered performance obligations. The undelivered performance obligations typically include manufacturing or development services or research and/or steering committee services. If the license is not considered as a distinct performance obligation, then the license and other undelivered performance obligations would be evaluated to determine if such should be accounted for as a single unit of accounting. If concluded to be a single performance obligation, the transaction price for the single performance obligation is recognized as revenue over the estimated period of when the performance obligation is satisfied. If the license is considered to be a distinct performance obligation, then the estimated revenue is included in the transaction price for the contract, which is then allocated to each performance obligation based on the respective standalone selling prices. If the revenue for a sales-based or usage-based royalty is promised in exchange for an intellectual property license, the Company recognizes revenue as the latter of the subsequent sale or usage occurs or the performance obligation to which the royalty has been allocated has been satisfied or partially satisfied.

Whenever the Company determines that an arrangement should be accounted for over time, the Company determines the period over which the performance obligations will be performed, and revenue will be recognized over the period the Company is expected to complete its performance obligations. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

The Company’s collaboration agreements typically entitle the Company to additional payments upon the achievement of development, regulatory and sales milestones. If the achievement of a milestone is considered probable at the inception of the collaboration, the related milestone payment is included with other collaboration consideration, such as upfront fees and research funding, in the Company’s revenue calculation. If these milestones are not considered probable at the inception of the collaboration, the milestones will typically be recognized in one of two ways depending on the timing of when the milestone is achieved. If the milestone is improbable at inception and subsequently deemed probable of achievement, such will be added to the transaction price, resulting in a cumulative adjustment to revenue. If the milestone is achieved after the performance period has been completed and all performance obligations have been delivered, the Company will recognize the milestone payment as revenue in its entirety in the period the milestone was achieved.

The Company’s collaborative agreements, for accounting purposes, represent contracts with customers and therefore are not subject to accounting literature on collaborative agreements. The Company grants licenses to its intellectual property, supplies raw materials or finished goods, provides research and development services and offers sales support for the co-promotion of products, all of which are outputs of the Company’s ongoing activities, in exchange for consideration. The Company does not develop assets jointly with collaboration partners, and does not share in significant risks of their development or commercialization activities. Accordingly, the Company concluded that its collaborative agreements must generally be accounted for pursuant to Topic 606, Revenue from Contracts with Customers.

For collaboration agreements that allow collaboration partners to select additional optioned products or services, the Company evaluates whether such options contain material rights (i.e., have exercise prices that are discounted compared to what the Company would charge for a similar product or service to a new collaboration partner). The exercise price of these options includes a combination of licensing fees, event-based milestone payments and royalties. When these amounts in aggregate are not offered at a discount that exceeds discounts available to other customers, the Company concludes the option does not contain a material right, and therefore is not included in the transaction price at contract inception. Rather, the Company evaluates grants of additional licensing rights upon option exercises to determine whether such should be accounted for as separate contracts. The Company concluded there is no material right in these options.

The Company follows detailed accounting guidance in measuring revenue and certain judgments affect the application of its revenue policy. For example, in connection with its existing collaboration agreements, the Company has recorded on its condensed consolidated balance sheets short-term and long-term deferred revenue based on its best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months. Amounts that the Company expects will not be recognized within the next 12 months are classified as long-term deferred revenue. However, this estimate is based on the Company's current project development plan and, if the development plan should change in the future, the Company may recognize a different amount of deferred revenue over the next 12-month period.

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, collaboration, other revenue, and earnings in the period of adjustment.

PPP loan — In April 2020, the Company received the proceeds from a loan in the amount of approximately $4.9 million (the "PPP loan") from JPMorgan Chase Bank, N.A., as lender, pursuant to the Paycheck Protection Program (the "PPP") of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The Company accounted for the PPP loan as a financial liability in accordance with ASC Topic 470, *Debt*. Accordingly, the PPP loan was recognized as current and long-term debt in the Company's consolidated balance sheets and is included as PPP loan — current and PPP loan — long term. In addition, a *de minimis* amount of accrued interest is included in accrued expenses and other current liabilities. On July 28, 2021, the Company received notification from the U.S. Small Business Administration ("SBA") that the full principal amount of the PPP loan was forgiven. See Note 6 – *Borrowings* for additional information.

Cost of Goods Sold — Cost of goods sold includes material, labor costs and manufacturing overhead. Cost of goods sold also includes a significant component of current period manufacturing costs in excess of costs capitalized into inventory (excess capacity costs). These costs, in addition to the impact of the revaluation of inventory for standard costing, and write-offs of inventory are recorded as expenses in the period in which they are incurred, rather than as a portion of inventory costs. The cost of goods sold excludes the cost of insulin purchased under the Company's Insulin Supply Agreement (the "Insulin Supply Agreement") with Amphastar Pharmaceuticals, Inc. ("Amphastar"). All insulin inventory on hand was written off and the full purchase commitment contract to purchase future insulin was accrued as a recognized loss on purchase commitments as of the end of 2015.

Cash and Cash Equivalents and Restricted Cash —The Company considers all highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase, that are readily convertible into cash to be cash equivalents. As of September 30, 2021 and December 31, 2020, cash equivalents were comprised of money market accounts and U.S. Treasury securities with maturities less than 90 days from the date of purchase.

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.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported on the condensed consolidated balance sheets that sum to amounts reported on the condensed consolidated statements of cash flows (in thousands):

	September 30, 2021	December 31, 2020	September 30, 2020
Cash and cash equivalents	$ 51,740	$ 67,005	$ 52,398
Restricted cash	—	158	316
Total cash, cash equivalents, and restricted cash	$ 51,740	$ 67,163	$ 52,714

Held-to-Maturity Investments — The Company's investments generally consist of commercial paper, corporate notes or bonds and U.S. Treasury securities. For the three and nine months ended September 30, 2021, the Company held short-term and long-term investments of debt securities, including commercial paper and bonds. The Company intends to hold its investments until maturity and are therefore stated at amortized cost. Those investments with maturities less than 12 months are included in short-term investments and investments with maturities in excess of twelve months are included in long-term investments in the condensed consolidated balance sheets. The amortization of the Company's investments is recognized as interest expense in the condensed consolidated statements of operations and was approximately $0.2 million and $0.3 million for the three and nine months ended September 30, 2021, respectively. There was no such amortization for the three or nine months ended September 30, 2020. *No allowance for credit losses on held-to-maturity securities was required as of September 30, 2021.*

Available-for-Sale Investment — In June 2021, the Company invested $3.0 million in Thirona Bio, Inc. ("Thirona") and received a $3.0 million convertible promissory note (the "Thirona convertible note"). Unless earlier converted into conversion shares pursuant to the note purchase agreement, the principal and accrued interest shall be due and payable by Thirona on demand by the Company at any time after the maturity date of December 2022. Interest shall accrue at a rate of 6% per annum. The Thirona convertible note is a general unsecured obligation of Thirona. The Thirona convertible note is classified as an available-for-sale security and is included in other assets in the condensed consolidated balance sheet. Available-for-sale investments are subsequently measured at fair value. Unrealized holding gains and losses are excluded from earnings and reported in other comprehensive income until realized. The Company determines fair value of its available-for-sale investments using level 3 inputs. As of September 30, 2021, the Company evaluated the fair value of its investment in Thirona and determined that the fair value approximates the carrying value of $3.0 million. In June 2021, the Company and Thirona also entered into a collaboration agreement to develop a compound for the treatment of fibrotic lung diseases. See Note 7 – *Collaboration, Licensing and Other Arrangements* for additional information.

Concentration of Credit Risk — Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and investments. Cash and cash equivalents are held in high credit quality institutions. Cash equivalents consist of interest-bearing money market accounts and U.S. Treasury securities with maturities less than 90 days. Investments generally consist of commercial paper, corporate notes or bonds and U.S. Treasury securities. The cash equivalents and investments are regularly monitored by management.

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.

Pre-Launch Inventory — An improvement to the manufacturing process for the Company's primary excipient, fumaryl diketopiperazine ("FDKP") was demonstrated to be viable and management expects to realize an economic benefit in the future as a result of such process improvement. Accordingly, the Company is required to assess whether to capitalize inventory costs related to such excipient prior to regulatory approval of the new supplier and the improved manufacturing process. In doing so, management must consider a number of factors in order to determine the amount of inventory to be capitalized, including the historical experience of achieving regulatory approvals for the Company's manufacturing process, feedback from regulatory agencies on the changes being effected and the amount of inventory that is likely to be used in commercial production. The shelf life of the excipient will be determined as part of the regulatory approval process; in the interim, the Company must assess the available stability data to determine whether there is likely to be adequate shelf life to support anticipated future sales occurring beyond the expected approval date of the new raw material. If management is aware of any specific material risks or contingencies other than the normal regulatory review and approval process, or if the criteria for capitalizing inventory produced prior to regulatory approval are otherwise not met, the Company would not capitalize such inventory costs, choosing instead to recognize such costs as a research and development expense in the period incurred.

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 Company analyzes its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value. The Company performs an assessment of projected sales and evaluates the lower of cost or net realizable value and the potential excess inventory on hand at the end of each reporting period.

Impairment of Long-Lived Assets — The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Assets are considered to be impaired if the carrying value is considered to be unrecoverable.

If the Company believes an asset to be impaired, the impairment recognized is the amount by which the carrying value of the asset exceeds the fair value of the asset. Fair value is determined using the market, income or cost approaches as appropriate for the asset. Any write-downs are treated as permanent reductions in the carrying amount of the asset and recognized as an operating loss.

In August 2019, the Company recorded a $1.5 million commitment asset and a $0.4 million other asset for deferred debt issuance costs related to the future funding commitments of the MidCap Credit Facility. A quarterly assessment was performed during the second quarter of 2020 to determine if the Company was on target to achieve certain required milestone conditions in order for the Company to access further borrowings under the MidCap credit facility. The Company determined that such milestone conditions related to Afrezza trailing net revenue were unlikely to be achieved. As a result, an asset impairment of $1.9 million is reflected in the Company's condensed consolidated statements of operations for the nine months ended September 30, 2020. See Note 6 – *Borrowings* for further information on the MidCap credit facility.

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 condensed consolidated statements of operations. The liability balance of the recognized loss on insulin purchase commitments was $85.3 million and $95.3 million as of September 30, 2021 and December 31, 2020, respectively. No new contracts were identified in 2020 or in the first nine months of 2021 that required a new loss on purchase commitment accrual.

Milestone Rights Liability — On July 1, 2013, in conjunction with the execution of a financing facility with Deerfield Private Design Fund II L.P. and Deerfield Private Design International I L.P., the Company issued to Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL (the "Milestone Purchasers") certain rights to receive payments of up to $90.0 million, of which $65.0 million remains payable as of September 30, 2021 upon the occurrence of specified strategic and sales milestones, including the achievement of specified net sales figures (the "Milestone Rights"). The Company analyzed the Milestone Rights and determined that they did not meet the definition of a freestanding derivative. Since the Company has not elected to apply the fair value option to the Milestone Rights, the Company recorded them at their estimated initial fair value and accounted for the Milestone Rights as a liability.

The initial fair value estimate of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones and discounted to present value using a selected market discount rate. The expected timing and probability of achieving the milestones was developed with consideration given to both internal data, such as progress made to date and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. The Milestone Rights liability will be remeasured as the specified milestone events are achieved. Specifically, as each milestone event is achieved, the portion of the initially recorded Milestone Rights liability that pertains to the milestone event being achieved, will be remeasured to the amount of the specified related milestone payment. The resulting change in the balance of the Milestone Rights liability due to remeasurement will be recorded in the Company's consolidated statements of operations as interest expense. Furthermore, the Milestone Rights liability will be reduced upon the settlement of each milestone payment. As a result, each milestone payment would be effectively allocated between a reduction of the recorded Milestone Rights liability and an expense representing a return on a portion of the Milestone Rights liability paid to the investor for the achievement of the related milestone event (see Note 6 – *Borrowings*).

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.

Income Taxes — The provisions for federal, foreign, state and local income taxes are calculated on pre-tax income based on current tax law and include the cumulative effect of any changes in tax rates from those used previously in determining deferred tax assets and liabilities. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which the temporary differences are expected to be recovered or settled. A valuation allowance is recorded to reduce net deferred income tax assets to amounts that are more likely than not to be realized.

For uncertain tax positions, the Company determines whether it is "more likely than not" that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. For those

tax positions where it is “not more likely than not” that a tax benefit will be sustained, no tax benefit is recognized. Penalties, if probable and reasonably estimable, are recognized as a component of income tax expense. The Company has reduced its deferred tax assets for uncertain tax positions but has not recorded liabilities for income tax expense, penalties, or interest.

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, RSUs, performance-based non-qualified stock options awards (“PNQs”), restricted stock units with market conditions (“Market RSUs”) 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. 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. RSUs are valued based on the market price on the grant date. Market RSUs are valued using a Monte Carlo valuation model and RSUs with performance conditions are evaluated for 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 condensed consolidated statements of operations, result from obligations under contracts with vendors, consultants and clinical site agreements in addition to internal costs associated with conducting clinical trials.

Recently Adopted Accounting Standards — In August 2020, the FASB issued ASU 2020-06, *Issuer’s Accounting for Convertible Instruments and Contracts on an Entity’s Own Equity*, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity’s own equity. The Company early adopted this standard as of January 1, 2021. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

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.

2. Accounts Receivable

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

	September 30, 2021	December 31, 2020
Accounts receivable – commercial		
Accounts receivable, gross	$ 7,297	$ 8,090
Wholesaler distribution fees and prompt pay discounts	(1,680)	(1,205)
Reserve for returns	(2,964)	(2,667)
Total accounts receivable – commercial, net	2,653	4,218
Accounts receivable – collaborations and services		
Accounts receivable, gross	7,559	—
Allowance for doubtful accounts	(767)	—
Total accounts receivable – collaborations and services, net	6,792	—
Total accounts receivable, net	$ 9,445	$ 4,218

As of September 30, 2021 and December 31, 2020, the allowance for doubtful accounts for accounts receivable – commercial was *de minimis*. The Company had three wholesale distributors representing approximately 87% of commercial accounts receivable as of September 30, 2021 and approximately 81% and 82% of gross sales for the three and nine months ended September 30, 2021, respectively.

As of September 30, 2021, the allowance for accounts receivable – collaborations and services was $0.8 million and was related to $1.5 million of accounts receivable for Vertice Pharma, a collaboration partner for the co-promotion of Thyquidity. The Company had one collaboration partner, United Therapeutics, that comprised approximately 79% of the collaboration and services accounts receivable as of September 30, 2021 and approximately 99% and 95% of gross sales from collaborations and services for the three and nine months ended September 30, 2021, respectively.

3. Inventories

Inventories consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Raw materials	$ 2,748	$ 1,393
Work-in-process	1,790	2,484
Finished goods	2,944	1,096
Total inventory	$ 7,482	$ 4,973

Work-in-process and finished goods as of September 30, 2021 and December 31, 2020 include conversion costs and exclude the cost of insulin. All insulin inventory on hand was written off and the projected loss on the purchase commitment contract to purchase future insulin was accrued as of the end of 2015. Raw materials inventory included $0.8 million of pre-launch inventory as of September 30, 2021 and December 31, 2020, which consisted of FDKP received in November 2019 that will be used to manufacture Afrezza under an enhanced manufacturing process for FDKP. The Company expects to receive FDA approval of the new source of FDKP in 2023, after which the pre-launch raw materials inventory will be reclassified as raw materials inventory for use in the manufacturing of Afrezza and Tyvaso DPI.

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 also performed an assessment of projected sales and evaluated the lower of cost or net realizable value and the potential excess inventory on hand. Inventory that was forecasted to become obsolete due to expiration is recorded in costs of goods sold in the condensed consolidated statements of operations. For the nine months ended September 30, 2020, there was an inventory write-off of $0.5 million as a result of this assessment. There were no inventory write-offs for the three months ended September 30, 2020 or the three and nine months ended September 30, 2021.

4. Property and Equipment

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

	Estimated Useful Life (Years)	September 30, 2021		December 31, 2020
Land	—	$ 875		$ 875
Buildings	39-40	17,389		17,389
Building improvements	5-40	38,651		37,543
Machinery and equipment	3-15	54,978		55,054
Furniture, fixtures and office equipment	5-10	3,004		3,004
Computer equipment and software	3	8,361		8,319
Construction in progress	—	5,262	(1)	503
		128,520		122,687
Less accumulated depreciation		(97,672)		(96,820)
Total property and equipment, net		$ 30,848		$ 25,867

(1) Construction in progress includes $1.6 million of equipment under construction for the manufacturing expansion for UT (the "UT Equipment"). See Note 7 – *Collaboration, Licensing and Other Arrangements*.

Depreciation expense related to property and equipment for the three and nine months ended September 30, 2021 and 2020 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Depreciation Expense	$ 508	$ 445	$ 1,449	$ 1,346

On November 8, 2021, the Company closed a transaction to sell certain real estate located at One Casper Street, Danbury, CT (the "Property") to an affiliate of Creative Manufacturing Properties (the "Purchaser") for a sales price of $102.3 million, subject to terms and the conditions contained in a purchase and sale agreement. Effective with the closing of this transaction, the Company entered into a 20-year lease agreement with the purchaser (the "Sale-Leaseback Transaction"). See Note 14 – *Subsequent Event*.

5. Accrued Expenses and Other Current Liabilities

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

	September 30, 2021	December 31, 2020
Salary and related expenses	$ 10,965	$ 11,250
Discounts and allowances for commercial product sales	4,680	3,688
Accrued interest	721	519
Deferred lease liability	1,257	1,422
Milestone rights liability — current	1,088	1,337
Danbury facility buildout	7	—
Professional fees	443	533
Sales and marketing services	357	99
Other	1,311	859
Total accrued expenses and other current liabilities	$ 20,829	$ 19,707

6. Borrowings

Carrying amount of principal borrowings consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Senior convertible notes	$ 223,580	$ —
MidCap credit facility	38,723	49,335
Mann Group promissory notes(1)	18,425	63,027
PPP loan	—	4,873
2024 convertible notes	—	5,000
Total debt — net carrying amount	$ 280,728	$ 122,235

(1) The amendment to the Mann Group convertible note in the second quarter of 2021 resulted in a substantial premium of $22.1 million based on the fair value post modification, which contributed to the loss on extinguishment in the condensed consolidated statement of operations for the nine months ended September 30, 2021 and was recognized as additional paid-in capital in the condensed consolidated balance sheet as of September 30, 2021. The accounting for the $22.1 million loss on extinguishment did not result in a change in the financial position of the Company.

The following table provides a summary of the Company's debt and key terms as of September 30, 2021:

	Amount Due		Terms		
	September 30, 2021	December 31, 2020	Annual Interest Rate	Maturity Date	Conversion Price
Senior convertible notes	$230.0 million	$ —	2.50%	March 2026	$5.21 per share
MidCap credit facility[1]	$40.0 million	$50.0 million	one-month LIBOR (1% floor) plus 6.25%	[1] August 2025	[1] N/A
Mann Group convertible note	$18.4 million (plus $0.3 million accrued interest paid-in-kind)	$28.0 million (plus $0.6 million accrued interest paid-in-kind)	2.50%	[2] December 2025	[2] $2.50 per share
Mann Group non-convertible note[3]	—	$35.1 million (plus $3.6 million accrued interest paid-in-kind)	7.00%	November 2024	N/A
PPP loan[4]	—	$4.9 million	0.98%	April 2022	N/A
2024 convertible notes[5]	—	$5.0 million	5.75%	November 2024	$3.00 per share

(1) In April 2021, the Company prepaid $10.0 million principal balance and amended the MidCap credit facility. The interest rate prior to the amendment was one-month LIBOR (2% floor) plus 6.75% and the maturity date was in August 2024.

(2) In April 2021, the Mann Group convertible note was amended. The interest rate prior to the amendment was 7.00% and the maturity date was in November 2024.

(3) In April 2021, the Company prepaid $35.1 million principal balance as well as accrued unpaid interest.

(4) In July 2021, the Company received full forgiveness from the SBA for the $4.9 million principal balance of the PPP loan and recognized a gain on extinguishment of debt for the full principal balance and a *de minimis* amount of accrued but unpaid interest.

(5) In February 2021, the $5.0 million principal balance was converted into 1,666,667 shares of the Company's common stock.

The maturities of the Company's borrowings as of September 30, 2021 are as follows (in thousands):

	Amounts
2021	$ —
2022	—
2023	6,667
2024	20,000
Thereafter	261,758
Total principal payments	288,425
Discount	(1,277)
Debt issuance cost	(6,420)
Total debt — net carrying amount	$ 280,728

Senior convertible notes – On March 4, 2021, the Company issued $200.0 million aggregate principal amount of Senior convertible notes in a private offering. Pursuant to an option to purchase additional senior convertible notes in the purchase agreement between the Company and the initial purchasers of the Senior convertible notes, the Company issued an additional $30.0 million aggregate principal amount of Senior convertible notes on March 15, 2021. The Senior convertible notes were issued pursuant to an indenture, dated March 4, 2021 (the "Indenture"), between the Company and U.S. Bank National Association, as trustee.

The Senior convertible notes are general unsecured obligations of the Company and will mature on March 1, 2026, unless earlier converted, redeemed or repurchased. The Senior convertible notes will bear cash interest from March 4, 2021 at an annual rate of 2.50% payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2021. The Senior convertible notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding December 1, 2025, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2021 (and only during such calendar quarter), if the last reported sale price of the Company's common stock, par value $0.01 per share, for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of

the conversion price for the Senior convertible notes on each applicable trading day; (2) during the five business day period after any ten consecutive trading day period in which the trading price (as defined in the Indenture) per $1,000 principal amount of the Senior convertible notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Common Stock and the conversion rate on each such trading day; (3) if the Company calls such Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date, but only with respect to the Senior convertible notes called (or deemed called) for redemption; or (4) upon the occurrence of specified corporate events as set forth in the Indenture. On or after December 1, 2025 until the close of business on the business day immediately preceding the maturity date, holders may convert all or any portion of their Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of the Common Stock or a combination of cash and shares of Common Stock, at the Company's election, in the manner and subject to the terms and conditions provided in the Indenture.

The initial conversion rate is 191.8281 shares of Common Stock per $1,000 principal amount of Notes (equivalent to an initial conversion price of approximately $5.21 per share of Common Stock). The initial conversion price of the Senior convertible notes represents a premium of approximately 30% to the last reported sale price of the Common Stock on the Nasdaq Global Market on March 1, 2021. The conversion rate for the Senior convertible notes is subject to adjustment under certain circumstances in accordance with the terms of the Indenture, but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date of the Senior convertible notes or if the Company delivers a notice of redemption in respect of the Senior convertible notes, the Company will, in certain circumstances, increase the conversion rate of the Senior convertible notes for a holder who elects to convert its Senior convertible notes in connection with such a corporate event or convert its Notes called for redemption during the related redemption period (as defined in the Indenture), as the case may be.

The Company may not redeem the Senior convertible notes prior to March 6, 2024. The Company may redeem for cash all or any portion of the Senior convertible notes, at its option, on or after March 6, 2024 and prior to the 36th scheduled trading day immediately preceding the maturity date, if the last reported sale price of Common Stock has been at least 130% of the conversion price for the Senior convertible notes then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the Senior convertible notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. If the Company elects to redeem less than all of the outstanding Senior convertible notes, at least $75.0 million aggregate principal amount of Senior convertible notes must be outstanding and not subject to redemption as of the relevant redemption notice date. No sinking fund is provided for the Senior convertible notes.

If the Company undergoes a fundamental change (as defined in the Indenture), then, subject to certain conditions and except as described in the Indenture, holders may require the Company to repurchase for cash all or any portion of their Notes at a fundamental change repurchase price equal to 100% of the principal amount of the Senior convertible notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Indenture includes customary covenants and sets forth certain events of default after which the Senior convertible notes may be declared immediately due and payable.

If certain bankruptcy and insolvency-related events of default involving the Company (and not just any of its significant subsidiaries) occur, 100% of the principal of and accrued and unpaid interest on the Senior convertible notes will automatically become due and payable. If an event of default with respect to the Senior convertible notes, other than certain bankruptcy and insolvency-related events of default involving the Company (and not just any of its significant subsidiaries), occurs and is continuing, the trustee, by notice to the Company, or the holders of at least 25% in principal amount of the outstanding Senior convertible notes by notice to the Company and the trustee, may, and the trustee at the request of such holders shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the Senior convertible notes to be due and payable. Notwithstanding the foregoing, the Indenture provides that, to the extent the Company so elects, the sole remedy for an event of default relating to certain failures by the Company to comply with certain reporting covenants in the Indenture will, for the first 365 days after the occurrence of such an event of default consist exclusively of the right to receive additional interest on the Senior convertible notes as set forth in the Indenture.

The Indenture provides that the Company shall not consolidate with or merge with or into, or sell, convey, transfer or lease all or substantially all of the consolidated properties and assets of the Company and its subsidiaries, taken as a whole, to, another person (other than any such sale, conveyance, transfer or lease to one or more of the Company's direct or indirect wholly owned subsidiaries), unless: (i) the resulting, surviving or transferee person (if not the Company) is a corporation organized and existing under the laws of the United States of America, any State thereof or the District of Columbia, and such corporation (if not the Company) expressly assumes by supplemental indenture all of the Company's obligations under the Senior convertible notes and the Indenture; and (ii) immediately after giving effect to such transaction, no default or event of default has occurred and is continuing under the Indenture.

The Company's net proceeds from the Offering were approximately $222.7 million, after deducting the initial purchasers' discounts and commissions and the estimated Offering expenses payable by the Company. As of September 30, 2021, the unamortized debt issuance cost was $6.4 million.

MidCap credit facility — In August 2019, the Company entered into the MidCap credit facility and borrowed the first advance of $40.0 million ("Tranche 1") in August 2019 and the second advance of $10.0 million ("Tranche 2") in December 2020. In April 2021, $10.0 million was prepaid. Under the terms of the MidCap credit facility, a third advance of $60.0 million ("Tranche 3") will be available to the Company between January 1, 2022 and June 30, 2022, subject to the satisfaction of certain milestone conditions associated with Tyvaso DPI™ through the Company's collaboration with United Therapeutics (see Note 7 – *Collaboration, Licensing and Other Arrangements*).

In December 2019, the Company entered into the first amendment to the MidCap credit facility, pursuant to which the parties agreed to (i) amend the financial covenant relating to trailing twelve month minimum Afrezza Net Revenue (as defined in the MidCap credit facility) requirements, (ii) add a condition to the third advance that requires the Company achieve certain amounts of Afrezza Net Revenue, and (iii) increase the exit fee from 6.00% to 7.00% of the principal amount of all term loans advanced to the Company under the MidCap credit facility.

In August 2020, the Company entered into the second amendment to the MidCap credit facility, pursuant to which the parties agreed that no breach of the minimum Afrezza net revenue covenant for any trailing twelve-month reporting period between July 31, 2020 and November 30, 2020 will be deemed to occur if the Company delivers satisfactory evidence that it had unrestricted cash of at least $40.0 million. Without this amendment, the Company would have been in violation of the minimum Afrezza net revenue covenant as of September 30, 2020.

In November 2020, the Company entered into the third amendment to the MidCap credit facility, pursuant to which the parties agreed to (i) amend the conditions to draw Tranche 2, which had become unavailable, such that the advance became available and was, in fact, funded to the Company on December 1, 2020, (ii) amend the conditions to Tranche 3 such that the third advance was available upon the satisfaction of certain conditions, including certain milestone conditions associated with Tyvaso DPI, (iii) add a covenant that requires the marketing of Tyvaso DPI if the third advance is funded, (iv) amend the financial covenant relating to trailing twelve month minimum Afrezza Net Revenue (as defined in the MidCap credit facility) requirements, (v) increase the minimum cash covenant to $30.0 million at all times, (vi) extend the interest only period until September 1, 2022, at which time principal on each term loan advance is payable in 24 equal monthly installments, and (vii) amend the prepayment fees.

In connection with the extension of the interest only period for the $40.0 million drawn under Tranche 1, a $0.2 million loss on extinguishment was recognized in the consolidated statements of operations for the year ended December 31, 2020. The funding of $10.0 million under Tranche 2 resulted in the recognition of approximately $0.3 million of debt discount and a *de minimis* amount of debt issuance costs.

In December 2020, the Company entered into the fourth and fifth amendments to the MidCap credit facility. Pursuant to the fourth amendment, MidCap consented to the acquisition by the Company of QrumPharma, Inc. Pursuant to the omnibus joinder and fifth amendment, QrumPharma was joined as a borrower to the MidCap credit facility and to certain related financing documents.

In March 2021 the Company entered into the sixth amendment to the MidCap credit facility to accommodate the issuance of the Senior convertible notes. On April 22, 2021, the Company entered into the seventh amendment of the MidCap credit facility, pursuant to which the parties agreed to, among other things, (i) increase the amount available under the third advance from $25.0 million to $60.0 million and extend the date through which the third advance is available to June 30, 2022, (ii) amend the conditions to the third advance of $60.0 million being available to draw, including certain milestone conditions associated with Tyvaso DPI, (iii) remove the Company's obligation to issue a warrant to purchase shares of the Company's common stock upon drawing down the third advance, (iv) extend the interest-only period until September 1, 2023 and extend the maturity date until August 1, 2025, (v) amend the financial covenant relating to trailing 12 month minimum Afrezza net revenue, (vi) decrease the minimum cash covenant, (vii) decrease the interest rate on any amounts outstanding, now or in the future, under the MidCap credit facility, (viii) permit the Company to make certain acquisitions, subject to requirements, and (ix) permit the Company to make investments of up to an additional $9.0 million so long as the Company has $90.0 million or more of unrestricted cash and short-term investments following such investment. Concurrent with entering into this amendment, the Company made a $10.0 million principal prepayment against outstanding term loans under the MidCap credit facility and paid a related $1.0 million exit fee in lieu of the unaccrued portion of the original exit fee and prepayment penalties that would otherwise have been due with respect to the partial prepayment.

Tranche 1, Tranche 2 and, if borrowed, Tranche 3, each accrue interest at an annual rate equal to the lesser of (i) 8.25% and (ii) the one-month LIBOR (subject to a one-month LIBOR floor of 1.00%) plus 6.25%. Interest on each term loan advance is due and payable monthly in arrears. Principal on each term loan advance under Tranche 1, Tranche 2 and, if applicable, Tranche 3 is payable in 24 equal monthly installments beginning September 1, 2023, until paid in full on August 1, 2025. The Company has the option to prepay its existing term loans, in whole or in part, subject to early termination fees in an amount equal to 3.00% of principal prepaid if prepayment occurs on or prior to April 22, 2022; 2.00% of principal prepaid if prepayment occurs on or after April 23, 2022 through and including April 22, 2023; and 1.00% of principal prepaid if prepayment occurs on or after April 23, 2023 through the maturity date. Tranche 3 will be subject to a similar scheme of early termination fees measured from the anniversary of the funding date for such tranche, if ever.

The prepayment penalty of $1.0 million related to the payment of $10.0 million was capitalized and will be amortized over the remaining life of the debt. As of September 30, 2021, the unamortized debt discount was $0.4 million and the unamortized prepayment penalty was $0.9 million.

The Company's obligations under the MidCap credit facility are secured by a security interest on substantially all of its assets, including intellectual property.

The MidCap credit facility, as amended, contains customary affirmative covenants and customary negative covenants limiting the Company's ability and the ability of the Company's subsidiaries to, among other things, dispose of assets, undergo a change in control, merge or consolidate, make acquisitions, incur debt, incur liens, pay dividends, repurchase stock and make investments, in each case subject to certain exceptions. The Company must also comply with a financial covenant relating to trailing twelve month minimum Afrezza net revenue, tested on a monthly basis, unless the Company has $90.0 million or more of unrestricted cash and short-term investments. The Company is also subject to a minimum cash covenant of $10.0 million at all times; however, this covenant will be eliminated in the event that Tyvaso DPI is approved by the FDA. As of September 30, 2021, the Company was in compliance with the financial and minimum cash covenants.

The MidCap credit facility also contains customary events of default relating to, among other things, payment defaults, breaches of covenants, a material adverse change, listing of the Company's common stock, bankruptcy and insolvency, cross defaults with certain material indebtedness and certain material contracts, judgments, and inaccuracies of representations and warranties. Upon an event of default, the agent and the lenders may declare all or a portion of the Company's outstanding obligations to be immediately due and payable and exercise other rights and remedies provided for under the MidCap credit facility. During the existence of an event of default, interest on the term loans could be increased by 2.00%.

The Company also agreed to issue warrants to purchase shares of the Company's common stock (the "MidCap warrants") upon the drawdown of Tranches 1 and 2 in an aggregate amount equal to 3.25% of the amount drawn, divided by the exercise price per share for that tranche. The exercise price per share is equal to the volume-weighted average closing price of the Company's common stock for the ten business days immediately preceding the second business day before the issue date. As a result of Tranche 1, the Company issued warrants to purchase an aggregate of 1,171,614 shares of the Company's common stock, at an exercise price equal to $1.11 per share. As a result of Tranche 2, the Company issued warrants to purchase an aggregate of 111,853 shares of the Company's common stock, at an exercise price equal to $2.91 per share. The Company determined that these warrants met the criteria for equity classification and accounted for such warrants in additional paid-in capital. Subsequent to September 30, 2021, the Tranche 1 and Tranche 2 MidCap warrants were exercised in full.

Mann Group promissory notes — In August 2019, the Company issued a $35.0 million note that is convertible into shares of the Company's common stock at $2.50 per share (the "Mann Group convertible note") and issued a non-convertible note to Mann Group in an aggregate principal amount of $35.1 million (the "Mann Group non-convertible note" and, together with the Mann Group convertible note, the "Mann Group promissory notes") as part of a restructuring of its then existing indebtedness to Mann Group.

The Mann Group promissory notes each accrued interest at the rate of 7.00% per year on the principal amount, payable quarterly in arrears on the first day of each calendar quarter beginning October 1, 2019. On April 22, 2021, the Company and Mann Group entered into an amendment of the Mann Group convertible note, pursuant to which the parties agreed to (i) reduce the interest rate from 7.0% to 2.5% effective on April 22, 2021, and (ii) extend the maturity date from November 3, 2024 to December 31, 2025.

The amendment to the Mann Group convertible note resulted in a debt extinguishment with a substantial premium based on the fair value post extinguishment. The fair value in excess of the face amount of $18.4 million contributed to a loss on extinguishment of $22.1 million in the condensed consolidated statement of operations for the three and nine months ended September 30, 2021 and resulted in a corresponding debt premium of $22.1 million which was recognized as additional paid-in capital in the condensed consolidated balance sheet as of September 30, 2021. The accounting for the $22.1 million loss on extinguishment did not result in a change in the financial position of the Company. The Company wrote off a *de minimis* amount of debt issuance cost.

The principal and any accrued and unpaid interest under the Mann Group convertible note may be converted, at the option of Mann Group, 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 a conversion rate of 400 shares per $1,000 of principal and/or accrued and unpaid interest, which is equal to a conversion price of $2.50 per share. The conversion rate will be subject to adjustment under certain circumstances described in the Mann Group convertible note. Interest on the convertible note will be payable in kind by adding the amount thereof to the principal amount; provided that with respect to interest accruing from and after January 1, 2021, the Company may, at its option, elect to pay any such interest on any interest payment date, if certain conditions are met, in shares of the Company's common stock at a price per shall equal to the last reported sale price on the trading day immediately prior to the payment date.

Pursuant to the terms of the Mann Group convertible note, Mann Group converted $3.0 million of accrued interest and $7.0 million of principal into 1.2 million shares and 2.8 million shares, respectively, of the Company's common stock in the fourth quarter of 2020. During the nine months ended September 30, 2021, Mann Group converted $0.4 million of interest and $9.6 million of principal into 4,000,000 shares of common stock.

On April 22, 2021, the Company repaid the entire principal amount of $35.1 million outstanding under the Mann Group non-convertible note, together with all accrued and unpaid interest thereon.

PPP loan – On April 10, 2020, the Company received the proceeds from the PPP loan from JPMorgan Chase Bank, N.A., as lender, in the amount of approximately $4.9 million pursuant to the PPP of the CARES Act. On July 28, 2021, the Company received notification from the SBA that the full principal amount of the PPP loan was forgiven. The Company recognized a $4.9 million gain on extinguishment of debt for the forgiveness of the principal amount and accrued but unpaid interest for the three and nine months ended September 30, 2021.

Prior to being forgiven, the PPP loan was evidenced by a promissory note dated April 9, 2020 that matured on April 9, 2022 and bore interest at a rate of 0.98% per annum (which was being deferred). The Company used all proceeds from the PPP loan to retain employees, maintain payroll and make lease, interest and utility payments.

2024 convertible notes — In August 2019, the Company issued 5.75% convertible senior subordinated exchange notes due November 2024 (the "2024 convertible notes") pursuant to an indenture, dated as of August 6, 2019, between the Company and U.S. Bank National Association, as trustee (the "2019 Indenture"). The 2024 convertible notes were the Company's general, unsecured obligations, and were subordinated in right of payment to the indebtedness incurred pursuant to the MidCap credit facility. The 2024 convertible notes ranked equally in right of payment with the Company's other unsecured senior debt. The 2024 convertible notes accrued interest at the rate of 5.75% per year on the principal amount, payable semiannually in arrears on February 15 and August 15 of each year, beginning February 15, 2020, with interest accruing from August 6, 2019. Interest on the 2024 convertible notes was payable in cash or, at the option of the Company if certain conditions are met, in shares of the Company's common stock at a price per share equal to the last reported sale price on the trading day immediately prior to the interest payment date.

The 2024 convertible notes were 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 a conversion rate of 333.3333 shares per $1,000 principal amount of 2024 convertible notes, which is equal to a conversion price of approximately $3.00 per share.

In February 2021, the Company converted the $5.0 million 2024 convertible notes with the issuance of 1,666,667 shares of the Company's common stock.

Amortization of debt discount and debt issuance cost related to all borrowings for the three and nine months ended September 30, 2021 and 2020 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Amortization of debt discount	$ 109	$ 53	$ 255	$ 232
Amortization of debt issuance cost	363	27	852	82

Milestone Rights — As of September 30, 2021 and December 31, 2020, the remaining Milestone Rights liability balance was $5.9 million and $7.3 million, respectively, which was based on initial fair value estimates calculated using the income approach and reduced by milestone achievement payments made. During the first quarter of 2021, the Company achieved the second Afrezza net sales milestone specified by the Milestone Rights. The milestone carrying value of the Milestone Rights liability related to the $5.0 million payment, which was made in the second quarter of 2021, was approximately $1.3 million, which represented the fair value as determined in 2013 (the most recent measurement date).

The agreement with the Milestone Purchasers that provides for the Milestone Rights 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 such agreement.

7. Collaboration, Licensing and Other Arrangements

Revenue from collaborations and services for the three and nine months ended September 30, 2021 and 2020 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
UT License Agreement	$ 12,313	$ 7,978	$ 33,475	$ 23,934
Vertice Pharma Co-Promotion Agreement	—	—	1,147	—
Receptor CLA	31	63	206	188
Cipla License and Distribution Agreement	37	36	110	108
Other	77	—	161	—
UT Research Agreement	—	—	—	211
Total revenue from collaborations and services	$ 12,458	$ 8,077	$ 35,099	$ 24,441

United Therapeutics License Agreement — In September 2018, the Company and UT 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 ("Tyvaso DPI") and associated inhalation delivery devices. Under the UT License Agreement, UT is responsible for global development, regulatory and commercial activities with respect to Tyvaso DPI. The Company is responsible for manufacturing clinical supplies and commercial supplies of Tyvaso DPI.

Under the terms of the UT License Agreement, the Company received an upfront payment of $45.0 million in October 2018 and four $12.5 million milestone payments between April 2019 and November 2020. The Company will also be entitled to receive low double-digit royalties on net sales of Tyvaso DPI as well as a manufacturing margin on commercial supplies of the product. UT, 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 arterial hypertension. Each such optioned product would be subject to UT's 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.

At the inception of the agreement, the Company identified one distinct, performance obligation. The Company determined that the key deliverables include the license, supply of product to be used in clinical development, and certain research services upon achievement of specified development targets ("R&D Services"). Due to the specialized and unique nature of these services and their direct relationship with the license, the Company has determined that these deliverables represent one distinct bundle and thus, one performance obligation. The Company also determined that UT's option to expand the scope of the products to include products with other active ingredients is not a material right, and thus, not a performance obligation at the onset of the agreement. The consideration for the option will be accounted for upon exercise of the option.

The Company expected to complete the activities specified in the initial development plan and to achieve the milestone events (including a $2.7 million increase in total consideration pursuant to the agreement executed in December 2020) by December 31, 2021 for total consideration of approximately $105.8 million, which included an upfront payment, four milestone payments, various pass-through costs and payments for clinical supplies. Revenue was allocated as follows:

Distinct Performance Obligation	Transaction Price	Allocation of Price	Recognition Method	Progress Measure	Recognition Period	
	(in millions)					
R&D Services and License	$ 105.8	100%	Over time	Ratably	Sep 2018 - Dec 2021	(1)

(1) Recognition period represents the estimated period to satisfy the performance obligation.

In May 2021, UT and the Company updated the development plan under the UT License Agreement to provide for additional process-development and stability-testing activities as well as the expansion of the Company's commercial manufacturing capacity. The activities and deliverables under the current development plan resulted in four distinct performance obligations which include: (1) the continued development and approval process for a new drug application ("NDA") ("R&D Services"); (2) certain pre-commercial services in preparation for commercial launch of Tyvaso DPI "(Pre-Commercial Services"); (3) development activities for the next generation of Tyvaso DPI ("Next-Gen R&D Services"); and (4) certain design and construction activities in anticipation of expansion of the Company's commercial manufacturing facility ("Facility Expansion Services").

The total consideration for the updated development plan of $50.2 million was allocated to the four distinct performance obligations based on management's assessment of the stand-alone selling price of each performance obligation. Consideration of $0.7 million for additional clinical supplies was added in June 2021 for a total of $50.9 million. Revenue was allocated as follows:

Description	Transaction Price	Allocation of Price(1)	Recognition Method	Progress Measure	Revenue Recognition	
	(in millions)					
Total transaction price	$ 50.9					
Distinct Performance Obligation						
R&D Services and License		$ 18.4	Over time	Ratably	May 2021 - Oct 2021	(2)
Pre-Commercial Services		$ 4.6	Over time	Input	% of completion of costs	(3)
Next-Gen R&D Services		$ 7.2	Over time	Input	% of completion of costs	(3)
Facility Expansion Services(4)		$ 20.7	Point in time		Transfer of control	(5)

(1) Allocation is based on management's assessment of the stand-alone selling price of each performance obligation.
(2) Represents the estimated period when the R&D Services performance obligation will be substantially complete.
(3) Pre-Commercial Services and Next-Gen R&D Services performance obligations will be satisfied over time using the input method based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer.
(4) The Company will also be acting as agent for the procurement of equipment for the manufacturing expansion for the UT Equipment. The $5.3 million received from UT for the UT Equipment was recognized as deposits from customer on the condensed consolidated balance sheet and will be released as the title is transferred to UT.
(5) The Facility Expansion Services performance obligation would be recognized as control of manufactured products is transferred to the customer.

On August 12, 2021, the Company and United Therapeutics entered into a commercial supply agreement (the "CSA"), pursuant to which the Company is responsible for manufacturing and supplying to United Therapeutics, and United Therapeutics is responsible for purchasing from the Company on a cost-plus basis, Tyvaso DPI and BluHale inhalation profiling devices, as required for commercial distribution and sale by United Therapeutics. In addition, United Therapeutics is responsible for supplying treprostinil at its expense in quantities necessary to enable the Company to manufacture Tyvaso DPI as required by the CSA.
The activities and deliverables under CSA and the current development plan resulted in three distinct performance obligations which include: (1) the license, supply of product to be used in clinical development, and continued development and approval support for Tyvaso DPI ("R&D Services and License"); (2) development activities for the next generation of Tyvaso DPI ("Next-Gen R&D Services"); and (3) a material right associated with future commercial manufacturing and supply of product ("Manufacturing Services").

The total revised anticipated cash flows of $221.5 million from the transaction was allocated to the three distinct performance obligations as follows.

Description	Anticipated Cash Flow	Allocation(1)	Recognition Method	Progress Measure	Revenue Recognition	
	(in millions)					
Total anticipated cash flow	$ 221.5					
Distinct Performance Obligation						
R&D Services and License(2)		$ 6.0	Over time	Ratably	Aug 2021 - Oct 2021	(3)
Next-Gen R&D Services		$ 8.8	Over time	Input	% of completion of costs	(4)
Manufacturing Services		$ 206.7	Point in time		Transfer of control	(5)

(1) Allocation is based on management's assessment of the stand-alone selling price of each performance obligation.
(2) The license for the Company's IP was considered to be interdependent with the development activities to support approval of Tyvaso DPI. A sales-based royalty is promised in exchange for the IP license; therefore, the royalties associated with the license are excluded from the determination of the transaction price and the Company will recognize revenue as the sale of Tyvaso DPI to a patient occurs.
(3) Represents the estimated period when the R&D Services performance obligation will be substantially complete.
(4) The Next-Gen R&D Services performance obligation will be satisfied over time using the input method based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer.

(5) The Manufacturing Services performance obligation will be recognized as control of manufactured products is transferred to the customer; therefore, no revenue associated with this obligation was recognized during the three or nine months ended September 30, 2021. The allocation of transaction price is based on the Company's estimated production and the ultimate cash flows may vary as manufacturing purchase orders are received.

As of September 30, 2021, deferred revenue consisted of $13.8 million, which was classified as current on the condensed consolidated balance sheet.

As amended by an amendment dated October 16, 2021, the term of the CSA continues until December 31, 2031 (unless earlier terminated) and is thereafter renewed automatically for additional, successive two-year terms unless (i) United Therapeutics provides notice to the Company at least 24 months in advance of such renewal that United Therapeutics does not wish to renew the CSA or (ii) the Company provides notice to United Therapeutics at least 48 months in advance of such renewal that the Company does not wish to renew the CSA. The Company and United Therapeutics each have normal and customary termination rights, including termination for material breach that is not cured within a specific timeframe or in the event of liquidation, bankruptcy or insolvency of the other party.

Vertice Pharma Co-Promotion Agreement — In December 2020, the Company entered into a co-promotion agreement with Vertice Pharma where the Company's sales force will promote Thyquidity to adult endocrinologists, pediatric endocrinologists and other healthcare providers who treat hypothyroidism. Following the commercial launch of Thyquidity, in consideration of the sales and promotional activities provided by the Company's sales force, Vertice Pharma is obligated to pay fixed quarterly payments to the Company, as well as variable consideration based on gross profits resulting from all sales of Thyquidity. Vertice Pharma launched Thyquidity in collaboration with the Company in February 2021.

At inception of the agreement, the Company identified a single performance obligation that the Company will satisfy over time. The Company estimates the total transaction price is approximately $6.3 million, consisting of fixed consideration and the unconstrained amount of estimated variable consideration, which is based on gross profit applied to defined revenue benchmarks. The amount of variable consideration is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur and the payments will be received. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price 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 in the period of adjustment. The total transaction price will be recognized over a two-year period. the period over which the Company is required to satisfy its performance obligation, using the input method based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. In July 2021, the Company and Vertice Pharma entered into an amendment to the Vertice Pharma Co-Promotion Agreement that modifies the terms of payment where 50% of the previously fixed consideration will be subject to certain promotional conditions, resulting in variable consideration.

In September 2021, the Company and Vertice Pharma mutually agreed that the Company would cease promotional activities under the co-promotion agreement effective September 30, 2021, other than certain transitional activities that continued until October 15, 2021. The Company and Vertice Pharma are currently negotiating a final settlement of all obligations related to the termination of the co-promotion agreement.

As of September 30, 2021, the Company fully reserved $0.8 million of revenue from the co-promotion of Thyquidity, which was recognized as allowance for doubtful accounts – collaborations and services, which is included in accounts receivable, net in the consolidated balance sheet. In addition, the Company recognized an impairment on contract assets of $0.1 million related to variable consideration from gross profits which was recognized during the nine months ended September 30, 2021. There was no variable consideration from gross profits recognized during the three months ended September 30, 2021.

Thirona Collaboration Agreement — In June 2021, the Company and Thirona entered into a collaboration agreement to evaluate the therapeutic potential of Thirona's compound for the treatment of pulmonary fibrosis. If initial studies are promising, the Company can exercise certain rights to seek a full license to the compound for clinical development and commercialization. The parties will perform their respective obligations and provide reasonable support for research, clinical development and regulatory strategy. The collaboration agreement will be accounted for under ASC 808, Collaborative Agreements; however, no consideration will be exchanged between the parties. The Company will expense the costs incurred as cost of revenue — collaborations and services in the condensed consolidated statements of operations.

Biomm Supply and Distribution Agreement — In May 2017, the Company and Biomm entered into a supply and distribution agreement for the commercialization of Afrezza in Brazil. Under this agreement, Biomm was responsible for pursuing regulatory approvals of Afrezza in Brazil, including from the Agência Nacional de Vigilância Sanitária ("ANVISA") and, with respect to pricing matters, from the Camara de Regulação de Mercado de Medicamentos ("CMED"), both of which have now been received. Biomm commenced product sales in January 2020.

In September 2019, the Company delivered its first shipment of Afrezza to Biomm and recorded it as net revenue — commercial product sales for $0.7 million, in advance of the planned launch of the product in Brazil by Biomm. During the second quarter of

2020, the Company sold $0.2 million of product to Biomm. No additional shipments were made to Biomm in 2020 or the first nine months of 2021.

Cipla License and 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 an additional regulatory milestone payment, 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 milestone payments represent variable consideration for which the Company has not recognized any revenue because of the uncertainty of obtaining marketing approval. As of September 30, 2021, the deferred revenue balance was $1.7 million, of which $0.1 million is classified as current and $1.6 million is classified as long term in the condensed consolidated balance sheets.

AMSL Distribution Agreement — In May 2019, the Company entered into an exclusive marketing and distribution agreement with Australasian Medical & Scientific Ltd. ("AMSL") for the commercialization of Afrezza in Australia. Under the terms of this agreement, AMSL is responsible for obtaining regulatory and reimbursement approvals to distribute Afrezza in Australia. On August 1, 2021, Dexcom, Inc. acquired all of the outstanding shares of AMSL As a result, on November 4, 2021, the Company exercised its right under the marketing and distribution agreement to terminate such agreement on ten days' written notice.

8. 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.

The carrying amounts reported in the condensed consolidated financial statements for cash, accounts receivable, accounts payable, and accrued expenses and other current liabilities (excluding the Milestone Rights liability) approximate their fair value due to their relatively short maturities. The fair value of the cash equivalents, MidCap credit facility, Mann Group promissory notes, 2024 convertible notes, Senior convertible notes and Milestone Rights liabilities are disclosed below.

Cash Equivalents and Restricted Cash— Cash equivalents consist of highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase that are readily convertible into cash. As of September 30, 2021 and December 31, 2020, the Company held $51.7 million and $67.0 million, respectively, of cash and cash equivalents. As of December 31, 2020, the Company held $0.2 million in restricted cash, which was comprised of money market funds for the collateralization of a letter of credit. 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). There was no restricted cash as of September 30, 2021.

Investments — Investments consist of highly liquid investments that are intended to facilitate liquidity and capital preservation. The fair value of investments approximates their carrying value. The measurement of which is based on a market approach using quoted market values (Level 1 in the fair value hierarchy). As of September 30, 2021, the Company held $87.3 million of short-term investments and $42.1 million of long-term investments.

Financial Liabilities — The following tables set forth the fair value of the Company's financial instruments (Level 3 in the fair value hierarchy) (in millions):

	September 30, 2021		
	Carrying Value	Significant Unobservable Inputs (Level 3)	Fair Value
Financial liabilities:			
Senior convertible notes[1]	$ 223.6	$ 234.7	$ 234.7
MidCap credit facility[2]	38.7	39.6	39.6
Mann Group convertible notes[3]	18.4	38.1	38.1
Milestone rights[4]	5.9	19.9	19.9

(1) Fair value determined by applying a discounted cash flow analysis to the straight note with a hypothetical yield of 12%, volatility of 95% and a Monte Carlo simulation for the value of the conversion feature. A change in yield of + or – 2% would result in a fair value of $223.4 million and $247.1 million, respectively.

(2) Fair value determined by applying a discounted cash flow analysis with a hypothetical yield of 10%. A change in yield of + or – 2% would result in a fair value of $37.6 million and $41.7 million, respectively.

(3) The April 2021 amendment to the Mann Group convertible note resulted in a substantial premium of $22.1 million based on the fair value post modification which was recognized as additional paid-in capital in the condensed consolidated balance sheet as of September 30, 2021. The accounting for the $22.1 million loss on extinguishment did not result in a change in the financial position of the Company. The fair value assessed as of September 30, 2021 was determined by applying a discounted cash flow analysis with a hypothetical yield of 12% and volatility of 95% to the straight note and a binomial option pricing model for the value of the conversion feature. A change in yield of + or – 2% would result in a fair value of $37.1 million and $39.1 million, respectively.

(4) Fair value determined by applying a Monte Carlo simulation.

	December 31, 2020		
	Carrying Value	Significant Unobservable Inputs (Level 3)	Fair Value
Financial liabilities:[1]			
MidCap credit facility	$ 49.3	$ 55.4	$ 55.4
Mann Group promissory notes[2]	63.0	78.9	78.9
2024 convertible notes	5.0	7.0	7.0
PPP loan	4.9	4.7	4.7
Milestone rights	7.3	19.8	19.8

(1) Fair value measurements were based on a discounted cash flow model, except for the Milestone rights for which a Monte Carlo simulation was applied.

(2) Mann Group promissory notes consisted of the following carrying values and fair values:
Mann Group convertible notes carrying value of $28.0 million and fair value of $52.2 million.
Mann Group non-convertible notes carrying value of $35.1 million and fair value of $26.7 million.

Milestone Rights Liability — The fair value measurement of the Milestone Rights liability is sensitive to the discount rate and the timing of achievement of milestones. The Company utilized Monte-Carlo Simulation Method to simulate the Net Sales under a neutral framework to estimate the payment. The Company then discounted the future expected payments at cost of debt with a term equal to the simulated time to payout based on cumulative sales.

9. Common and Preferred Stock

The Company is authorized to issue 400,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.01 per share, issuable in one or more series as designated by the Company's board of directors. No other class of capital stock is authorized. As of September 30, 2021 and December 31, 2020, 250,245,831 and 242,117,089 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding.

In February 2018, the Company entered into a controlled equity offering sales agreement (the "CF Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), as sales agent, pursuant to which the Company may offer and sell, from time to time, through Cantor Fitzgerald, shares of the Company's 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. For the nine months ended September 30, 2021, the Company sold an aggregate of 578,063 shares of the Company's common stock at a weighted average purchase price of $3.26 per share for an aggregate gross proceeds of approximately $1.9 million pursuant to the Sales Agreement. For the nine months ended September 30, 2020, the Company sold an aggregate of 9,401,827 shares of the Company's common stock at a

weighted average purchase price of $1.66 per share for an aggregate gross proceeds of approximately $15.6 million pursuant to the CF Sales Agreement.

In the first quarter of 2021, Mann Group converted $0.4 million of interest and $9.6 million of principal into 4,000,000 shares of common stock in accordance with the terms of the Mann Group convertible note. See Note 6 – *Borrowings*.

In February 2021, the Company converted $5.0 million principal amount of 2024 convertible notes into 1,666,667 shares of the Company's common stock in accordance with the terms of the 2024 convertible notes. See Note 6 – *Borrowings*.

For the nine months ended September 30, 2021, the Company received $0.1 million from the market price stock purchase plan ("MPSPP") for 25,000 shares and a *de minimis* amount for the nine months ended September 30, 2020. There were no MPSPP transactions during the three months ended September 30, 2021 and 2020.

Subsequent to September 30, 2021, MidCap exercised all outstanding warrants to purchase 1,283,467 shares of the Company's common stock through a cashless exercise that resulted in the net issuance of 964,113 shares. See Note 6 – *Borrowings*.

10. Earnings per Common Share ("EPS")

Basic EPS excludes dilution for potentially dilutive securities and is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted EPS 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 EPS as they would be antidilutive.

The following tables summarize the components of the basic and diluted EPS computations (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
EPS — basic and diluted:				
Net loss (numerator)	$ (4,426)	$ (11,255)	$ (52,865)	$ (30,829)
Weighted average common shares (denominator)	249,910	229,668	248,624	218,559
Net loss per share	$ (0.02)	$ (0.05)	$ (0.21)	$ (0.14)

Common shares issuable represents incremental shares of common stock which consist of stock options, restricted stock units, warrants, and shares that could be issued upon conversion of the Senior convertible notes and the Mann Group convertible notes.

Potentially dilutive securities outstanding that are considered antidilutive are summarized as follows (in shares):

	Nine Months Ended September 30,	
	2021	2020
Senior convertible notes	44,120,463	—
Mann Group convertible notes	7,370,000	14,000,000
Warrants associated with MidCap credit facility	1,283,467	1,171,614
Common stock options and PNQs	10,910,655	12,689,522
RSUs and Market RSUs (1)	7,564,632	8,897,020
Employee stock purchase plan	84,544	107,003
2024 convertible notes	—	1,666,667
Common stock warrants	—	31,856
Total shares	71,333,761	38,563,682

(1) Market RSUs are included at the maximum share delivery percentage.

11. Stock-Based Compensation Expense

During the nine months ended September 30, 2021, the Company granted the following awards:

	Three Months Ended March 31, 2021		Three Months Ended June 30, 2021		Three Months Ended September 30, 2021		Nine Months Ended September 30, 2021
Employee awards:							
RSUs	370,137	(1)	1,476,059	(2)	80,370	(5)	1,926,566
Market RSUs	—		918,775	(3)	—		918,775
Non-employee director RSUs	—		316,232	(4)	—		316,232
Total awards	370,137		2,711,066		80,370		3,161,573

(1) RSUs had a weighted average grant date fair value of $5.53 per share, of which 202,237 RSUs had a vesting period of 1 year and 167,900 RSUs had a vesting period of four years.
(2) RSUs had a weighted average grant date fair value of $4.26 per share and a vesting period of 4 years.
(3) Market RSUs had a grant date fair value of $9.30 per share and will vest on May 17, 2024 provided the closing price of the Company's common stock on such vesting date is not less than the closing price on May 17, 2021. The number of shares delivered on the vesting date is determined by the percentile ranking of MannKind total shareholder return (TSR) over the period from May 18, 2021 until May 17, 2024 relative to the TSR of the Russell 3000 Pharmaceutical & Biotechnology Index over the same three-year period, as follows: less than 25th percentile=0% of target, 25th percentile=50% of target, 50th percentile=100% of target, 75th percentile=200% of target, 90th percentile or higher=300% maximum. Payout values will be interpolated between the percentile rankings above.
(4) RSUs had a weighted average grant date fair value of $4.31 per share and vested immediately upon grant, but the underlying shares of common stock will not be delivered until there is a separation of service, such as resignation, retirement or death.
(5) RSUs had a weighted average grant date fair value of $3.97 per share and a vesting period of 4 years.

As of September 30, 2021, there was $0.3 million of unrecognized stock-based compensation expense related to options and PNQs, which is expected to be recognized over a weighted average period of approximately 1.72 years, and $11.6 million and $11.2 million of unrecognized stock-based compensation expense related to RSUs and Market RSUs, respectively, which is expected to be recognized over a weighted average period of approximately 3.19 and 2.31 years, respectively.

Total stock-based compensation expense recognized in the condensed consolidated statements of operations for the three and nine months ended September 30, 2021 and 2020 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
RSUs and options	$ 2,983	$ 1,225	$ 8,628	$ 4,413
Employee stock purchase plan	196	69	412	194
Total stock compensation expense	$ 3,179	$ 1,294	$ 9,040	$ 4,607

Employee Stock Purchase Plan

The Company provides all employees, including executive officers, the ability to purchase common stock at a discount under the Company's 2004 employee stock purchase plan (the "ESPP"). The ESPP is designed to comply with Section 423 of the Internal Revenue Code and provides all employees with the opportunity to purchase up to $25,000 worth of common stock (based on the undiscounted fair market value at the commencement of the offering period) each year at a purchase price that is the lower of 85% of the fair market value of the common stock on either the date of purchase or the commencement of the offering period. An employee may not purchase more than 5,000 shares of common stock on any purchase date. The executives' rights under the ESPP are identical to those of all other employees.

The Company issued 527,049 and 626,818 shares of common stock pursuant to the ESPP for the nine months ended September 30, 2021 and 2020, respectively. There were approximately 1.1 million shares of common stock available for issuance under the ESPP as of September 30, 2021.

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 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, 2021, 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.

Contingencies — In July 2013, the Company entered into an agreement with the Milestone Purchasers, pursuant to which the Company granted the Milestone Rights to receive payments up to $90.0 million upon the occurrence of specified strategic and sales milestones, $65.0 million of which remains payable upon achievement of such milestones (see Note 6 – *Borrowings*). The fair value of the Milestone Rights is recorded in the condensed consolidated balance sheet, including $1.1 million in accrued expenses and other current liabilities and $4.8 million in milestone rights liability.

Commitments — In July 2014, the Company entered into the Insulin Supply Agreement with 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.

In May 2021, the Company and Amphastar amended the Insulin Supply Agreement to extend the term and restructure the annual purchase commitments. In connection with the amendment, the Company agreed to pay $2.0 million of amendment fees, which were recognized in cost of goods sold for the nine months ended September 30, 2021. The remaining purchase commitments as of September 30, 2021 and March 31, 2021 (pre-amendment) were as follows:

	September 30, 2021	March 31, 2021
2021	€ 0.8 million	€ 7.0 million
2022	€ 5.4 million	€ 8.5 million
2023	€ 8.8 million	€ 10.9 million
2024	€ 14.6 million	€ 14.6 million
2025	€ 15.5 million	€ 15.5 million
2026	€ 19.4 million	€ 19.4 million
2027	€ 9.2 million	€ —

Pursuant to the amendment, the term of the Insulin Supply Agreement expires on December 31, 2027, unless terminated earlier, 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 a 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 the latter 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.

Warrants – In August 2019, in connection with the MidCap credit facility, the Company issued warrants to purchase an aggregate of 1,171,614 shares of the Company's common stock, at an exercise price equal to $1.11 per share, to the lenders. On November 30, 2020, in connection with the third amendment to the MidCap credit facility, the Company issued warrants to purchase an aggregate of 111,853 shares of the Company's common stock, at an exercise price of $2.91 per share. Subsequent to September 30, 2021, MidCap exercised all outstanding warrants (see Note 6 – *Borrowings*).

Vehicle Leases – During the second quarter of 2018, the Company entered into a master lease agreement with Enterprise Fleet Management Inc. During the nine months ended September 30, 2021, 50 vehicles were retired and 37 of those vehicles were replaced, resulting in a fleet size of 76 vehicles. No gain or loss was recorded. The revised monthly payment inclusive of maintenance fees, insurance and taxes is approximately $0.1 million and the additional right of use asset and lease obligation is approximately $0.5 million in the consolidated balance sheets. The lease expense is included in selling, general and administrative expenses in the condensed consolidated statements of operations.

Office Leases — In May 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 Company agreed to pay initial monthly lease payments of $40,951, subject to 3% annual increases, plus the estimated cost of maintaining the property and common areas by the landlord, with a five-month concession from October 2017 through February 2018. The lease also provides for allowances for tenant alterations and maintenance. The lease expires in January 2023 and provides the Company with a five-year renewal option. The lease expense is included in selling, general and administrative expenses in the condensed consolidated statements of operations.

In November 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 commenced in October 2018. The Company agreed to pay initial monthly lease payments of $35,969, subject to a 3% annual increase, plus the estimated operating cost of maintaining the property by the landlord, which are allocable based an annual assessment made by the landlord. In addition, the Company received reimbursement from the landlord of $56,325 for tenant improvements and was not required to pay a first-year common area maintenance fee. The lease expires in January 2023 and provides the Company with a five-year renewal option.

Lease information is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease costs	$ 323	$ 350	$ 1,008	$ 1,053
Variable lease costs	128	116	359	296
Cash paid	451	466	1,367	1,349

	September 30, 2021	December 31, 2020
Weighted average remaining lease term (in years)	2.0	1.9
Weighted average discount rate	7.3%	7.5%

Future minimum office and vehicle lease payments as of September 30, 2021 and December 31, 2020, are as follows (in thousands):

	September 30, 2021	December 31, 2020
2021	$ 354	$ 1,494
2022	1,302	1,239
2023	266	88
2024	178	—
2025	119	—
Total	$ 2,219	$ 2,821

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. The Company's tax years since 2016 remain subject to examination by federal, state and foreign tax authorities.

14. Subsequent Event

Sale-Leaseback Transaction of our Manufacturing Facility —On November 8, 2021, the Company closed the Sale-Leaseback Transaction with a sales price of $102.3 million for the Property, which included the Company's manufacturing facility (commonly known as Building *1) consisting of approximately 263,900 square feet, but did not include the Company's adjacent research and development facility (commonly known as Building 8).*

Effective with the closing of the Sale-Leaseback Transaction, the Company and the Purchaser entered into a lease agreement (the "Lease"), pursuant to which the Company leased the Property from the Purchaser for an initial term of 20 years, with four renewal options of five years each. The total annual rent under the Lease starts at approximately $9.5 million per year, subject to a 50% rent abatement during the first year of the Lease, and will increase annually by (i) 2.5% in the second through fifth year of the Lease and (ii) 3% in the sixth and each subsequent year of the Lease, including any renewal term. The Company is responsible for payment of operating expenses, property taxes and insurance for the Property. The Purchaser will hold a security deposit of $2.0 million during the Lease term. Pursuant to the terms of the Lease, the Company has four options to repurchase the Property, in 2026, 2031, 2036 and 2041, for the greater of (i) $102.3 million and (ii) the fair market value of the Property.

Effective with the closing of the Sale-Leaseback Transaction, the Company and the Purchaser also entered into a right of first refusal agreement (the "ROFR"), pursuant to which the Company has a right to re-purchase the Property from the Purchaser in accordance with terms and conditions set forth in the ROFR. Specifically, if the Purchaser receives, and is willing to accept, a bona fide purchase offer for the Property from a third-party purchaser, the Company has certain rights of first refusal to purchase the Property on the same material terms as proposed in such bona fide purchase offer.

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. 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, 2020 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 endocrine and orphan lung diseases. Our lead product is Afrezza (insulin human) Inhalation Powder, an ultra rapid-acting inhaled insulin indicated to improve glycemic control in adults with diabetes, which was approved by the FDA in June 2014. Since September 2018, we have been collaborating with United Therapeutics to develop an inhaled formulation of treprostinil known as Tyvaso DPI. In April 2021, United Therapeutics submitted an NDA to the FDA seeking approval of Tyvaso DPI for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). In October 2021, the FDA issued a complete response letter to United Therapeutics pursuant to which the FDA declined to approve the NDA at this time, noting one deficiency related to an open inspection issue at a third-party analytical testing center for treprostinil. The complete response letter did not pertain to us, and no issues were cited by the FDA as it relates to our facility in Connecticut for manufacturing, testing and packaging of finished Tyvaso DPI, including its associated device. On October 18, 2021, UT stated that it believes that the single deficiency identified in the complete response will be resolved quickly and that Tyvaso DPI can receive approval by the summer of 2022, if not earlier.

Our business is subject to significant risks, including but not limited to our ability to commercialize Afrezza successfully, our ability to manufacture sufficient quantities of Afrezza and Tyvaso DPI and our potential need to raise additional capital to fund our operations. Other significant risks also include the risks inherent in drug development, clinical trials and the regulatory approval process for our product candidates, which in some cases depends upon the efforts of our partners.

We continue to manage the risk to our business posed by the global COVID-19 pandemic. Our sales representatives are conducting in-person sales calls to the extent permitted by state and local public health authorities and by the policies of individual healthcare providers that they interact with. Employees in California and Connecticut are mostly working in-person at our facilities in these states, although some remote work arrangements are still in place. Although our productivity has been impacted by the global pandemic and we may face challenges or disruptions as employees return back to the workplace, including re-integration challenges by our employees and distractions to management related to such transition, we have suitably adapted to the changed business environment that now exists.

The impact of the COVID-19 pandemic continues to be uncertain. We do not yet know the full extent of potential delays or impacts on our business, our collaboration arrangements, commercialization efforts, healthcare systems or to the global economy as a whole. The COVID-19 pandemic has the potential to have additional adverse impacts on our operations. We will continue to monitor the COVID-19 situation closely.

As of September 30, 2021, we had an accumulated deficit of $3.1 billion and a stockholders' deficit of $184.7 million. Our net loss was $4.4 million and $52.9 million for the three and nine months ended September 30, 2021, respectively. To date, we have funded our operations through the sale of convertible debt securities and equity, from the receipt of upfront and milestone payments from certain collaborations, from borrowings, from sales of Afrezza and, most recently, from the proceeds of the Sale-Leaseback Transaction. See Note 14 — *Subsequent Event.*

CRITICAL ACCOUNTING POLICIES

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, 2020. 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

Three and nine months ended September 30, 2021 and 2020

Revenues

The following tables provide a comparison of the revenue categories for the three and nine months ended September 30, 2021 and 2020 (dollars in thousands):

	Three Months Ended September 30,			
	2021	2020	$ Change	% Change
Net revenue — commercial product sales:				
Gross revenue from commercial product sales	$ 16,335	$ 12,393	$ 3,942	32%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(6,582)	(5,118)	$ 1,464	29%
Net revenue — commercial product sales	9,753	7,275	$ 2,478	34%
Revenue — collaborations and services	12,458	8,077	$ 4,381	54%
Total revenues	$ 22,211	$ 15,352	$ 6,859	45%

	Nine Months Ended September 30,			
	2021	2020	$ Change	% Change
Net revenue — commercial product sales:				
Gross revenue from commercial product sales	$ 46,520	$ 38,225	$ 8,295	22%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(18,692)	(15,965)	$ 2,727	17%
Net revenue — commercial product sales	27,828	22,260	$ 5,568	25%
Revenue — collaborations and services	35,099	24,441	$ 10,658	44%
Total revenues	$ 62,927	$ 46,701	$ 16,226	35%

Gross revenue from sales of Afrezza increased by $3.9 million, or 32%, for the three months ended September 30, 2021 compared to the same period in the prior year. The increase reflects higher product demand and price. The gross-to-net adjustment was 40.3% of gross revenue, or $6.6 million, for the three months ended September 30, 2021, compared to 41.3% of gross revenue, or $5.1 million, for the same period in the prior year. The decrease in the gross-to-net percentage was primarily driven by a decrease in wholesaler distribution fees (as a percentage of gross sales) as a result of the termination of our free goods program on December 31, 2020 and a decrease in product returns, partially offset by an increase in co-pay assistance. As a result, net revenue from sales of Afrezza increased by $2.5 million, or 34%, for the three months ended September 30, 2021 compared to the prior year period.

Net revenue from collaborations and services increased by $4.4 million, or 54%, for the three months ended September 30, 2021 compared to the same period in the prior year. The increase in collaborations and services revenue was primarily attributed to additional development work associated with our collaboration with UT and the change in the estimated completion date related to the amortization of deferred revenue for R&D Services. In August 2021, we entered into a commercial supply agreement with UT (the “CSA”). Revenue associated with the CSA is deferred until Tyvaso DPI is approved by the FDA for commercialization. See Note 7 – *Collaboration, Licensing and Other Arrangements*.

Gross revenue from sales of Afrezza increased by $8.3 million, or 22%, for the nine months ended September 30, 2021 compared to the same period in the prior year. The increase reflects higher product demand as a result of increased promotional activity in addition to the negative impact the COVID-19 pandemic had on the demand of Afrezza prescriptions in 2020, a more favorable mix of Afrezza cartridges and price. The gross-to-net adjustment was 40.2% of gross revenue, or $18.7 million, for the nine months ended September 30, 2021, compared to 41.8% of gross revenue, or $16.0 million, for the same period in the prior year. The decrease in the gross-to-net percentage was primarily driven by a decrease in wholesaler distribution fees and rebates as a result of the termination of our free goods program on December 31, 2020, partially offset by an increase in co-pay assistance. As a result, net revenue from sales of Afrezza increased by $5.6 million, or 25%, for the nine months ended September 30, 2021 compared to the prior year period.

Net revenue from collaborations and services increased by $10.7 million, or 44%, for the nine months ended September 30, 2021 compared to the same period in the prior year. The increase in collaborations and services revenue was primarily attributed to additional development work associated with our collaboration with UT and the change in the estimated completion date related to the amortization of deferred revenue for R&D Services. In August 2021, we entered into the CSA with UT. Revenue associated with the CSA is deferred until Tyvaso DPI is approved by the FDA for commercialization. See Note 7 – *Collaboration, Licensing and Other Arrangements*.

Commercial product gross profit

The following tables provide a comparison of the commercial product gross profit categories for the three and nine months ended September 30, 2021 and 2020 (dollars in thousands):

	Three Months Ended September 30,			
	2021	2020	$ Change	% Change
Commercial product gross profit:				
Net revenue — commercial product sales	$ 9,753	$ 7,275	$ 2,478	34%
Less: cost of goods sold	3,812	3,591	$ 221	6%
Commercial product gross profit	$ 5,941	$ 3,684	$ 2,257	61%
Gross margin	61%	51%		

	Nine Months Ended September 30,			
	2021	2020	$ Change	% Change
Commercial product gross profit:				
Net revenue — commercial product sales	$ 27,828	$ 22,260	$ 5,568	25%
Less: cost of goods sold	12,538	11,432	$ 1,106	10%
Commercial product gross profit	$ 15,290	$ 10,828	$ 4,462	41%
Gross margin	55%	49%		
Non-GAAP gross margin(1)	62%	49%		

(1) See the reconciliation of gross margin to non-GAAP gross margin under Non-GAAP Measures below.

Commercial product gross profit for the three months ended September 30, 2021 increased by $2.3 million, or 61%, compared to the same period in the prior year. Gross margin for the three months ended September 30, 2021 was 61% compared to 51% for the same period in the prior year. The increase in gross profit and gross margin was attributable to an increase in Afrezza sales partially offset by an increase in cost of goods sold. Cost of goods sold increased by $0.2 million, or 6%, for the three months ended September 30, 2021 compared to the same period in the prior year. The increase in cost of goods sold was primarily attributable to a decrease in manufacturing activities, which resulted in a lower amount of costs capitalized to inventory, partially offset by a decrease in manufacturing-related spending.

Commercial product gross profit for the nine months ended September 30, 2021 increased by $4.5 million, or 41%, compared to the same period in the prior year. Gross margin for the nine months ended September 30, 2021 was 55% compared to 49% for the same period in the prior year. The increase in gross profit and gross margin was attributable to an increase in Afrezza sales, partially offset by an increase in cost of goods sold. Cost of goods sold increased by $1.1 million, or 10%, for the nine months ended September 30, 2021 compared to the same period in the prior year, primarily due to a $2.0 million fee for the amendment of the Insulin Supply Agreement and a $1.1 million decrease in manufacturing activities, which resulted in a lower amount of costs capitalized to inventory, partially offset by $0.9 million of costs associated with lower cost per unit and the termination of the free goods program in December 31, 2020. On a non-GAAP basis, which excludes the $2.0 million insulin supply amendment fee, gross margin was 62% for the nine months ended September 30, 2021 compared to 49% for the same period in 2020. See the reconciliation to non-GAAP net loss and EPS under Non-GAAP Measures below.

Expenses

The following tables provide a comparison of the expense categories for the three and nine months ended September 30, 2021 and 2020 (dollars in thousands):

	Three Months Ended September 30,			
	2021	2020	$ Change	% Change
Expenses:				
Cost of goods sold	$ 3,812	$ 3,591	$ 221	6%
Cost of revenue — collaborations and services	6,075	1,581	$ 4,494	284%
Research and development	3,655	1,484	$ 2,171	146%
Selling	10,839	8,270	$ 2,569	31%
General and administrative	6,382	5,629	$ 753	13%
Asset impairment	106	—	$ 106	*
(Gain) loss on foreign currency translation	(2,068)	3,927	$ (5,995)	*
Total expenses	$ 28,801	$ 24,482	$ 4,319	18%

	Nine Months Ended September 30,			
	2021	2020	$ Change	% Change
Expenses:				
Cost of goods sold	$ 12,538	$ 11,432	$ 1,106	10%
Cost of revenue — collaborations and services	14,885	6,926	$ 7,959	115%
Research and development	8,426	4,703	$ 3,723	79%
Selling	31,992	23,687	$ 8,305	35%
General and administrative	22,698	18,232	$ 4,466	24%
Asset impairment	106	1,889	$ (1,783)	(94%)
(Gain) loss on foreign currency translation	(5,003)	3,998	$ (9,001)	*
Loss on purchase commitments	339	—	$ 339	*
Total expenses	$ 85,981	$ 70,867	$ 15,114	21%

* Not meaningful

Cost of revenue — collaborations and services increased by $4.5 million, or 284%, for the three months ended September 30, 2021 and $8.0 million, or 115%, for the nine months ended September 30, 2021 compared to the respective periods in the prior year. The increases were attributable to an increase in costs for the UT License agreement, specifically an increase in manufacturing activities in preparation for supplying commercial product to UT, and the allocation of selling expenses related to the Vertice Pharma Co-Promotion Agreement.

Research and development expenses increased by $2.2 million, or 146%, for the three months ended September 30, 2021 compared to the same period in the prior year. The increase was primarily attributable to costs incurred for research activities in our product pipeline and to the initiation of the Afrezza pediatrics clinical study (INHALE-1).

Research and development expenses increased by $3.7 million, or 79%, for the nine months ended September 30, 2021 compared to the same period in the prior year. The increase was primarily attributable to costs incurred for the research activities in our product pipeline and to the initiation of the INHALE-1 study, as well as personnel costs associated with additional headcount.

Selling expenses increased by $2.6 million, or 31%, for the three months ended September 30, 2021 compared to the same period in the prior year. The increase was primarily attributable to promotional expenses and patient support services of $2.0 million as well as personnel-related expenses of $1.5 million, which was driven by increased stock-based compensation and additional headcount to support Afrezza growth. The increases in selling expenses were partially offset by a reduction related to the co-promotional cost for Thyquidity which was recognized as cost of revenue — collaboration and services.

Selling expenses increased by $8.3 million, or 35%, for the nine months ended September 30, 2021 compared to the same period in the prior year. The increase was primarily attributable to promotional expenses and patient support services of $5.8 million and personnel-related expenses of $4.8 million, which reflected increased stock-based compensation, additional headcount to support Afrezza growth and our voluntary reduction in compensation in response to the COVID-19 pandemic in the prior year. The increases in selling expenses were partially offset by a reduction related to the co-promotional cost for Thyquidity which was recognized as cost of revenue — collaboration and services.

General and administrative expenses increased by $0.8 million, or 13%, for the three months ended September 30, 2021 compared to the same period in the prior year. This increase was primarily attributable to increased stock-based compensation.

General and administrative expenses increased by $4.5 million, or 24%, for the nine months ended September 30, 2021 compared to the same period in the prior year. This increase was primarily attributable to increased stock-based compensation and our voluntary reduction in compensation expense in response to the COVID-19 pandemic in the prior year. Additional increases consisted of professional fees and business development expenses.

An impairment of $0.1 million was recognized for the three and nine months ended September 30, 2021 for the contract asset associated with variable consideration for gross profits for sales of Thyquidity under Vertice Pharma's co-promotion agreement. See Note 7 – *Collaboration, Licensing and Other Arrangements.* An impairment of $1.9 million was recognized for the nine months ended September 30, 2020 for a commitment asset related to the future funding commitments of the MidCap credit facility. There were no asset impairments for the three months ended September 30, 2020.

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 gain or loss on purchase commitments. The foreign currency translation gain was $2.1 million for the three months ended September 30, 2021 compared to a $3.9 million loss for the same period in the prior year. The foreign currency translation gain was $5.0 million for the nine months ended September 30, 2021 compared to a $4.0 million loss for the same period in the prior year.

Other Income (Expense)

The following tables provide a comparison of the other income (expense) categories for the three and nine months ended September 30, 2021 and 2020 (dollars in thousands):

	Three Months Ended September 30,			
	2021	2020	$ Change	% Change
Interest income	$ 36	$ 18	$ 18	100%
Interest expense on notes	(2,709)	(1,057)	$ 1,652	156%
Interest expense on Mann Group promissory notes	(94)	(1,318)	$ (1,224)	(93%)
Gain on extinguishment of debt	4,930	—	$ 4,930	*
Other income	1	14	$ (13)	(93%)
Total other expense	$ 2,164	$ (2,343)	$ (4,507)	*

	Nine Months Ended September 30,			
	2021	2020	$ Change	% Change
Interest income	$ 64	$ 165	$ (101)	(61%)
Interest expense on notes	(10,943)	(3,212)	$ 7,731	241%
Interest expense on Mann Group promissory notes	(1,492)	(3,858)	$ (2,366)	(61%)
Loss on extinguishment of debt, net	(17,200)	—	$ 17,200	*
Other (expense) income	(240)	24	$ (264)	*
Total other expense	$ (29,811)	$ (6,881)	$ 22,930	333%

* Not meaningful

Interest expense on notes increased by $1.7 million, or 156%, for the three months ended September 30, 2021 compared to the same period in the prior year. The increase was primarily due to the interest expense from the Senior convertible notes issued in the first quarter of 2021. Interest expense on notes increased by $7.7 million, or 241%, for the nine months ended September 30, 2021 compared to the same period in the prior year. The increase was primarily due to a $3.7 million milestone obligation that was achieved during the first quarter of 2021 and interest expense on the Senior convertible notes.

Interest expense on Mann Group promissory notes decreased by $1.2 million, or 93%, for the three months ended September 30, 2021 and $2.4 million, or 61%, for the nine months ended September 30, 2021 compared to the same periods in the prior year. The decrease was primarily due to the repayment of $35.1 million of outstanding principal under the Mann Group non-convertible note, the $10.0 million repayment of principal and interest on the Mann Group convertible note and the reduction of the interest rate from 7.00% to 2.50% pursuant to the first amendment on the remaining promissory note. See Note 6 — *Borrowings*.

Gain on extinguishment of debt of $4.9 million for the three months ended September 30, 2021 consisted of the principal amount and related accrued and unpaid interest for our PPP loan, which was forgiven by the SBA in July 2021. Loss on extinguishment of debt, net of $17.2 million for the nine months ended September 30, 2021 consisted of $22.1 million loss on extinguishment of debt for the amendment to the Mann Group convertible note, which did not result in a change in our financial position, partially offset by a $4.9 million gain on extinguishment of debt as a result of the SBA's forgiveness of the PPP loan. See Note 6 — *Borrowings*.

Other expense or income for the nine months ended September 30, 2021 consisted primarily of the loss associated with a foreign currency hedging transaction which was entered into to mitigate our exposure to foreign currency exchange risks associated with our insulin purchase obligation in 2021 under the Insulin Supply Agreement. There were no hedging transaction for the three months ended September 30, 2021 and 2020 or the nine months ended September 30, 2020.

Net Loss and Earnings Per Share ("EPS")

The net loss for the three months ended September 30, 2021 was $4.4 million, or $0.02 per share, compared to a $11.3 million net loss in the same period in the prior year, or $0.05 per share. The decreased net loss of $6.8 million was primarily due to an increase in

Afrezza net revenues and revenues from collaboration and services as well as a non-cash gain on extinguishment of the PPP loan of $4.9 million, partially offset by an increase of cost of revenue from collaboration and services and SG&A expenses.

The net loss for the nine months ended September 30, 2021 was $52.9 million, or $0.21 per share, compared to a $30.8 million net loss in the nine months ended September 30, 2020, or $0.14 per share. The increased net loss of $22.0 million was primarily due to the non-cash loss on extinguishment of the Mann Group convertible note of $22.1 million net of a non-cash gain on extinguishment of the PPP loan of $4.9 million, as well as an increase in SG&A expenses, cost of revenue – collaboration and services, partially offset by an increase in Afrezza net revenues and revenues from collaboration and services.

Non-GAAP net loss, adjusted to exclude the $4.9 million non-cash gain on extinguishment of the PPP loan was $9.4 million, or $0.04 per share, for the three months ended September 30, 2021 compared to $11.3 million, or $0.05 per share, for the same period in the prior year. Non-GAAP net loss, adjusted to exclude $17.2 million net loss on extinguishment of debt, net, which consisted of the $22.1 million non-cash loss on extinguishment of the Mann Group convertible note partially offset by the $4.9 million gain on extinguishment of the PPP loan, in addition to the Amphastar amendment fee of $2.0 million was $33.7 million or $0.14 per share, for the nine months ended September 30, 2021 compared to $30.8 million, or $0.14 per share, for the same period in the prior year. See the reconciliation to non-GAAP net loss and EPS under Non-GAAP Measures below.

Non-GAAP Measures

To supplement our unaudited condensed consolidated financial statements presented under GAAP, we are presenting certain non-GAAP financial measures. We are providing these non-GAAP financial measures to disclose additional information to facilitate the comparison of past and present operations, and they are among the indicators management uses as a basis for evaluating our financial performance. We believe that these non-GAAP financial measures, when considered together with our GAAP financial results, provide management and investors with an additional understanding of our business operating results, including underlying trends.

These non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with our unaudited condensed consolidated financial statements prepared in accordance with GAAP; have no standardized meaning prescribed by GAAP; and are not prepared under any comprehensive set of accounting rules or principles. In addition, from time to time in the future there may be other items that we may exclude for purposes of our non-GAAP financial measures; and we may in the future cease to exclude items that we have historically excluded for purposes of our non-GAAP financial measures. Likewise, we may determine to modify the nature of its adjustments to arrive at our non-GAAP financial measures. Because of the non-standardized definitions of non-GAAP financial measures, the non-GAAP financial measures as used by us in this Quarterly Report on Form 10-Q have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

The following tables reconcile our financial measure for net loss and EPS as reported in our condensed consolidated statement of operations to a non-GAAP presentation as adjusted for the $4.9 million non-cash gain on extinguishment of the PPP loan for the three months ended September 30, 2021 and the $22.1 million non-cash loss on extinguishment of the Mann Group convertible note net of the $4.9 million gain on extinguishment of the PPP loan for the nine months ended September 30, 2021, which did not result in a change in our financial position, as well as the $2.0 million Amphastar amendment fee.

	Three Months Ended September 30,			
(In thousands, except per share data)	**2021**	**2020**	**$ Change**	**% Change**
GAAP to Non-GAAP Net Loss and EPS				
Net loss	$ (4,426)	$ (11,255)	$ (6,829)	(61%)
Net loss per share - basic and diluted	$ (0.02)	$ (0.05)	$ (0.03)	(60%)
Less non-cash gain on extinguishment of debt(1)	(4,930)	—	$ (4,930)	*
Non-GAAP net loss	$ (9,356)	$ (11,255)	$ (1,899)	(17%)
Non-GAAP net loss per share - basic and diluted	$ (0.04)	$ (0.05)	$ (0.01)	(20%)
Shares used to compute non-GAAP net loss per share - basic and diluted	249,910	229,668	20,242	9%

	Nine Months Ended September 30,			
	2021	2020	$ Change	% Change
GAAP to Non-GAAP Net Loss and EPS				
Net loss	$ (52,865)	$ (30,829)	$ 22,036	71%
Net loss per share - basic and diluted	$ (0.21)	$ (0.14)	$ 0.07	50%
Less non-cash loss on extinguishment of debt, net(1)	17,200	—	$ 17,200	*
Less Amphastar amendment fee(1)	2,000	—	$ 2,000	*
Non-GAAP net loss	$ (33,665)	$ (30,829)	$ 2,836	9%
Non-GAAP net loss per share - basic and diluted	$ (0.14)	$ (0.14)	$ —	0%
Shares used to compute non-GAAP net loss per share - basic and diluted	248,624	218,559	30,065	14%

* Not meaningful

(1) There is no impact for income taxes associated with the non-cash loss on extinguishment of debt, net or the Amphastar amendment fee as a result of our full valuation allowance.

The following table reconciles our gross margin financial measure as reported in Management's Discussion and Analysis of Financial Condition and Results of Operations to a non-GAAP presentation as adjusted for the nonrecurring amendment fee related to an amendment to our Insulin Supply Agreement in May 2021.

	Nine Months Ended September 30,			
	2021	2020	$ Change	% Change
Net revenue — Afrezza	$ 27,828	$ 22,260	$ 5,568	25%
Less cost of goods sold	(12,538)	(11,432)	$ 1,106	10%
GAAP gross profit — Afrezza	15,290	10,828	$ 4,462	41%
Exclude Amphastar amendment fee	2,000	—	$ 2,000	*
Non-GAAP gross profit — Afrezza	$ 17,290	$ 10,828	$ 6,462	60%
Non-GAAP gross margin	62%	49%		

* Not meaningful

LIQUIDITY AND CAPITAL RESOURCES

To date, we have funded our operations through the sale of equity and convertible debt securities, from the receipt of upfront and milestone payments from certain collaborations, from borrowings and from sales of Afrezza.

As of September 30, 2021, we had $288.4 million principal amount of outstanding debt, consisting of:

- $230.0 million aggregate principal amount of Senior convertible notes bearing interest at 2.50% payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2021 and will mature on March 1, 2026, unless earlier converted, redeemed or repurchased. The Senior convertible notes are convertible at an initial conversion price of approximately $5.21 per share of Common Stock. The conversion rate is subject to adjustment under certain circumstances in accordance with the terms of the Indenture.
- $40.0 million principal amount under the MidCap credit facility, bearing interest at an annual rate equal to one-month LIBOR plus 6.25%, subject to a one-month LIBOR floor of 1.00%, payable in equal monthly installments beginning in September 2023 through maturity in August 2025.
- $18.4 million principal amount of indebtedness under the Mann Group convertible note bearing interest at a fixed rate of 2.50% per annum compounded quarterly and maturing in December 2025, which is convertible into shares of our common stock at the option of Mann Group at a conversion price of $2.50 per share. Interest is paid-in-kind from August 2019 until the end of 2020, after which we have the option to pay interest in-kind or in shares.

In February 2021, we elected to convert the $5.0 million principal amount of 2024 convertible notes into 1,666,667 shares of our common stock in accordance with the terms of the 2024 convertible notes. There can be no assurance that we will have sufficient resources to make any required repayments of principal under the Senior convertible notes, the MidCap credit facility or the Mann Group convertible note. The Senior convertible notes and Mann Group convertible note are fully convertible prior to maturity as further disclosed in Note 6 – *Borrowings*.

To date, we have been able to timely make our required interest payments, but we cannot guarantee that we will be able to do so in the future. If we fail to repurchase the Mann Group promissory notes, 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 noteholders initiating bankruptcy proceedings or causing us to cease operations altogether.

In July 2013, we issued Milestone Rights to the Milestone Purchasers. The Milestone Rights provide the Milestone Purchasers certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones, $65.0 million of which remains payable upon achievement of such milestones. See Note 12 – *Commitments and Contingencies* and Note 6 – *Borrowings* for further information related to the Milestone Rights.

During the nine months ended September 30, 2021, we used $49.4 million of cash for our operating activities, which primarily consisted of $47.7 million of selling, general and administrative expenses, $25.5 million of cost of goods sold, $7.7 million of costs for research and development and $5.6 million of cash paid for interest, partially offset by $37.6 million of revenue.

During the nine months ended September 30, 2020, we used $28.4 million of cash for our operating activities as a result of our net loss of $30.8 million, in addition to a net cash outflow from changes in balances of operating assets and liabilities of $14.9 million, partially offset by non-cash charges of $17.4 million. The change in operating asset and liabilities was primarily a result of deferred revenue amortization of $24.4 million, partially offset by a milestone payment from UT of $12.5 million.

Cash used in investing activities of $139.0 million for the nine months ended September 30, 2021 was primarily due to the purchase of $238.4 million of debt securities and $6.3 million purchase of property and equipment, partially offset by the sale of $105.7 million of debt securities.

Cash provided by investing activities of $19.7 million for the nine months ended September 30, 2020 was primarily due to the proceeds from the sale of treasury bills.

Cash provided by financing activities of $172.9 million for the nine months ended September 30, 2021 was primarily due to net proceeds from the offering of Senior convertible notes of $222.7 million, partially offset by the repayment of $35.1 million of Mann Group non-convertible notes and related unpaid accrued interest and the repayment of $10.0 million of principal and $1.0 million prepayment penalty for the MidCap credit facility.

Cash provided by financing activities of $31.2 million for the nine months ended September 30, 2020 was primarily due to the receipt of $15.1 million in gross proceeds from at the market offerings for an aggregate of 9,401,827 shares of our common stock under the CF Sales Agreement, the exercise of outstanding warrants to purchase shares of our common stock of $11.6 million, and proceeds from the PPP Loan of $4.9 million.

Future Liquidity Needs

We are not currently profitable and have rarely generated positive net cash flow from operations. In addition, we expect to continue to incur significant expenditures for the foreseeable future in support of our manufacturing operations, sales and marketing costs for Afrezza, and development costs for other product candidates in our pipeline. As of September 30, 2021, we had capital resources of $51.7 million in cash and cash equivalents, $87.3 million in short-term investments and $42.1 million in long-term investments, and total principal amount of outstanding borrowings of $288.4 million.

In March 2021, we issued $230.0 million of Senior convertible notes. In April 2021, we made a $10.0 million principal prepayment against outstanding term loans under the MidCap credit facility and repaid the entire principal amount of $35.1 million outstanding under the Mann Group non-convertible note (together with all accrued and unpaid interest thereon) as further disclosed in Note 6 – *Borrowings*. As amended, the MidCap credit facility provides a secured term loan facility with an aggregate principal amount of up to $100.0 million, of which $60.0 million remains available for borrowing if the conditions for Tranche 3 are met. In November 2021, we closed the Sale-Leaseback Transaction for a sales price of $102.3 million. See Note 14 — *Subsequent Event*.

We believe our resources will be sufficient to fund our operations for the next twelve months from the date of issuance of our condensed consolidated financial statements included in Part I – Financial Statements (Unaudited).

Off-Balance Sheet Arrangements

As of September 30, 2021 and December 31, 2020, we did not have any off-balance sheet arrangements.

Contractual Obligations

See Note 6 – *Borrowings*, Note 12 – *Commitments and Contingencies* and Note 14 – *Subsequent Event* for a discussion of material changes outside of the ordinary course of business in our contractual obligations from those disclosed within "Management's Discussion and Analysis of Financial Condition and Results of Operations," as contained in the Annual Report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Interest on borrowings under the MidCap credit facility accrues interest at an annual rate equal to the lesser of (i) 8.25% and (ii) the one-month LIBOR (subject to a one-month LIBOR floor of 1.00%) plus 6.25%. Accordingly, our interest expense under the MidCap credit facility is subject to changes in the one-month LIBOR rate. All other debt has fixed interest rates, so the interest expense associated with such debt is not exposed to changes in market interest rates. Specifically, the interest rate on amounts borrowed under the Mann Group promissory notes is fixed at 2.50% and the interest rate under the Senior convertible notes is fixed at 2.50%. See Note 6 – *Borrowings* for information about the principal amount of outstanding debt.

Foreign Currency Exchange Risk

In April 2021, we entered into 90-day foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks associated with our insulin purchase obligation under the Insulin Supply Agreement. The hedging transaction hedges against short-term currency fluctuations for the remaining current year purchase obligation under the Insulin Supply Agreement of €0.8 million. We realized a *de minimis* currency gain during the three months ended June 30, 2021. This amount is recorded in other income and expense.

We incur and will continue to incur significant expenditures for insulin supply obligations under our Insulin Supply Agreement with Amphastar. Such obligations are denominated in Euros. At the end of each reporting period, the recognized gain or 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 the Euro. For the three months ended September 30, 2021, we realized a $2.1 million currency gain, which was included in loss (gain) on foreign currency translation in the condensed consolidated statements of operations. 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, 2021 were to have occurred, this change would have resulted in a foreign currency impact to our pre-tax loss of approximately $8.5 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 (the “Exchange Act”), as of September 30, 2021. 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, 2021, our Chief Executive Officer and our Chief Financial Officer 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

We are subject to legal proceedings and claims that 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*

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission before making investment decisions regarding our common stock.

Summary Risk Factors

We face risks and uncertainties related to our business, many of which are beyond our control. In particular, risks associated with our business include:

RISKS RELATED TO OUR BUSINESS

- Our only approved product, Afrezza, may only achieve a limited degree of commercial success. The continued commercialization and development of Afrezza will require substantial capital that we may not be able to obtain.
- If we fail as an effective manufacturing organization, we may be unable to support commercialization of Afrezza or Tyvaso DPI.
- We may need to raise additional capital to fund our operations.
- 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 business, product sales, results of operations and ability to access capital could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic, in regions where we or third parties distribute our products or where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.
- If we do not obtain regulatory approval of Afrezza in foreign jurisdictions, we will not be able to market Afrezza in such jurisdictions, which could limit our commercial revenues. We may not be able to establish additional regional partnerships or other arrangements with third parties for the commercialization of Afrezza outside of the United States.
- We may not be successful in our efforts to develop and commercialize our product candidates.
- 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.
- We have a substantial amount of debt, and we may be unable to make required payments of interest and principal as they become due.
- 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.
- Afrezza or our product candidates may be rendered obsolete by rapid technological change.
- 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.
- If our suppliers fail to deliver materials and services needed for commercial manufacturing 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.
- If Afrezza or any other product that we develop does not become widely accepted by physicians, patients, third-party payers and the healthcare community, we may be unable to generate significant revenue, if any.
- If third-party payers 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.

- 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.
- We are increasingly dependent on information technology systems, and infrastructure, which are vulnerable to service interruptions, data breaches, and other similar incidents and attacks.

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.
- 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.
- We are subject to stringent, ongoing government regulation.
- If we or any future partner fails to comply with federal and state healthcare or privacy and data security laws, including fraud and abuse and health information laws and other laws governing the processing of personal data, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

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

GENERAL RISK FACTORS

- 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.

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 contains 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.

Risk Factors

RISKS RELATED TO OUR BUSINESS

Our only approved product, Afrezza, may only achieve a limited degree of commercial success. 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 commercialization and development of Afrezza, which has been on the market since February 2015. To date, Afrezza sales have been modest by comparison to other mealtime insulins. If we remain on the existing growth curve, we may never generate significant revenues from Afrezza in the United States.

Successful commercialization of Afrezza is subject to many risks, including some that are outside our control. There are numerous examples of failures to fully exploit the market potential of drug products, including by pharmaceutical companies with more experience and resources than us. We ultimately may be unable to gain widespread market acceptance of Afrezza for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, pricing and availability relative to alternative products and lack of coverage or adequate reimbursement by payers. We may need to enhance 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 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 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 payer coverage of, and adequate reimbursement 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.

As part of the approval of Afrezza, the FDA required us to conduct certain additional clinical studies of Afrezza. These studies will require significant capital resources, some of which may not be available to us. We have to initiated one of these studies, a Phase 3 clinical trial to evaluate the safety and efficacy of Afrezza in 4-17 year-old children and adolescents. We have engaged a clinical research organization to assist us with conducting this study and have budgeted the projected costs of the study in our operating plans. The other required study is a long-term safety study that was originally intended to compare the incidence of pulmonary malignancy observed with Afrezza to that observed in a standard of care control group. We have an ongoing dialogue with the FDA regarding the agency’s current interest in the long-term safety of Afrezza and an appropriate study design to address any concerns. To date, we have not commenced a long-term safety study or budgeted any amount for it, but such a study in its original design would be anticipated to require substantial capital resources that we may not be able to obtain.

We are responsible for the NDA for Afrezza and its maintenance. We 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.

If we fail to achieve better commercial success with Afrezza in the United States, our prospects for generating significant revenues from this product will be materially and adversely affected.

If we fail as an effective manufacturing organization, we may be unable to support commercialization of Afrezza or Tyvaso DPI.*

We use our Danbury, Connecticut facility to formulate both the Afrezza and Tyvaso DPI inhalation powders, fill plastic cartridges with the powders, package the cartridges in blister packs, and place the blister packs into foil pouches. A contract packager assembles the foil-pouched blister packs along with inhalers and package inserts into the final kits for commercial sale.

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 production to commercial batch sizes, which is the stage of production that we have now reached with Tyvaso DPI. These problems include difficulties with production costs and yields and quality control and assurance. We may experience shortages of qualified personnel, which could impact our ability to meet production schedules. There is also a need to comply with strictly enforced federal, state and foreign regulations, including inspections. Our facility is inspected on a regular basis by the FDA, most recently in July 2021 when the FDA conducted a pre-approval inspection related to Tyvaso DPI and a GMP inspection related to Afrezza. The FDA made one observation during its most recent inspection, which we corrected and addressed with the FDA following the site visit. If the FDA makes any major observations during future inspections, the corrective actions required could be onerous and time-consuming.

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 drug products 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 such drug products and we would lose potential revenues.

In addition, in October 2021, the FDA issued a complete response letter to United Therapeutics pursuant to which the FDA declined to approve the NDA for the approval of Tyvaso DPI for the treatment of PAH and PH-ILD at this time, noting only one deficiency related to an open inspection issue at a third-party analytical testing center for treprostinil. In light of these developments, it is currently unclear when, or whether, approval of Tyvaso DPI in PAH and PH-ILD can be obtained.

We may need to raise additional capital to fund our operations.*

As of September 30, 2021, we had cash and cash equivalents of $51.7 million, short-term investments of $87.3 million and long-term investments of $42.1 million, and we had $288.4 million principal amount of outstanding debt. Although we subsequently closed the Sale-Leaseback Transaction for a sales price of $102.3 million, we may need to raise additional capital, whether through the sale of equity or debt securities, additional strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to support our ongoing activities, including the commercialization of Afrezza and the development of our product candidates. It may be difficult for us to raise additional funds on favorable terms, or at all. The extent of our additional funding requirements will depend on a number of factors, including:

- the degree to which revenue from Afrezza exceeds or does not exceed the minimum revenue covenants under the MidCap credit facility, if applicable;
- the degree to which we are able to generate revenue from our Technosphere drug delivery platform, including through our collaborations;
- the costs of developing and commercializing Afrezza on our own in the United States, including the costs of expanding our commercialization capabilities;
- 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 facility;
- our obligation to make lease payments and milestone payments;
- our success in establishing additional 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, Tyvaso DPI 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. In addition, the COVID-19 pandemic continues to have the potential for disruption of global financial markets. This disruption, if sustained or recurrent, could prevent us or make it more difficult for us to access capital.

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 may also 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, borrowing 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 may 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. 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.

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 may need to raise additional capital to fund our operations.”

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.

Our business, product sales, results of operations and ability to access capital could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic, in regions where we or third parties distribute our products or where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations.*

Our business could be adversely affected by the effects of health pandemics or epidemics in regions where we have business operations, and could cause significant disruption in the operations of third-party manufacturers and distributors upon whom we rely. In particular, the ongoing COVID-19 pandemic could materially affect our operations, including at our manufacturing facility in Connecticut and with respect to our sales force and their ability to interact with health care professionals, as well as the business or operations of our suppliers, distributors or other third parties with whom we conduct business.

The ongoing COVID-19 pandemic has resulted in a number of restrictions to reduce the spread of the disease, many of which have been eased or lifted in recent months. The emergence of new variants of the SARS-CoV-2 virus raises the possibility that recurring cycles of infection and corresponding restrictions will be imposed in the future, notwithstanding vaccination efforts. The effects of the restrictions related to the COVID-19 pandemic and our related policies addressing the pandemic, including the evolving nature of such policies, may negatively impact productivity, disrupt our business and delay our development programs, regulatory and commercialization timelines. We may also face challenges or disruptions as employees return back to the workplace, including re-integration challenges by our employees and distractions to management related to such transition. These and similar, and perhaps more severe, disruptions in our operations due to the COVID-19 pandemic could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Although we believe we have sufficient quantities of raw materials for planned manufacturing operations in 2021, a prolonged supply interruption of certain components could adversely affect our ability to conduct commercialization activities and planned clinical trials. In addition, we believe that the severity of the COVID-19 pandemic in Brazil has the potential to continue to negatively impact the distribution of Afrezza by our partner in that country.

Sales and demand for Afrezza have been adversely affected by the global COVID-19 pandemic, and we expect that the COVID-19 pandemic will continue to negatively impact near-term revenues from Afrezza. Although our sales representatives are conducting in-person sales calls to the extent permitted by state and local public health authorities and by the policies of individual healthcare providers that they interact with, they have not fully returned to conducting in-person office visits with healthcare providers, which impacts their productivity. Disruptions in the prescription volume of Afrezza could also occur:

- if patients are physically quarantined or are unable or unwilling to visit healthcare providers,
- if physicians restrict access to their facilities for a material period of time,
- if healthcare providers prioritize treatment of acute or communicable illnesses over diabetes management,

- if pharmacies are closed or suffering supply chain disruptions,
- if patients lose access to employer-sponsored health insurance due to period of high unemployment, or
- as a result of general disruptions in the operations of payers, distributors, logistics providers and other third parties that are necessary for Afrezza to be prescribed and reimbursed.

In addition, our planned clinical trials of Afrezza may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 would adversely impact our clinical trial operations.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic continues to have the potential for disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

We are still in the midst of the COVID-19 pandemic. The ultimate impact of the COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, commercialization efforts, healthcare systems or to the global economy as a whole. These effects could have a material impact on our operations. We will continue to monitor the COVID-19 situation closely.

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

Although Afrezza has been approved in the United States by the FDA and in Brazil by ANVISA, we have not yet obtained approval in any other jurisdiction. In order to market Afrezza in a foreign jurisdiction, we must obtain regulatory approval in each such foreign jurisdiction, and we may never be able to obtain such approvals. The research, testing, manufacturing, labeling, 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 the 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 approval of Afrezza in the United States.

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 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, 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. Other than Tyvaso DPI, which UT submitted for regulatory approval in April 2021, 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, our need to support the regulatory submission and launch preparations of Tyvaso DPI and our ongoing attention on the development and commercialization of Afrezza, we may not be able to advance these programs into clinical development unless we are able to obtain specific funding for these programs or enter into collaborations with third parties. In addition, in October 2021, the FDA issued a complete response letter to United Therapeutics pursuant to which the FDA declined to approve the NDA for the approval of Tyvaso DPI for the treatment of PAH and PH-ILD at this time, noting only one deficiency related to an open inspection issue at a third-party analytical testing center for treprostinil. In light of these developments, it is currently unclear when, or whether, approval of Tyvaso DPI in PAH and PH-ILD can be obtained.

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.

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.*

We are not currently profitable and have rarely generated positive net cash flow from operations. As of September 30, 2021, we had an accumulated deficit of $3.1 billion. The accumulated deficit has resulted principally from costs incurred in our research and development programs, the write-off of assets (including 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 and advance product candidates in our pipeline. In addition, under our Insulin Supply Agreement with Amphastar, we agreed to purchase certain annual minimum quantities of insulin through 2027. As of September 30, 2021, there was €73.7 million remaining in aggregate purchase commitments under this agreement. We may not have the necessary capital resources 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.*

The notes to our condensed consolidated financial statements in this Quarterly Report on Form 10-Q provide details about our various debt obligations. As of September 30, 2021, we had $288.4 million principal amount of outstanding debt, consisting of:

- $230.0 million aggregate principal amount of Senior convertible notes bearing interest at 2.50% payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2021 and will mature on March 1, 2026, unless earlier converted, redeemed or repurchased. The Senior convertible notes are convertible at an initial conversion price of approximately $5.21 per share of Common Stock. The conversion rate is subject to adjustment under certain circumstances in accordance with the terms of the Indenture.
- $40.0 million principal amount under the MidCap credit facility, bearing interest at an annual rate equal to one-month LIBOR plus 6.25%, subject to a one-month LIBOR floor of 1.00%, payable in equal monthly installments beginning in September 2023 through maturity in August 2025.
- $18.4 million principal amount of indebtedness under the Mann Group convertible note bearing interest at a fixed rate of 2.50% per annum compounded quarterly and maturing in December 2025, which is convertible into shares of our common stock at the option of Mann Group at a conversion price of $2.50 per share. Interest is paid-in-kind from August 2019 until the end of 2020, after which we have the option to pay interest in-kind or in shares.

Under the MidCap credit facility, our interest rate on borrowed amounts is dependent on one-month LIBOR, which is the basic rate of interest used in lending between banks on the London interbank market. LIBOR is widely used as a reference for setting the interest rate on loans globally and is currently scheduled to be phased out in 2023. Before one-month LIBOR is phased out, we may need to renegotiate the MidCap credit facility to replace one-month LIBOR with a new standard, which has not yet been agreed upon. The consequences of these developments cannot entirely be predicted, but could result in higher interest rates on our loans under the MidCap credit facility. We cannot provide assurance that future interest rate changes will not have a material negative impact on our business, financial position, or operating results.

Under the MidCap credit facility, we must comply with a minimum cash covenant of $10.0 million at all times and may be required to comply with additional covenants in the future under certain circumstances. Further, the MidCap credit facility requires us, and any debt arrangements we may enter into in the future may require us, to comply with various covenants that limit our ability to, among other things:

- dispose of assets;
- complete mergers or acquisitions;
- incur indebtedness or modify existing debt agreements;
- amend or modify certain material agreements;

- engage in additional lines of business;
- encumber assets;
- pay dividends or make other distributions to holders of our capital stock;
- make specified investments;
- change certain key management personnel or organizational documents; and
- engage in transactions with our affiliates.

The restrictive covenants in the MidCap credit facility could prevent us from pursuing business opportunities that we or our stockholders may consider beneficial.

If our unrestricted cash and short-term investments balance falls below $90.0 million, we will be subject to a covenant relating to trailing twelve-month minimum Afrezza net revenue, tested on a monthly basis, which is set forth in the MidCap credit facility Agreement, as amended. If we fail to meet this covenant or the minimum cash covenant, any outstanding borrowings, together with accrued interest, under the MidCap credit facility could be declared immediately due and payable.

A breach of any of these covenants could result in an event of default under the MidCap credit facility. If we default under our obligations under the MidCap credit facility, the lender could proceed against the collateral granted to them to secure our indebtedness or declare all obligations under the MidCap credit facility to be due and payable. In certain circumstances, procedures by the lender could result in a loss by us of all of our equipment and inventory, which are included in the collateral granted to the lender. In addition, upon any distribution of assets pursuant to any liquidation, insolvency, dissolution, reorganization or similar proceeding, the holders of secured indebtedness will be entitled to receive payment in full from the proceeds of the collateral securing our secured indebtedness before the holders of other indebtedness or our common stock will be entitled to receive any distribution with respect thereto.

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. 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, or repay, our outstanding term loan under the MidCap credit facility or borrowings under the Mann Group promissory notes 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.

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.*

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. 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;
- actions by regulators; and
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic.

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 may depend not only on our ability to develop our product candidates, but also our ability to improve them and to improve Afrezza in order to 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. 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;
- 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; and
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic.

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 commercial manufacturing 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 inhaled drug products, we need access to sufficient, reliable and affordable supplies of FDKP, the inhaler, the related cartridges and other materials. For Afrezza, we also require a supply of insulin. Currently, the only source of insulin that we have qualified for Afrezza is manufactured by Amphastar. We must rely on all of our suppliers 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. 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 a supplier fails to comply with these requirements or the 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, we will need to evaluate that supplier's ability to provide material that meets regulatory requirements, including cGMP or QSR requirements, as well as our specifications and quality requirements, which would require significant time and expense and could delay the production of Afrezza. In general, if any of our suppliers is unwilling or unable to meet its supply obligations or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, 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 Afrezza or any other product that we develop does not become widely accepted by physicians, patients, third-party payers 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 payers 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 following:

- Approved labeling claims;
- Effectiveness of efforts by us or any future marketing partner to support and educate physicians about the benefits and advantages of Afrezza or our other products, 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 payers, regarding the safety, efficacy and benefits compared to competing products or therapies;
- Convenience and ease of administration relative to existing treatment methods;
- Coverage and reimbursement, as well as pricing 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 payers 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.*

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 payers, such as government health administration authorities and private insurance plans. Third-party payers 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 payers' drug formularies, which are the lists of medications for which third-party payers 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 payers 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. Even if favorable coverage and reimbursement status is attained for Afrezza or our product candidates for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, because each third-party payer 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 payer 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.

The requirements governing drug pricing vary widely from country to country. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. 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 and maintain coverage of, and adequate payment levels reimbursement for, Afrezza or any of our other product candidates that receive marketing approval from third-party payers, 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.

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 payers to contain or reduce the costs of healthcare through various means. In certain foreign markets the pricing of prescription pharmaceuticals is subject to direct governmental control. In the United States, there have been several congressional inquiries and proposed and enacted federal and 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.

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

The testing, manufacturing, marketing and sales 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 as well as an errors and omissions policy 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, we may be required to expand our workforce, 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, commercial 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, commercial 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.

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 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 and presentation or classification of cash flows. New pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future and as a result we may be required to make changes in our accounting policies. Any difficulties in adopting or implementing new accounting standards, and updating or modifying 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.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (the "Tax Act"), enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets and could increase our future U.S. tax expense.

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

As of December 31, 2020, we had federal and state net operating loss carryforwards of $2.4 billion and $1.3 billion, respectively, which we assess annually. A portion of our federal and state net operating loss carryforwards have begun to expire. Net operating loss carryforwards that expire unused will be unavailable to offset future income tax liabilities. Under the Tax Act as modified by the CARES Act, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (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. We have completed a Section 382 analysis beginning from the date of our initial public offering through December 31, 2020, to determine whether additional limitations may be placed on our net operating loss carryforwards and other tax attributes, and no additional changes in ownership that met the Section 382 ownership change threshold were identified through December 31, 2020. There is a risk that changes in ownership may occur in tax years after December 31, 2020. If a change in ownership were to occur, our net operating loss carryforwards and other tax attributes could be further limited or restricted. If an ownership change were to occur 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. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the U.S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable nexus, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

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.

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

At least for the foreseeable future, we expect that our manufacturing facility in Connecticut will be the sole location for the manufacturing of Afrezza and Tyvaso DPI. 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, public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic), 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 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 our facility in 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 and infrastructure, which are vulnerable to service interruptions, data breaches, and other similar incidents and attacks.*

We, and third parties acting on our behalf, employ and are increasingly dependent upon information technology systems, infrastructure, applications, websites and other resources. Our business requires collecting, manipulating, analyzing, storing and otherwise processing large amounts of data, including proprietary data, sensitive data, personal data and other confidential information. In addition, we rely on an enterprise software system to operate and manage our business. Our business, including our ability to conduct clinical trials, therefore depends on the continuous, effective, reliable and secure operation of our information technology resources and those of third parties acting on our behalf, including computer hardware, software, networks, Internet servers and related infrastructure. These resources, including due to their multitude and complexity, and the data they transit or store (which includes valuable information) are vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or security breaches by employees or others (whether intentional or accidental) may pose a risk that sensitive data including intellectual property, trade secrets, personal data or other confidential data belonging to us or our customers or other business partners may be exposed to unauthorized persons or to the public. We, and third parties acting on our behalf, are also potentially subject to cyber-attacks and other malicious internet-based activity, including ransomware attacks and supply chain attacks, which can be highly sophisticated, are constantly evolving and may be difficult to predict and detect and costly to investigate and attempt to remediate. Such attacks, which are increasingly prevalent and severe, are often carried out by motivated, well-resourced, skilled and persistent actors, including nation states, organized crime groups and “hacktivists,” but threats come from a wide variety of actors. 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, including our service providers, face similar risks and any security breach of their systems could adversely affect our security status. Additionally, natural disasters, public health pandemics or epidemics (including, for example, the COVID-19 pandemic), terrorism, war, telecommunication and electrical failures and similar events may result in damage to or the interruption or impairment of key business processes, including disruptions of clinical trials, or the loss or corruption of confidential information, including intellectual property, proprietary business information and personal data. 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 (or the efforts of third parties with whom we do business) will prevent or detect service interruptions, vulnerabilities or breaches in our systems or the systems of third parties that process our data, which could adversely affect our business and operations and/or result in the loss of critical, personal or other sensitive or confidential information and could result in financial, legal, business or reputational harm to us, including in connection with government enforcement actions, investigations, fines, penalties, audits and inspections, additional reporting requirements and/or oversight, temporary or permanent bans on all or some processing of personal data (which could impact our clinical trials or training of our algorithm), lawsuits (including class action litigation), indemnity obligations, negative publicity, diversions of funds and resources, notification obligations (including to affected individuals and governmental authorities), and other adverse events or outcomes. Our contracts, which often contain privacy- and data security-related obligations, may not have limitations of liability and there can be no assurance that any limitations of liability that are included in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable data protection laws, contracts, policies or other obligations related to privacy, information security or security incidents. We also cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or adequately mitigate liabilities or damages with respect to claims, costs, litigation, fines, penalties, and other losses or material adverse impacts arising out of our privacy and security practices or security incidents, or that such coverage will continue to be available on commercially reasonable terms or at all.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes.

Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The withdrawal of the United Kingdom from the European Union, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our product candidates in the European Union, result in restrictions or imposition of taxes and duties for importing our product candidates into the European Union, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the European Union.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as "Brexit." Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period that ended December 31, 2020, or the Transition Period, during which EU rules continued to apply. A trade and cooperation agreement, or the Trade and Cooperation Agreement, that outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from EU directives and regulations, Brexit has had, and may continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom or the European Union. For example, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, and a separate marketing authorization will be required to market our product candidates in Great Britain. It is currently unclear whether the Medicines & Healthcare products Regulatory Agency, or MHRA, in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom or the European Union and restrict our ability to generate revenue and achieve and sustain profitability.

While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the United Kingdom ("UK") and the EU there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the UK diverge from the EU from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom.

RISKS RELATED TO GOVERNMENT REGULATION

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

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

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

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

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

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

If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be 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.

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.

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 significant 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;
- revisions to the approved labeling to add new safety information;
- 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.

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. Prescription drugs may be promoted only for the approved indications in accordance with the approved label. The FDA and other regulatory authorities may take enforcement action against a company for promoting unapproved uses of a product or for other violations of its advertising and labeling laws and regulations. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer’s communications on the subject of off-label use of their products. Enforcement action may include product seizures, injunctions, significant civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. 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.

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. For example, in October 2018, we received a warning letter from the FDA’s Office of Prescription Drug Promotion (“OPDP”) 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 temporarily inactivated all Afrezza social media accounts (including Facebook, Instagram and Twitter) then, after consultation with OPDP, placed a corrective post on Facebook and Instagram.

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, delay the submission or review of an application or require additional expenditures by us. In addition, interested parties (such as individuals, advocacy groups and competing pharmaceutical companies) can file a citizen petition with the FDA to request policy change or some form of administrative action on the FDA's part, including with respect to an NDA. For example, a third party has submitted a citizen petition to the FDA requesting that the FDA refuse to approve Tyvaso DPI, and/or impose additional requirements in order to approve the product. If successful, a citizen petition can significantly delay, or even prevent, the approval of a drug product.

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 be denied marketing approval or lose any marketing approval that we have already obtained. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals on a timely basis, if at all, for any of our product candidates under development, and delays in receipt or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business and results of operations.

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, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, "PPACA") became law in the United States. PPACA substantially changed 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;
- 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 federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- A Medicare Part D coverage gap discount program, in which manufacturers must agree to now offer 75% 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;
- Requirements to report annually to CMS certain financial arrangements with physicians, certain other healthcare professionals, and teaching hospitals, 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, as described in more detail below;
- A requirement to annually report drug samples that certain manufacturers and authorized distributors provide to physicians; and
- A Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive, judicial and congressional challenges to certain provisions of the PPACA. For example, the Tax Act included a provision that repealed, 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". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the PPACA will remain in effect in its current form. Moreover, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA

marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, other litigation, and the healthcare reform measures of the Biden administration will impact the PPACA.

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 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. 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 and enacted legislation 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.

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 payers to contain or reduce the costs of healthcare through various means. In the United States, there have been several congressional inquiries and proposed and enacted federal and 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 Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services ("HHS"), finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of this rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, the Centers for Medicare & Medicaid Services ("CMS") issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court for the Northern District of California issued a nationwide preliminary injunction against implementation of the interim final rule. On January 13, 2021, in a separate lawsuit brought by industry groups in the United States District Court of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the United States District Court for the Northern District of California and that performance for any final regulation stemming from the Most Favored Nation Model interim final rule shall not commence earlier than sixty (60) days after publication of that regulation in the Federal Register. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. At the state level, legislatures have increasingly passed legislation and implemented 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 third-party payers may take in response to any drug pricing and reimbursement reform proposals or legislation. For example, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. 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.

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. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payers. 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 partner fails to comply with federal and state healthcare or privacy and data security laws, including fraud and abuse and health information laws and other laws governing the processing of personal data, 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 payers, 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. Additionally, there are numerous U.S. and foreign laws, regulations and industry standards that govern the processing of personal data, including privacy, data security, consumer protection and health information privacy laws. The number and scope of these laws, regulations and industry standards are changing, subject to differing applications and interpretations, and may be inconsistent between jurisdictions or in conflict with each other, making compliance difficult. The key 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 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;
- The federal Health Insurance Portability and Accountability Act ("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 the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as certain 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 as well as their covered subcontractors.
- We may be or may become subject to the European General Data Protection Regulation ("EU GDPR") and the EU GDPR as it forms part of UK law by virtue of section 3 of the European Union (Withdrawal) Act of 2018 ("UK GDPR"), which contain significant and complex compliance burdens with respect to processing personal data, including provisions specifically directed at the processing of health information and other categories of "special category" data, higher sanctions (including, for example, under the EU GDPR, fines of up to the higher of €20 million or 4% of global annual revenue for the preceding financial year), restrictions on transferring personal data outside of the European Economic Area ("EEA") or UK and extra-territoriality measures that bring companies outside of the EEA and UK under the regulation. We anticipate that over time we may expand our business operations to include additional operations in the EU and UK, 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 and the UK, including the EU GDPR and UK GDPR;

- Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais or LGPD) (Law No. 13,709/2018), which broadly regulates the processing of personal data and imposes compliance obligations and penalties comparable to the EU GDPR and UK GDPR, including similar cross-border data transfer restrictions.
- The California Consumer Privacy Act ("CCPA"), which created individual privacy rights for California consumers (as that word is broadly defined in the law) and placed increased privacy and security obligations on entities handling personal data of such consumers or households. The CCPA requires covered companies to, among other things, provide new disclosures to California consumers, provide such consumers with various rights with respect to their data (including ways to opt-out of certain sales of personal data), and provides for significant civil penalties as well as a new private right of action for data breaches and statutory damages. In addition, it is anticipated that the California Privacy Rights Act of 2020 ("CPRA"), effective January 1, 2023, will expand the CCPA. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal data, expand the types of data breaches subject to the CCPA's private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law. Furthermore, other U.S. states have enacted or proposed data privacy laws, which could further complicate the legal landscape. These laws will likely impact (possibly significantly) our business activities and exemplify the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data.
- The federal Physician Payments Sunshine Act under PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians (defined to include defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- Other 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 payer, including commercial insurers, and state and foreign laws governing the privacy and security and other processing of personal data (including 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; state and local laws that require the registration of pharmaceutical sales representatives; 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, marketing expenditures or drug pricing.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. With Afrezza now available in Brazil and as we pursue additional international approvals, we will 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, or any contractual obligations related to the same, we may be subject to governmental enforcement actions, investigations, litigation (including class action lawsuits) and other penalties, including significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, defense costs, exclusion from U.S. federal or state healthcare programs, additional reporting requirements and/or oversight (including if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws), bans or restrictions on our processing of personal data, indemnity obligations and the curtailment or restructuring of our operations. Any such event or consequence, including penalties, damages, fines, and curtailment or restructuring of our operations, could materially adversely affect our ability to operate our business, including our ability to run clinical trials, and our financial results and harm our reputation. Although compliance programs can help mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be 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 payers 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. For example, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price ("AMP"), for single source and innovator multiple source drugs, beginning January 1, 2024. 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 HHS 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 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 payers. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in a civil monetary penalty. 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.

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 patients 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.

Furthermore, patents already issued to us or our pending applications may become subject to disputes that could be resolved against us. In the United States and certain other countries, applications are generally published 18 months after the application's priority date. 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"), the United States moved to a first inventor to file system. In general, the AIA 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, various patents providing protection for the powder component of Afrezza have terms extending into 2026, 2028, 2029 or 2030. In addition, patents providing protection for our inhaler and cartridges have terms extending into 2023, 2031 or 2032. Our method of treatment claims extends into 2026, 2029, 2030 or 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. However, disputes may arise as to the ownership of proprietary rights to the extent that outside collaborators apply technological information to our projects that are developed independently by them or others, or apply our technology to outside projects, and there can be no assurance that any such disputes would be resolved in our favor. In addition, any of these parties may breach the agreements and disclose our confidential information or our competitors might learn of the information in some other way. Thus, 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 AIA 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 do not believe that Afrezza infringes any third-party patents, if a plaintiff was to allege that Afrezza infringed their patent rights, we would have to establish with the court that their 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 and commitments. We may be forced to take other actions to satisfy our obligations or we may experience a financial failure.

Our ability to make scheduled payments on our lease and 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 obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness and lease obligations. 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 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.

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

The trading price of our common stock has been and 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 COVID-19 pandemic, for example, has negatively affected the stock market and investor sentiment and has resulted in significant volatility.

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;
- future estimates of Afrezza sales, Tyvaso DPI royalties, prescriptions or other operating metrics;
- our ability to successfully commercialize other products (in addition to Afrezza) based on 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;

- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic;
- changes in the structure of the healthcare payment systems;
- 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, Tyvaso DPI 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;
- the trades of short sellers;
- 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 Global 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, Tyvaso DPI, 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. 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.

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 October 29, 2021, we had 251,256,353 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 the Mann Group promissory notes, or the Senior convertible notes, 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 may 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.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated bylaws provide that, to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants, the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and certificate of incorporation or amended and restated bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us or any of our directors, officers or other employees that is governed by the internal affairs doctrine.

This provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act of 1933, as amended, or the Securities Act, creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

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. In addition, pursuant to the MidCap credit facility, 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.

GENERAL RISK FACTORS

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, the vesting of restricted stock unit awards and purchases under our employee stock purchase program. 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.

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.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

On November 8, 2021, the previously announced transaction between us and 1 Casper, LLC (the “Purchaser”) closed, pursuant to which we sold the Property for a purchase price of $102.3 million, subject to terms and the conditions under the agreement for the

Sale-Leaseback Transaction. The Property included our manufacturing facility (commonly known as Building 1), which consists of approximately 263,900 square feet, but did not include our adjacent research and development facility (commonly known as Building 8).
Effective with the closing of the Sale-Leaseback Transaction, we and the Purchaser entered into the Lease, pursuant to which we leased the Property from the Purchaser for an initial term of 20 years, with four renewal options of five years each. The total annual rent under the Lease starts at approximately $9.5 million per year, subject to a 50% rent abatement during the first year of the Lease, and will increase annually by (i) 2.5% in the second through fifth year of the Lease and (ii) 3% in the sixth and each subsequent year of the Lease, including any renewal term. We are responsible for payment of operating expenses, property taxes and insurance for the Property. The Purchaser will hold a security deposit of $2.0 million during the Lease term. Pursuant to the terms of the Lease, we have four options to repurchase the Real Property, in 2026, 2031, 2036 and 2041, for the greater of (i) $102.3 million and (ii) the fair market value of the Real Property.

Effective with the closing of the Sale-Leaseback Transaction, we and the Purchaser also entered into the ROFR, pursuant to which we have a right to re-purchase the Property from the Purchaser in accordance with terms and conditions set forth in the ROFR. Specifically, if the Purchaser receives, and is willing to accept, a bona fide purchase offer for the Property from a third-party purchaser, we have certain rights of first refusal to purchase the Property on the same material terms as proposed in such bona fide purchase offer.

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	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 May 27, 2020).
3.5	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 27, 2020).
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5.
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	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).
4.4	Form of Warrant to Purchase Stock issued to MidCap Financial Trust on August 6, 2019 (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 August 7, 2019).
4.5	Indenture, dated as of August 6, 2019, by and between MannKind Corporation and U.S. Bank National Association (incorporated by reference to Exhibit 4.3 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.6	Convertible Promissory Note made by MannKind Corporation in favor of The Mann Group LLC, dated August 6, 2019 (incorporated by reference to Exhibit 4.6 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.7	Promissory Note made by MannKind Corporation in favor of The Mann Group LLC, dated August 6, 2019 (incorporated by reference to Exhibit 4.7 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.8	Promissory Note, dated April 9, 2020, by and between MannKind Corporation and JPMorgan Chase Bank, N.A. (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 April 15, 2020).
4.9	Indenture, dated as of March 4, 2021, by and between MannKind Corporation and U.S. Bank National Association, as Trustee (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 March 5, 2021).
4.10	Form of Global Note, representing MannKind Corporation's 2.50% Convertible Senior Notes due 2026 (included as Exhibit A to the Indenture filed as Exhibit 4.15) (incorporated by reference to Exhibit 4.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on March 5, 2021).
10.1*	Commercial Supply Agreement, dated August 12, 2021, by and between MannKind Corporation and United Therapeutics Corporation.
10.2*	First Amendment to Commercial Supply Agreement, dated October 16, 2021, by and between MannKind Corporation and United Therapeutics Corporation.
10.3*	Purchase and Sale Agreement, dated September 23, 2021, by and between MannKind Corporation and 1 Casper, LLC.
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).

Exhibit Number	Description of Document
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	Inline Interactive Data Files pursuant to Rule 405 of Regulation S-T.
104	The cover page has been formatted in Inline XBRL.

* Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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 9, 2021

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
(Principal Financial and Accounting Officer)

Exhibit10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT MANNKIND CORPORATION TREATS AS PRIVATE OR CONFIDENTIAL.

COMMERCIAL SUPPLY AGREEMENT

This commercial supply agreement (this "**Agreement**") is entered into as of August 12, 2021 (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.

RECITALS

WHEREAS, MannKind and United Therapeutics entered into a license and collaboration agreement dated September 3, 2018 (such license and collaboration agreement, as amended and supplemented from time to time, the "**License Agreement**") under which MannKind and United Therapeutics have collaborated on the development of Tyvaso DPI™, formerly known as Treprostinil Technosphere®, a prescription drug/device combination product comprising a dry powder inhalation formulation of treprostinil, and an inhalation device;

WHEREAS, MannKind and United Therapeutics entered into a clinical supply agreement effective January 21, 2019 (the **"Clinical Supply Agreement"**), under which MannKind agreed to Supply United Therapeutics with clinical supplies needed to enable United Therapeutics to conduct its clinical trials for the product covered by the License Agreement;

WHEREAS, MannKind and United Therapeutics entered into a quality agreement effective December 24, 2018 (as amended and supplemented from time-to-time, the "**Quality Agreement**"), defining the roles and responsibilities of MannKind and United Therapeutics with respect to the quality of drug/device combination products and related services supplied to United Therapeutics;

WHEREAS, United Therapeutics has submitted a New Drug Application to the US Food and Drug Administration for Tyvaso DPI, with possible approval as early as October 2021, and wishes to obtain commitments from MannKind related to the manufacture and supply of Tyvaso DPI (as further defined below), for commercial distribution and sale, and MannKind has agreed to provide such commitments, subject to the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants herein contained, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, MannKind and United Therapeutics hereby agree, as evidenced by their signatures below, as follows:

1. **DEFINITIONS**

When used in this Agreement the following terms shall have the meanings as set forth below:

1.1 **"Affiliate"** of a party means any individual or legal entity which directly or indirectly controls, is controlled by, or is under common control with such party. As used herein, "control" means the authority, directly or indirectly, to direct or cause the direction of the management and policies of an entity, whether through the direct or indirect beneficial ownership of at least 50% of voting share capital or other equity interest, or by contract.

1.2 **"Annual Budget"** means an annual budget for all amounts to be invoiced to United Therapeutics pursuant to this Agreement over the course of a calendar year, in a format reasonably agreed to by United Therapeutics and MannKind, and at a minimum providing a breakdown of costs by Price, Staffing Payments (if any) and Packaging Services, and other discrete categories as reasonably requested by United Therapeutics.

1.3 **"API"** means treprostinil sodium.

1.4 **"Applicable Law"** has the meaning set forth in the License Agreement, but means at a minimum, the Food, Drug, and Cosmetic Act, Good Manufacturing Practices, all implementing regulations of the foregoing, and all other laws or regulations issued by the United States Government or any state or local government having applicability to the goods and services provided under this Agreement.

1.5 **"Approved Suppliers"** means the initial Product Material suppliers and providers of Third Party Manufacturing Services listed in Appendix D or listed in the Quality Agreement, in addition to any Product Material suppliers or providers of Third Party Manufacturing Services approved by the parties in accordance with the requirements set forth in the Quality Agreement. For the avoidance of doubt, any Approved Suppliers as defined under this Agreement shall also be considered Approved Suppliers for the purposes of the License Agreement.

1.6 **"Cap-Ex Letter Agreement"** is defined in section 2.2.3 below.

1.7 **"Certificate of Conformance"** means a document that is signed and dated by a duly authorized representative of MannKind's quality organization certifying that the Product contained in the associated batch conforms to the Product Specifications. The Certificate of Conformance shall identify each batch by batch number, provide the quantity of the batch, as well as any further information required by Applicable Law or by United Therapeutics, that United Therapeutics provides notice of in writing.

1.8 **"Cold Storage Area"** means the cold storage area within the Facility, which has a minimum initial capacity of **[***]** pallets of Product or Semi-Finished Product, and future storage capacity of at least **[***]** pallets of Product or Semi-Finished Product.

1.9 **"Commercially Reasonable Efforts"** has the meaning set forth in the License Agreement.

1.10 **"Confidential Information"** has the meaning set forth in the License Agreement.

1.11 **"Cost of Goods"** or **"COGs"** means the actual costs and expenses of the Manufacture and Supply of Product and/or Semi-Finished Product that MannKind Supplies to United Therapeutics under this Agreement, consisting of the cost of Product Materials (except for API), Direct Labor, Indirect Costs and Fixed Overhead incurred in the Manufacture and Supply of such items as calculated in accordance with GAAP (excluding sales, general and administrative costs (SG&A)). In addition, COGs will include a facility utilization expense (or rent) of $**[***]** per square foot for the portion of the Facility allocated to activities under this Agreement; provided, however, that such facility utilization expense shall not be subject to the Margin. The components of COGs, and the applicability of the Margin to such components, are described in more detail in Appendix B. For clarity, COGs will exclude any costs of Manufacturing that are separately reimbursed or paid for by United Therapeutics under this Agreement (such as Packaging Services) or are made as prepayments of commercial Manufacturing costs under the Cap-Ex Letter Agreement, the License Agreement, or the Clinical Supply Agreement.

1.12 **"Direct Labor"** means the cost of employees directly involved in Manufacturing, including employees working directly in the bulk and fill/pack manufacturing process, inhaler assembly, packaging, quality testing and quality assurance/release as well as the costs associated with the supervision of these functions.

1.13 **"DMF"** has the meaning set forth in the License Agreement.

1.14 **"Facility"** means MannKind's manufacturing facility located at One Casper Street, Danbury, CT 06801.

1.15 **"FDA"** means the United States Food and Drug Administration.

1.16 **"FDKP"** means fumaryl diketopiperazine.

1.17 **"Fixed Overhead"** means operating expenses associated with Manufacturing operations not directly related to inputs to production and that do not increase or decrease with production, including property tax, insurance, depreciation and similar costs. For purposes of Appendix B, Fixed Overhead is allocated to COGs using total machine hours required relative to the maximum production capacity (in machine hours), with the exception of Facility costs (e.g., utilities, insurance, property tax, labor, purchased services related to the maintenance of the Facility), which will be allocated on the basis of square footage.

1.18 **"Food, Drug, and Cosmetic Act"** means a set of laws passed by the United States Congress in 1938, as amended from time to time, giving authority to the FDA to oversee the safety of food, drugs, medical devices, and cosmetics.

1.19 **“Force Majeure Event”** means any event not reasonably anticipated at the time this Agreement is executed by the parties, that renders a party’s performance under this Agreement impossible to perform lawfully, or impossible to perform with reasonable safety of the employees of the party affected by such event, including without limitation natural disasters, outbreaks of contagious disease, war, hostilities, terrorist threats or acts, embargoes, and national or regional emergency declared by applicable government authorities.

1.20 **“GAAP”** means generally accepted accounting principles in the United States of America, consistently applied.

1.21 **“Good Manufacturing Practices”** or **“cGMP”** means current good manufacturing practices required by the FDA for the Manufacture and testing of pharmaceutical and medical device materials, including within the meaning of 21 CFR, Parts 210, 211 and 820, or as agreed upon by the parties in the Quality Agreement.

1.22 **“Indirect Costs”** means indirect materials, labor and overhead costs that support, and occur during, Manufacturing, such as the employees and costs associated with environmental health and safety, technical services, facilities and other related cost centers. For purposes of Appendix B, Indirect Costs are allocated to COGs using the total machine hours required for the planned production.

1.23 **“Intellectual Property”** means all Data, Information, Inventions, Joint Inventions, Joint Patents, MannKind Information, MannKind Know-How, MannKind Patents, MannKind Technology, Patents, United Therapeutics Inventions, United Therapeutics Know-How, United Therapeutics Patents, and United Therapeutics Technology, as those terms are individually defined in the License Agreement.

1.24 **“Inventory Report”** means a report sent by MannKind to United Therapeutics on a schedule set forth in section 2.6.6, where such report provides the specific quantity of Product, Semi-Finished Product, and API, categorized by item number, held by MannKind in the Cold Storage Area or elsewhere at the Facility, or held by any Third Party on MannKind’s behalf, along with the batch number, where such report is formatted in a manner reasonably specified by United Therapeutics.

1.25 **“Latent Defect”** means a defect in Product or Semi-Finished Product that is not discoverable upon reasonable physical inspection and testing performed pursuant to section 2.12.2, but is discoverable at a later time, through long-term stability studies or otherwise, that causes Product or Semi-Finished Product to fail to conform to the warranties set forth in this Agreement or the Product Specifications for such product. Latent Defects shall exclude defects in Product or Semi-Finished Product caused by defects in API not reasonably discoverable through testing required by section 2.12.1.

1.26 **“Manufacture”** means all activities related to the manufacture, testing, storage, transportation, handling, and packaging of Products and Semi-Finished Products, whether

conducted by MannKind or by any Third Party under MannKind's direction, and including testing and release of any component or ingredient of any Product or Semi-Finished Product, quality assurance activities related to manufacturing and release of Product and Semi-Finished Product, and ongoing stability and regulatory activities related to any of the foregoing. **"Manufactured"** or **"Manufacturing"** shall have correlative meaning.

1.27 **"Marketing Approval"** has the meaning set forth in the License Agreement.

1.28 **"Margin"** means **[***]** percent.

1.29 **"Maximum Capacity"** means, with respect to Existing Equipment or Expansion Equipment, the maximum output based on (i) process qualification and validation runs and (ii) the shift configuration, as agreed by the parties. The anticipated Maximum Capacity is set forth in Appendix C.

1.30 **"NDA"** means any of the following: (i) a New Drug Application filed with the FDA seeking authorization and approval to manufacture, package, ship, and sell the Product in the United States pursuant to the Food, Drug, and Cosmetic Act including, without limitation, an application under 21 U.S.C. § 355(b)(1); (ii) any other similar or equivalent FDA regulatory filing pursuant to 21 U.S.C. § 355(b)(2); (iii) any other similar or equivalent regulatory filing seeking authorization and approval to Manufacture, package, ship, market, and sell the Product in the Territory; and (iv) all supplements and amendments that may be filed with respect to the foregoing.

1.31 **"Packaging Services"** means certain Third Party Manufacturing Services for packaging Semi-Finished Product into fully kitted Product (as well as the transportation to and from such Third Party) that the parties have agreed to exclude from COGs. The parties agree that any payments in respect of Packaging Services shall reflect MannKind's actual out of pocket expenses associated with such Packaging Services, without Margin or other markup of any manner. For clarity, all Third Party Manufacturing Services that are not Packaging Services shall be included in COGs.

1.32 **"party"** means either United Therapeutics or MannKind.

1.33 **"parties"** means United Therapeutics and MannKind.

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

1.35 **"Pre-Commercial Product"** means product that is manufactured pursuant to the Clinical Supply Agreement or other written agreement between MannKind and United Therapeutics, having the same or similar specifications as the Product and Semi-Finished Product covered by this agreement, but where such Product or Semi-Finished Product is not intended for commercial distribution or sale.

1.36 **"Price"** has the meaning set forth in section 3.1.

1.37 **“Product”** means those products listed in Appendix A, intended for commercial distribution and sale.

1.38 **“Product Materials”** means the raw materials, packaging, and labeling components used to Manufacture Product and Semi-Finished Product that are procured, sampled, tested, and stored in accordance with the Quality Agreement, including but not limited to API to be supplied by United Therapeutics to MannKind.

1.39 **“Product Specifications”** means the specifications for the Product as set forth or referenced in the Quality Agreement.

1.40 **“Regulatory Authority”** means the United States Food and Drug Administration (“**FDA**”), and any governmental agency, in any jurisdiction in which Marketing Approval for Product is sought, having jurisdiction over such marketing authorization.

1.41 **“Regulatory Filing”** has the meaning set forth in the License Agreement.

1.42 **“Release Certificate”** means a certificate issued by United Therapeutics’ quality assurance department upon review of the Certificate of Conformance and other manufacturing records as applicable, signifying United Therapeutics’ determination that such records are determined to be accurate in accordance with cGMP.

1.43 **“Rolling Forecast”** has the meaning set forth in section 2.4.1.

1.44 **“Semi-Finished Product”** means those semi-finished products listed in Appendix A.

1.45 **“Semi-Finished Product Specifications”** means the specifications for the Semi-Finished Products set forth or referenced in the Quality Agreement.

1.46 **“Shipment Order”** means a request made by United Therapeutics to MannKind to prepare Product or Semi-Finished Product for pickup by United Therapeutics (or United Therapeutics’ shipping vendor), such request specifying the specific quantity of Product or Semi-Finished Product by item number, lot number or batch number, time, date and location for pickup, shipping company name, and any other relevant details.

1.47 **“Staffing Payments”** means payments made directly by United Therapeutics to MannKind in accordance with section 3.2, to reimburse MannKind for the cost of its (i) Direct Labor plus the Margin, (ii) the labor component of Indirect Costs plus the Margin, and (iii) certain internal MannKind activities (such as human resource support for recruiting Manufacturing personnel) for which the parties have agreed that MannKind will be reimbursed by United Therapeutics on a pass-through basis only, all as required to Manufacture or Supply Product or Semi-Finished Product, or to be prepared to Manufacture or Supply Product or Semi-Finished Product, at the Facility, in accordance with the Rolling Forecast.

1.48 **"Supply"** means to make Product or Semi-Finished Product Manufactured in accordance with this Agreement available for physical transfer to United Therapeutics, or United Therapeutics' shipping vendor, at the designated time and place, in accordance with all Applicable Laws and with this Agreement.

1.49 **"Supply Failure"** means MannKind's inability to Supply at least 75% of the quantity of Product or Semi-Finished Product meeting the definition of a Firm Order over a 3 month period, or MannKind's inability to deliver 95% of the quantity of Product or Semi-Finished Product meeting the definition of a Firm Order over a 12 month period, other than failure to Supply resulting from: (i) a Force Majeure Event; or (ii) delayed delivery of API to MannKind or delivery of nonconforming API (other than delays or nonconformance caused by MannKind).

1.50 **"Territory"** means everywhere.

1.51 **"Third Party"** means any individual or entity other than the parties to this Agreement and their Affiliates.

1.52 **"Third Party Manufacturing Services"** means Manufacturing services provided by a Third Party pursuant to a written contract between MannKind and such Third Party, where United Therapeutics may or may not be a party to the contract with such Third Party.

2. GOVERNANCE, SUPPLY, AND COORDINATION

2.1 **Governance**.

2.1.1 Upon execution of this Agreement each party shall appoint one of its employees to be a relationship manager responsible for acting as liaison between the parties with regard to matters covered by this Agreement, and shall notify the other party as to the identity of such individual, and update the other party as to any changes to the identity of such relationship manager over time. The relationship managers from United Therapeutics and MannKind shall meet routinely or as needed to review the current status of the business relationship and manage any issues that may arise, and will escalate any unresolved issues to the MSC defined below.

2.1.2 Each party shall designate at least 3 employees of such party to serve on a manufacturing steering committee ("**MSC**"), comprised of representatives of each party's technical operations, manufacturing, and quality organizations, or other functional area representatives of such party as reasonably agreed by the other party. The MSC shall meet on a regular schedule as determined by United Therapeutics in its reasonable discretion, but not more often than monthly unless required by circumstances giving rise to more frequent meetings. The MSC shall operate to ensure that obligations related to Product and Semi-Finished Product quality, Manufacture, and Supply requirements as specified in this Agreement are met. MannKind shall maintain written minutes of all meetings of the MSC, and shall circulate such minutes to United

Therapeutics' relationship manager for United Therapeutics' review and approval within 5 business days from the date of each meeting. The MSC may advise on any required modifications to this Agreement, but the decisions of the MSC shall not have any capacity to modify the terms of this Agreement unless mutually agreed to by the parties and documented by a signed amendment to this Agreement.

2.1.3 MannKind shall provide United Therapeutics an estimated Annual Budget by October 1 of each year for the following calendar year, based on the Rolling Forecast current as of September 1 of the year in which the Annual Budget is provided. Upon finalization of MannKind's operating budget for the following calendar year, MannKind will provide United Therapeutics with any significant updates to the Annual Budget.

2.2 **Facility Use, Capital Improvements, and Capacity Obligations.**

2.2.1 Except as specifically authorized by this Agreement, MannKind shall Manufacture all Product and Semi-Finished Product at the Facility. MannKind shall not delegate nor subcontract any or all of its Manufacturing and Supply obligations under this Agreement to any Third Party other than Approved Suppliers without the prior written consent of United Therapeutics. The applicable requirements set forth or referenced in the Quality Agreement shall in all cases apply to Manufacturing by Third Parties. Approved Third Party Manufacturing Services providers are listed in Appendix D, for the specific services as stated.

2.2.2 MannKind currently operates at the Facility one dedicated automated powder filling/blister pack line capable of producing up to **[***]** cartridges annually (the "**Existing Line**"), one dedicated spray dryer capable of producing bulk drug product powder in adequate quantities to support the Existing Line (the "**Existing Spray Dryer**"), and a shared cold storage (2-8℃) with at least **[***]** pallet locations reserved for United Therapeutics' use (the "**Existing Cold Storage**") (collectively, the Existing Line, the Existing Spray Dryer, and the Existing Cold Storage, the "**Existing Equipment**").

2.2.3 MannKind and United Therapeutics are parties to a letter agreement dated May 14, 2021, that amended the Development Plan and Budget as those terms are defined under the License Agreement, to provide for procurement by MannKind of additional capital equipment needed to enable the Manufacture and Supply of Product and Semi-Finished Product as provided for by this Agreement (such letter agreement, the "**Cap-Ex Letter Agreement**"; such additional capital equipment to be procured under the Cap-Ex Letter Agreement, the "**Expansion Equipment**"). Under the terms of the Cap-Ex Letter Agreement, United Therapeutics will fully fund the purchase of the Expansion Equipment, and such Expansion Equipment will be titled in United Therapeutics' name. The parties hereby incorporate all of the terms of the Cap-Ex Letter Agreement into this Agreement, including without limitation, all rights and obligations related to the Expansion Equipment. MannKind shall reserve adequate space and resources in the Facility for the installation and operation of the Expansion Equipment.

2.2.4 MannKind will use the Existing Equipment and the Expansion Equipment solely for Manufacture and Supply of Product and Semi-Finished Product, and, pursuant to the Clinical Supply Agreement or other written agreement between MannKind and United Therapeutics Corporation, Pre-Commercial Product. Upon installation and commissioning of the Expansion Equipment, MannKind shall be free to use the Existing Equipment for other purposes if demand for Product and Semi-Finished Product can be satisfied by the Expansion Equipment, taking into account any requirements for backup supply of Product as set forth in the Business Continuity Plan, provided that MannKind shall not be entitled to use components of the Existing Equipment paid for by United Therapeutics (i.e., the 50 liter collection vessel) for any use other than for United Therapeutics' benefit. Following termination or expiration of this Agreement, MannKind shall deliver and/or dispose of the Expansion Equipment in accordance with United Therapeutics' instructions, at United Therapeutics' expense.

2.2.5 Upon United Therapeutics' request, MannKind shall provide office space free of charge for up to two United Therapeutics employees at the Facility to provide coordination between the parties, facilitate issue resolution and conduct batch release.

2.2.6 MannKind shall use Commercially Reasonable Efforts throughout the Term, to identify potential investments in and improvements to the Facility, the Manufacturing process, and Facility staffing arrangements, including without limitation staffing arrangements reimbursed by United Therapeutics according to Appendix E, to enable improved cost efficiencies for the Manufacturing and Supply of Product and Semi-Finished Product, and MannKind shall notify United Therapeutics through the MSC upon identifying such potential investments and improvements, and shall reasonably cooperate with United Therapeutics to assess the merits of implementing such investments and improvements. If the parties mutually agree to proceed with an identified investment or improvement, the parties shall reasonably negotiate a shared burden of implementation cost, and shared benefit of cost savings resulting from, such investments and improvements, and shall reasonably cooperate throughout the implementation process.

2.3 **Supply Obligations.**

2.3.1 Subject to the terms and conditions of this Agreement, MannKind shall Manufacture the minimum quantities established through the Rolling Forecast and Supply Product and Semi-Finished Product to United Therapeutics or its designee, in the quantities specified in the Purchase Order, Firm Order, and Shipment Order processes described in sections 2.4, 2.5, and 2.6 below, at the applicable Prices, and in accordance with the applicable Product Specifications and/or Semi-Finished Product Specifications, and the Quality Agreement, for commercial distribution and sale by United Therapeutics or its agents.

2.3.2 United Therapeutics shall supply API to MannKind in quantities necessary to enable Manufacture of Product and Semi-Finished Product as required by this Agreement, in accordance with the specifications for API set forth in or referenced in the Quality Agreement, at United Therapeutics' expense. MannKind shall place orders for API with

sufficient lead time, based on the minimum Product and Semi-Finished Product quantities specified in the Rolling Forecast. MannKind shall not sell, transfer, disclose or otherwise provide access to the API to any Third Party except to Third Party Manufacturing Services providers listed in Appendix D, as necessary for such Third Party Manufacturing Service provider to complete its Manufacturing obligations. Following termination or expiration of this Agreement for any reason, MannKind shall return any unused API to United Therapeutics, or destroy or reallocate such API for other use in accordance with Applicable Laws, as directed by United Therapeutics. Notwithstanding any physical transfer of API to MannKind, title to API shall at all times remain with United Therapeutics.

2.4 **Rolling Forecast.**

2.4.1 Within 10 business days following execution of this Agreement, United Therapeutics shall submit to MannKind an 18-month forecast for Product and Semi-Finished Product for the period commencing on the anticipated approval date. Such forecast shall be updated by United Therapeutics within the first 10 business days of each month during the Term. Such forecast, as updated on a monthly basis, shall be referred to as the "**Rolling Forecast**" throughout this Agreement. Subject to the limitations and requirements set forth in section 2.4.2 below, the full 18 months of the initial Rolling Forecast shall be binding on the parties (i.e., United Therapeutics shall place Purchase Orders for, and MannKind shall Supply, not less than the minimum quantity of Product and Semi-Finished Product specified in such Rolling Forecast). Upon passage of the first 18 months of the initial Rolling Forecast, subject to the limitations and requirements set forth in section 2.4.2 below, only the first six months of the Rolling Forecast shall continue to be binding on the parties, with the remaining 12 months considered to be a good faith non-binding estimate for planning purposes.

2.4.2 MannKind shall be obligated to accept any Rolling Forecast, including any monthly updates thereto, requiring manufacturing output up to the Maximum Capacity of the Existing Equipment. Upon installation and validation of the Expansion Equipment in accordance with the Cap-Ex Letter Agreement, MannKind shall be obligated to accept any Rolling Forecast amount requiring manufacturing output up to 90% of the Maximum Capacity of the Existing Equipment in addition to the Expansion Equipment, provided such capacity utilization is first disclosed in the non-binding portion of the Rolling Forecast.

2.4.3 Without affecting the overall capacity usage of the Existing Equipment or the Expansion Equipment, United Therapeutics may request a change to mix of Product or Semi-Finished Product at any time, including during the binding period of the Rolling Forecast, and MannKind shall comply with such request unless such change would be economically detrimental to MannKind or operationally impracticable.

2.4.4 United Therapeutics may, if justified based on changed demand forecast, request a reduction in Manufacturing at any time, including during the binding period of the

Rolling Forecast, and MannKind shall comply with such request provided that United Therapeutics compensates MannKind by way of a lost profit payment reasonably calculated to compensate MannKind for the shortfall in profit that would have been earned under this Agreement, but without accounting for any profits earned as result of any other agreement between the parties, including any royalties earnable under the License Agreement, had the binding portion of the Rolling Forecast not been reduced.

2.5 **Purchase Orders and Firm Orders.**

2.5.1 For each order of Semi-Finished Product or Product, at least 90 days prior to the specified date of Manufacture, United Therapeutics shall issue to MannKind a purchase order that specifies: (a) purchase order number; (b) the name, Item Number, and quantity of each Product or Semi-Finished Product to be Manufactured; (c) the latest date of Manufacture; and (d) price of the Product or Semi-Finished Product as specified in Appendix B (such purchase order, a "**Purchase Order**"). For clarity, a Purchase Order shall specify a quantity of Product or Semi-Finished Product but not both Product and Semi-Finished Product. Each Purchase Order shall reference this Agreement and shall be governed exclusively by the terms of this Agreement.

2.5.2 MannKind shall be obligated to accept any Purchase Order that when aggregated with other Purchase Orders submitted by United Therapeutics, specifies a quantity of Product or Semi-Finished Product that is at or below the quantities specified in the binding portion of the Rolling Forecast for the period covered by such Purchase Orders (each such Purchase Order, a "**Firm Order**"), and MannKind shall confirm acceptance of each Firm Order within 5 days of receipt of such Firm Order, unless a valid reason that specifically excuses performance under this Agreement exists and is described to United Therapeutics within such 5 day period. If MannKind fails to confirm acceptance of a Firm Order within 5 days of receipt, then such Firm Order shall be deemed to have been accepted by MannKind, and MannKind shall provide confirmation in writing upon request of United Therapeutics. MannKind shall additionally exercise Commercially Reasonable Efforts to Manufacture any quantities of Semi-Finished Product or Product requested by Purchase Order that equal up to 120% of the quantities specified in the Rolling Forecast for such period ("**Excess Order Quantity**"), and shall acknowledge its ability to do so within the same 5 day acceptance period allotted for Firm Orders.

2.5.3 The parties agree that the terms and conditions of this Agreement shall supersede any term or condition in any purchase order, confirmation or other document furnished by United Therapeutics or MannKind that is in any way inconsistent with the terms and conditions of this Agreement.

2.6 **Storage, Inventory Reports, Risk of Loss, Title Transfer, Shipment Orders, and Physical Transfer of Product and Semi-Finished Product to United Therapeutics.**

2.6.1 *Storage of Product, Semi-Finished Product, and Product Materials*. At all times following completion of Manufacture and until Product or Semi-Finished Product is physically

transferred to United Therapeutics or United Therapeutics' shipping vendor, MannKind shall be solely responsible, directly or through an approved Third Party Manufacturing Services provider listed in Appendix D, for storing the Product in complete accordance with the Product Specifications or Semi-Finished Product Specifications, cGMP, the Quality Agreement, and all Applicable Laws, in the Cold Storage Area, or in other storage area mutually approved by the parties in writing. MannKind shall additionally be responsible for storing Product Materials whenever in MannKind's possession in complete accordance with Product Materials Specifications, cGMP, the Quality Agreement, and all Applicable Laws. Without diminishing its obligations under this Agreement, MannKind shall promptly notify United Therapeutics of any deviations in storage conditions or other circumstances that could potentially give rise to quality concerns. MannKind shall take all necessary and appropriate actions, including and in addition to all specific obligations of MannKind with respect to storage of Product, Semi-Finished Product, and Product Material storage set forth in this Agreement, to protect Product, Semi-Finished Product, and Product Material from loss or damage while in MannKind's possession.

2.6.2 *Transfer of Title*. Title to Semi-Finished Product will transfer to United Therapeutics at the time of quality release by United Therapeutics as evidenced by issuance of Release Certificate, and shall remain with United Therapeutics through conversion to Product and physical transfer of Product to United Therapeutics (or alternatively until physical transfer of Semi-Finished Product directly to United Therapeutics). The parties will reasonably cooperate with respect to any documentation required to transfer title to the Semi-Finished Product and Product.

2.6.3 *Insurance Responsibilities*. The respective insurance responsibilities of the parties with respect to Product, Semi-Finished Product, and Product Materials, are as set forth in Appendix F.

2.6.4 *Shipment Orders*. For each physical transfer of Product or Semi-Finished Product to United Therapeutics or its shipping vendor, United Therapeutics will provide MannKind with a Shipment Order at least 7 days prior to the proposed date of pickup. MannKind shall confirm availability for the proposed pickup time within 2 business days, and United Therapeutics shall arrange for pickup of the Product or Semi-Finished Product at the designated time and place, and shall be responsible for all transportation costs of Product and Semi-Finished Product upon physical transfer to United Therapeutics.

2.6.5 *Certificates of Conformance*. With each transfer of Product or Semi-Finished Product, MannKind shall provide the Certificate of Conformance and a copy of the Firm Order (or other ordering document if applicable). If the required documentation is not supplied United Therapeutics may reject the Product and/or Semi-Finished Product.

2.6.6 *Inventory Reports*. MannKind shall provide United Therapeutics with an Inventory Report each month during the Term, by the close of business on the third business day

of each month, such Inventory Report being current as of close of business on the final business day of the immediately preceding month. The Inventory Report shall be provided by email to **[***]**, and/or such additional email addresses as instructed by United Therapeutics in writing from time to time.

2.6.7 *Serialization*. The parties shall cooperate with each other to implement serialization of Product using bi-dimensional codes to allow the tracking of Product from the Facility to United Therapeutics' end-users. MannKind's costs of such serialization shall be included in COGs.

2.7 **Failure to Supply.**

2.7.1 Without diminishing any obligation of MannKind to Supply Product and Semi-Finished Product pursuant to the terms of this Agreement, or any right of United Therapeutics to require such Supply, if MannKind anticipates it will be unable to Manufacture or Supply Product or Semi-Finished Product in the quantities specified in a Firm Order, in the Rolling Forecast, or in a Shipment Order, MannKind shall immediately notify United Therapeutics of such anticipated shortfall in writing. Such notice shall describe the reason for the anticipated shortfall and the extent to which MannKind will not meet the requirements of such Rolling Forecast, Firm Order, and/or Shipment Order, and provide United Therapeutics with the expected date of Manufacture or Supply of such Product or Semi-Finished Product.

2.7.2 If it is commercially reasonable for United Therapeutics to accept a new date for delayed Manufacture or Supply of Product or Semi-Finished Product, or if such inability to Manufacture or Supply is not due to a Supply Failure, United Therapeutics shall issue an amended Firm Order or Shipment Order reflecting such new delivery date.

2.7.3 Notwithstanding anything else to the contrary, any Supply Failures, anticipated Supply Failures, or anticipated shortfalls in Supply or Manufacture of Product or Semi-Finished Product, shall be immediately escalated to the MSC.

2.7.4 Without diminishing MannKind's duty to mitigate any Supply Failure or anticipated Supply Failure, in the event of a Supply Failure or an anticipated Supply Failure that cannot be resolved within 30 days of escalating such Supply Failure or anticipated Supply Failure to the MSC as required hereunder, United Therapeutics may elect to have its own employees or contractors enter the Facility to continue the Manufacturing and Supply operations, or supplement MannKind's ongoing Manufacturing and Supply operations under the supervision and direction of MannKind's manufacturing leadership team (**"Step-In Right"**). Any expenses incurred by United Therapeutics will be used to offset any future payments otherwise due to MannKind under this Agreement. MannKind will provide reasonable assistance and cooperation to United Therapeutics in connection with the foregoing, in order to ensure a stable supply of Product and Semi-Finished Product. Additionally, if MannKind declares a Force Majeure Event, United Therapeutics may exercise its Step-In Right if it is possible for United Therapeutics to do

so in compliance with Applicable Laws. Upon resolution by MannKind of the root cause of the Supply Failure or anticipated Supply Failure to the reasonable satisfaction of United Therapeutics, United Therapeutics shall cease to exercise its Step-In Right and MannKind shall resume the Manufacturing and Supply of Product and Semi-Finished Product in accordance with this Agreement.

2.8 **Business Continuity Plan.** MannKind shall, with input and reasonable approval of the MSC, develop, implement and keep current, a written plan detailing strategies for responses to and recovery from a range of events with potential to disrupt Manufacture and/or Supply, as necessary to ensure continuity of Manufacture and Supply, and in accordance with reasonable and customary risk management practices in the pharmaceutical and medical device contract manufacturing industry (such written plan, the "**Business Continuity Plan**"). United Therapeutics may, at its sole option and expense, implement a separate business continuity program, including without limitation ensuring adequate backup supply for the Product through Third Party vendors or otherwise.

2.9 **Representations and Warranties of Both Parties.** Each party represents and warrants that:

2.9.1 such party is duly organized and validly existing under the laws of the location of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out such party's obligations hereunder;

2.9.2 the execution, delivery and performance of this Agreement by such party does not conflict with any other 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 authority over it;

2.9.3 it has not used, and shall not use at any time during the term of this Agreement, in any capacity, the services of any person debarred under Applicable Law and further has not used, and will not use at any time during the term of this Agreement, any person who has been convicted of a crime as defined under Applicable Law in connection with any of the services provided under this Agreement;

2.9.4 it shall, at all times, comply with all Applicable Laws relating to its performance under this Agreement, including, but not limited to, those relating to health, safety and the environment, fair labor practices, unlawful discrimination, debarment, anti-corruption and anti-bribery laws; and

2.9.5 each party shall conduct its business and affairs in an ethical manner, consistent with the provisions of its respective Code of Conduct as may be amended from time to time.

Each party shall promptly notify the other in writing, within not more than 7 calendar days, of any facts or circumstances, whether occurring prior to or after the Effective Date, that cause any of the representations or warranties contained in this section 2.9, or in sections 2.10 or 2.11, to not be true, accurate and/or complete at any time during the term of this Agreement.

2.10 **MannKind Representations, Warranties and Covenants.**

2.10.1 MannKind represents and warrants that the Product and Semi-Finished Product Supplied by MannKind to United Therapeutics hereunder, and the manufacturing, packaging, labeling, storage, destruction (if necessary) and handling of the Products and Semi-Finished Product by MannKind prior to physical transfer to United Therapeutics, comply with the applicable Product Specifications or Semi-Finished Product Specifications as set forth or referenced in the Quality Agreement, the applicable Marketing Approvals, cGMP and Applicable Law, and that it holds the required manufacturing authorization pursuant to the local legal requirements for the Manufacture and Supply of the Products.

2.10.2 MannKind shall not interact directly with government agencies, entities or authorities on behalf of United Therapeutics without the prior written authorization of United Therapeutics. If such interaction with government agencies, entities or authorities is authorized in writing, it is agreed that certain due diligence, additional inquiries, and potentially other agreed upon measures will be required prior to or coincident with such authorization being granted and that the Agreement may also need to be amended to include certain standard provisions including regular satisfactory reviews and updated due diligence by United Therapeutics and its agents relating to MannKind. Nothing in this Section shall prevent MannKind from interacting directly with government agencies, entities or authorities without the prior written authorization of United Therapeutics on its own behalf or in respect of Facility-related matters that are not solely or specifically associated with Product or Semi-Finished Product.

2.11 **United Therapeutics Representations, Warranties and Covenants.**

2.11.1 United Therapeutics represents and warrants that it has and will maintain throughout the Term of this Agreement all permits, licenses, registrations and other forms of governmental authorization and approval as required by Applicable Laws to perform its obligations hereunder.

2.11.2 United Therapeutics represents and warrants that the API supplied by United Therapeutics shall comply with the applicable specifications as set forth or referenced in the Quality Agreement, applicable current Marketing Approvals, cGMP, and Applicable Law. United Therapeutics further warrants that such API is free of all liens, encumbrances, and defects in title, and shall not be adulterated or misbranded in accordance with the Food, Drug, and Cosmetic Act.

2.12 **Testing, Disposition and Acceptance, and Investigations for Claimed Non-Conformance.**

2.12.1 Responsibilities for testing (release and stability), disposition and acceptance of Product and Semi-Finished Product are set forth or referenced in the Quality Agreement.

2.12.2 In addition to any rights to reject Product and Semi-Finished Product set forth in the Quality Agreement, United Therapeutics shall have the right to reject Product or Semi-Finished Product that is affected by a Latent Defect within 12 months of the date of release of such Product or Semi-Finished Product by United Therapeutics.

2.12.3 MannKind and United Therapeutics agree to conduct any investigations into any deviations, non-conformance, or other cause for non-acceptance by United Therapeutics of any Product or Semi-Finished Product in accordance with the Quality Agreement. To the extent not specified in the Quality Agreement, all such investigations shall be conducted promptly and in a commercially reasonable manner. If MannKind does not agree with United Therapeutics' claim of noncompliance with the Product Specifications, Semi-Finished Product Specifications, or other defect resulting in non-acceptance, the parties shall designate a mutually acceptable Third Party laboratory, directly or through other mutually agreed to Third Party capable of assisting parties resolve contractual disputes of a technical nature (such Third Party laboratory or other Third party, the "**Third Party Adjudicator**"), to make a determination on the compliance or non-compliance of the Product or Semi-Finished Product using samples obtained from the allegedly non-compliant or defective batch. The decision of the Third Party Adjudicator shall be binding on the parties and all expenses related to such Third Party investigation shall be borne by United Therapeutics if the Product or Semi-Finished Product is deemed conforming, or by MannKind if the Product or Semi-Finished Product is deemed non-conforming. MannKind and United Therapeutics further agree that any time periods for acceptance set forth in this Agreement or the Quality Agreement shall toll during any investigations related to conformance of such Product or Semi-Finished Product.

2.12.4 MannKind shall replace any Product or Semi-Finished Product that is properly rejected pursuant to Section 2.12.2 or adjudicated to be non-conforming pursuant to Section 2.12.3 at MannKind's sole expense, including any related Staffing Payments and Packaging Services, except that United Therapeutics shall supply API free of charge. MannKind shall reimburse United Therapeutics for transportation charges related to transportation of such rejected Product and Semi-Finished Product, whether such charges are otherwise the responsibility of United Therapeutics or MannKind. United Therapeutics may in its sole discretion require a credit or refund in lieu of Product or Semi-Finished Product replacement. The remedies set forth in this section 2.12.4 shall be in addition to MannKind's indemnification obligations under section 7.1.

2.12.5 If rejection of Product or Semi-Finished Product occurs after physical transfer to United Therapeutics, United Therapeutics shall dispose of such rejected Product or Semi-Finished Product at MannKind's expense; provided, that if MannKind does not agree with United Therapeutics claim of noncompliance of such Product or Semi-Finished Product, MannKind may require a Third Party assessment in accordance with section 2.12.3. Neither party shall dispose of rejected Product or Semi-Finished Product until the other party provides written acknowledgement of the cause for rejection, or until

after a final determination is made by a Third Party Adjudicator that such Product or Semi-Finished Product is non-compliant. Provided that if United Therapeutics agrees to bear the cost of replacement and destruction, United Therapeutics may proceed with destruction without assessment by such Third Party Adjudicator.

3. BUDGET, PRICE, OTHER DIRECT PAYMENTS, PASS-THROUGH PAYMENTS, AND INVOICING

3.1 **Purchase Price**. In general, MannKind shall Supply Product and Semi-Finished Product to United Therapeutics at an aggregate amount not to exceed COGs plus the Margin (such total, the "**Price**"). Subject to Section 3.2, the Price will be invoiced by MannKind on a per-item basis for Product and Semi-Finished Product as set forth in Appendix B. In addition, United Therapeutics shall reimburse MannKind for any Packaging Services as incurred, as provided for in Appendix D, subject to a mutually agreed estimated budget for such Packaging Services as part of the Annual Budget.

3.2 **Staffing Payments**. From April 1, 2021 until December 31, 2022 (or such later date as may be agreed by the parties), United Therapeutics shall reimburse MannKind monthly for the Staffing Payment as part of the Annual Budget in accordance with Appendix E, subject to a mutually agreed estimated budget for such Staffing Payments. During the period of time that United Therapeutics is making Staffing Payments, the per-item Prices shall exclude the components of COGs that are being invoiced in such Staffing Payments.

3.3 **Invoices.** MannKind shall send all invoices to United Therapeutics by email to **[***]**, with cc to **[***]**, and/or such additional email addresses as instructed by United Therapeutics in writing from time to time, such invoice including the PO number provided by United Therapeutics, and any other information reasonably requested by United Therapeutics, and in a form reasonably specified by United Therapeutics. United Therapeutics shall have no obligation to pay incomplete invoices. MannKind shall submit invoices as follows:

3.3.1 On the fifth business day of each month, MannKind shall invoice United Therapeutics for the Staffing Payment in respect of the preceding month;

3.3.2 On the fifth business day of each month, MannKind shall invoice United Therapeutics for the total charges for Packaging Services incurred by MannKind in the preceding month; and

3.3.3 Upon transfer of title in accordance with section 2.6.2, the Price of Product and/or Semi-Finished Product specified in the applicable Release Certificate, stating the name, item Number, and quantity of each Product and/or Semi-Finished Product; provided, however, that MannKind shall bundle invoices under this section 3.3.3 whenever possible and deliver such bundled invoices to United Therapeutics no more than twice per calendar month.

3.4 **Payment Terms**. Unless provided otherwise in section 3.3, United Therapeutics shall pay each undisputed invoice no later than 45 days after receipt. All payments shall be in U.S.

dollars. Payments by United Therapeutics to MannKind, including, but not limited to, any payment for the Price of Product or Semi-Finished Product, shall not be deemed as an acknowledgement by United Therapeutics that MannKind has performed properly or that MannKind has fulfilled its contractual obligations under this Agreement, regardless of whether the respective payments were made with any reservation.

3.5 **Taxes.** All Prices shall be exclusive of taxes, levies, and duties, whether direct or indirect, including, without limitation, sales tax, corporate income and transfer taxes, as may be imposed on MannKind, or for which MannKind is required to act as withholding agent by any governmental body or authority on the subject matter of this Agreement. Such taxes shall be set forth separately on each applicable invoice and payable by United Therapeutics.

3.6 **No Double-Counting.** Notwithstanding anything to the contrary in this Agreement (including Appendix B), MannKind shall not charge United Therapeutics under this Agreement for any costs or activities separately required to be reimbursed and/or paid for by United Therapeutics under the License Agreement, the Cap-Ex Letter Agreement, the Clinical Supply Agreement, or any other agreement between the parties. Additionally, notwithstanding anything to the contrary in this Agreement, MannKind shall not charge United Therapeutics for any item or service under this Agreement where such item or service is separately compensated by United Therapeutics. If such double counting of any item or service is discovered by either party, such party shall notify the other party, and MannKind shall promptly refund United Therapeutics for any overcharge related to such double counting.

4. QUALITY AND REGULATORY MATTERS; USE OF APPROVED SUPPLIERS; CHANGES TO MANUFACTURING PROCESS AND PRODUCT SPECIFICATIONS

4.1 **Quality Agreement**. The Quality Agreement shall govern any quality assurance and quality control issues related to the Manufacture, Supply, and release of Product and Semi-Finished Product, and acceptance, testing, storage, and release of Product Material, under this Agreement. In the event of a conflict between the terms of the Quality Agreement and the terms of section 4 of this Agreement, the provisions of the Quality Agreement shall govern.

4.2 **Use of Approved Suppliers**. MannKind shall only use the Approved Suppliers (i) listed in Appendix D or (ii) approved in accordance with procedures, identified on the MannKind Approved Vendors List (AVL), and the Quality Agreement, to carry out the Manufacturing and Supply under this Agreement, and MannKind shall ensure that any conditions set forth in this Agreement and the Quality Agreement are met with respect to such Approved Suppliers. Notwithstanding anything to the contrary set forth in this section 4.2 or the Quality Agreement, MannKind shall notify United Therapeutics in writing in the event of any change in any Approved Supplier.

4.3 **Changes to the Manufacturing Process.** Neither party shall not make any changes to the Manufacturing process for Semi-Finished Product or Product without the other party’s

prior written approval prior, in accordance with the requirements set forth or referenced in the Quality Agreement. Such changes include, but are not limited to: (i) any method, process, or equipment used for Manufacturing any Product or Semi-Finished Product; (ii) the site of Manufacture of the Product or Semi-Finished Product; (iii) the storage conditions or location of the Product or Semi-Finished Product; and (iv) any other changes that could have an impact on the quality, regulatory status, or legal status of the Product or Semi-Finished Product.

4.4 **Changes to Product Specifications or Semi-Finished Product Specifications**. Any changes to the Product or Semi-Finished Product Specifications will be made in accordance with the requirements set forth or referenced in the Quality Agreement. This includes, but is not limited to, changes needed to satisfy regulatory requirements under Marketing Approvals and Applicable Laws throughout the Territory, including any such Marketing Approvals that arise after the Effective Date.

4.5 **Regulatory Responsibilities.** United Therapeutics shall be responsible for any Regulatory Filings related to Marketing Approvals of the Product, and MannKind shall be responsible for any Regulatory Filings related to the Facility as required by Applicable Law. If a change is required as a result of changes to Applicable Law or the order of any Regulatory Authority, the parties shall cooperate in good faith to implement the applicable change as soon as reasonably practicable. United Therapeutics shall be responsible for any expenses related to changes to Product Specifications Semi-Finished Product Specifications, whether incurred by United Therapeutics, or by MannKind, except for changes that are carried out at MannKind's request, for MannKind's benefit.

4.6 **Retention Samples**. MannKind shall retain samples of each lot of Product and Semi-Finished Product in accordance with the requirements set forth or referenced in the Quality Agreement.

4.7 **Validation and Maintenance**. MannKind shall ensure that all facilities, utilities, equipment and the processes utilized to Manufacture the Product and Semi-Finished Product, including without limitation the Existing Equipment and the Expansion Equipment, are satisfactorily validated and maintained in compliance with cGMP and the Quality Agreement. The costs of validation and maintenance shall be allocated to COGs in accordance with GAAP.

4.8 **Marketing Approvals**. United Therapeutics shall be responsible for any actions necessary to obtain and maintain the Marketing Approvals necessary to commercialize the Product, in accordance with the standards and diligence requirements set forth in the License Agreement, provided that United Therapeutics shall not, as result of this Agreement, carry any additional obligation to obtain Marketing Approval for or commercialize the Product.

4.9 **Audit Rights.**

4.9.1 *Records*. During the Term of this Agreement, and for at least two years thereafter (or such longer period as may be required by Applicable Law), MannKind shall maintain complete and systematic written records of its business operations in connection with the Manufacture and Supply of the Product; provided, however, records relating to quality and Manufacturing processes and control steps shall be retained for a minimum of seven years from the end of the Term, or such longer period as may be required by Applicable Law or the Quality Agreement.

4.9.2 *Annual Audits*. United Therapeutics may, using its personnel and its Third Party agents, conduct an annual audit of the Facility, Cold Storage Area, Product and Semi-Finished Product inventory, and Product Material inventory, and any records maintained by MannKind related to the Product, Semi-Finished Product, Product Material, or inventory, to confirm compliance with MannKind's obligations hereunder; provided, however, that any audit of financial records pursuant to this Section shall be conducted only by a Third Party agent acceptable to MannKind and not by United Therapeutics personnel. United Therapeutics shall notify MannKind in writing of any planned audit along with proposed dates and times, and MannKind and United Therapeutics shall reasonably cooperate to schedule such audit at a mutually agreeable date and time; provided that such audit shall be scheduled within 60 days of United Therapeutics notice, unless United Therapeutics agrees to a longer timeframe. Such audits shall be conducted at United Therapeutics' cost, and shall have a duration of up to 3 days at United Therapeutics discretion, unless a longer period is required due to findings that require further investigation.

4.9.3 *For Cause Audits*. United Therapeutics may additionally conduct "for-cause" audits at the Facility at any time to address suspected Product quality or safety concerns potentially related to the Manufacture of the Product. Product quality or safety concerns include, without limitation, issues related to Product stability, out of specification test results, Product efficacy, mislabeling, container failures, device performance, potential raw material contamination, and adverse event and product complaint reporting, no matter how such observations are discovered. United Therapeutics shall notify MannKind in writing in advance of any for cause audit and the Parties shall mutually determine the timing of the audit, provided the audit shall not be more than 30 days from the date of United Therapeutics' request unless United Therapeutics agrees to a longer deadline, or unless safety considerations warrant a more immediate audit. Such audits shall be conducted at United Therapeutics' cost.

4.9.4 The rights and obligations of United Therapeutics and MannKind, respectively, set forth in this section 4.9, shall supplement, and not diminish, any quality related rights set forth in the Quality Agreement, including any audit rights, obligations to retain quality related documents, and otherwise.

4.10 **Product Recalls.**

4.10.1 Without limiting the rights and obligations of the parties set forth in this Agreement related to Product recalls, the parties shall conduct any Product recalls in accordance with the requirements set forth in the Quality Agreement.

4.11 **Support for Regulatory Filings.**

4.11.1 MannKind shall provide to United Therapeutics all information related to the Manufacture of the Product that is necessary for filing and/or maintaining the NDA for the Product, or as otherwise necessary to obtain and maintain Marketing Approval for the Product in any jurisdiction within the Territory. United Therapeutics will own and maintain the NDA or other Marketing Approval for the Product, including the chemistry, manufacturing, and control data supporting the NDA or other Marketing Approval, whether such data is physically possessed by United Therapeutics or MannKind or both, and United Therapeutics shall have the right to direct the submission of such data to Regulatory Authorities as necessary to support any Regulatory Filing.

4.11.2 MannKind will own and maintain the DMF for the Product and any relevant chemistry, manufacturing, and control data, including facility information, supporting the DMF. United Therapeutics shall supply Product information to MannKind necessary to maintain the DMF.

4.11.3 This Agreement shall not modify the provisions of the License Agreement related to coordination and support for Regulatory Filings and other regulatory responsibilities.

5. **CONFIDENTIALITY**

5.1 Article 8 of the License Agreement is incorporated into this Agreement by reference, and shall apply to any Confidential Information exchanged in connection with this Agreement.

5.2 Sections 8.4 and 8.5 of the License Agreement shall apply to this Agreement, as if this Agreement were included within the defined term “Agreement” under the License Agreement, provided that the first sentence of section 8.5(a) of the License Agreement shall not apply to this Agreement.

6. **INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER RIGHTS**

6.1 The provisions set forth in Article 9 of the License Agreement, and any related provisions set forth in any section of the License Agreement, related to definition of, ownership of, prosecution of, cooperation related to, maintenance of, enforcement of, notifications related to, settlement related to, and other obligations related to Intellectual Property, are incorporated by reference into this Agreement, and shall apply to any Intellectual Property related to this Agreement whether such Intellectual Property is developed during the Term or prior to the Term.

6.2 Nothing in this Agreement shall limit United Therapeutics’ rights, or MannKind’s obligations, to prompt and reasonable technology transfer assistance (“TTA”) upon

request, as set forth in the License Agreement; and the parties further agree that such TTA shall extend to any processes and procedures developed as necessary for MannKind to carry its Manufacturing obligations under this Agreement.

7. INDEMNIFICATION, LIMITATION OF LIABILITY, AND INSURANCE

7.1 **Indemnification by MannKind**. In addition to any remedies expressly set forth in this Agreement related to non-conforming Product or Semi-Finished Product or otherwise, MannKind shall indemnify and hold harmless each of United Therapeutics and its Affiliates and the shareholders, directors, officers, and employees of such entities, and the successors and assigns of any of the foregoing ("**United Therapeutics Indemnitees**"), from and against any and all losses, liabilities, damages, penalties, fines, costs, and expenses (including reasonable attorneys' fees and other expenses of litigation) ("**Losses**") from any claims, actions, suits, or proceedings brought by a Third Party ("**Third Party Claims**") incurred by any United Therapeutics Indemnitee, arising from, or occurring as a result of: (i) negligence or willful misconduct of MannKind, including its Affiliates, in connection with performing its obligations or exercising its rights under this Agreement; or (ii) any breach of this Agreement by MannKind; or (iii) the Manufacture or Supply of Product by MannKind; except to the extent such Third Party Claim falls within the scope of the indemnification obligations of United Therapeutics set forth in section 7.2.

7.2 **Indemnification by United Therapeutics**. 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 ("**MannKind Indemnitees**"), from and against any and all Losses, from any **Third Party Claim**, incurred by any MannKind Indemnitee, arising from, or occurring as a result of: (i) negligence or willful misconduct of United Therapeutics, including its Affiliates, in connection with performing its obligations or exercising its rights under this Agreement; (ii) any breach of this Agreement by United Therapeutics; or (iii) the distribution and marketing of the Product; except to the extent such Third Party Claim falls within the scope of MannKind's indemnification obligations set forth in section 7.1.

7.3 **Procedure.** Promptly after receipt of any written claim or notice of any action giving rise to a claim for indemnification, the individual or entity seeking indemnification (**"Indemnitee"**) will provide the party providing indemnification (**"Indemnitor"**) with written notice of the claim or action. Failure to so notify the Indemnitor will not relieve the Indemnitor of its indemnification obligations, except to the extent that the failure or delay is prejudicial to the defense of the claim or action. The Indemnitee will provide the Indemnitor with reasonable cooperation and assistance in the defense or settlement of any claim, and grant the Indemnitor control over the defense and settlement of the same, provided that any Indemnitee shall be entitled to participate in the defense of the claim and to employ counsel at its own expense to assist in the handling of the claim, provided that such participation and assistance does not materially hinder or prejudice Indemnitor's ability to conduct such defense. The Indemnitor shall not agree to any

settlement which results in an admission of liability by the Indemnitee without the Indemnitee's prior written consent, which consent shall not be unreasonably withheld or delayed. If the Indemnitor fails to assume the defense of any Claim, or does not diligently pursue such defense, the Indemnitee may retain counsel and assume the defense of such Claim at the cost of the Indemnitor.

7.4 **Insurance Responsibilities and Requirements.**

7.4.1 Each party shall comply with its respective insurance responsibilities and requirements as set forth in Appendix F.

7.5 **Limitation of Liability.**

7.5.1 EXCEPT FOR THIRD PARTY CLAIMS FOR WHICH INDEMNIFICATION IS PROVIDED UNDER THIS AGREEMENT, NEITHER PARTY NOR ITS AFFILIATES SHALL SEEK NOR BE LIABLE FOR ANY INCIDENTAL, PUNITIVE, EXEMPLARY, CONSEQUENTIAL OR INDIRECT LOSS OR DAMAGE, INCLUDING, BUT NOT LIMITED TO LOST SALES, PROFITS OR OPPORTUNITY COSTS OR OTHER SPECIAL DAMAGES, REGARDLESS OF LEGAL THEORY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

8. **TERM AND TERMINATION**

8.1 **Term**. The term of this Agreement (the "**Term**") shall begin on the Effective Date and continue for a period of 5 years. This Agreement shall thereafter be automatically renewed for two-year renewal terms (each such period a "**Renewal Term**") unless a party provides notice to the other party at least 24 months in advance of such renewal that such party does not wish to renew this Agreement.

8.2 **Termination for Cause.** Either party may terminate this Agreement upon notice to the other party if such other party materially breaches this Agreement, and if such breach is not cured within 60 days after the non-breaching party provides written notice describing such material breach to the breaching party, or such additional time reasonably necessary to enable the breaching party to cure such breach provided that the breaching party has initiated reasonable and appropriate actions to remedy the breach, and notifies the non-breaching party of such actions, within the 60 day period. The termination rights provided for under this section 8.2 shall be in addition to the other rights of and remedies available to the terminating party.

8.3 **Bankruptcy**. To the extent permitted by Applicable Law, either party may terminate the Agreement effective immediately with written notice if the other party becomes insolvent or bankrupt assigns its business or assets for the benefit of creditors, permits the appointment of a receiver for its business or assets, becomes subject to a legal proceeding related to insolvency, reorganization or the protection of creditors' rights or otherwise ceases to conduct business in the normal course.

8.4 **Survival.** The following provisions shall survive expiration or termination of this Agreement: section 2.2.4 (last sentence only), section 2.6.1 through 2.6.7, section 4, section 5, for a period of 5 years from expiration or termination of this Agreement, section 6, section 7, section 8, and section 9, for the stated duration or such duration as necessary to ensure neither parties' rights as provided for by this Agreement are unreasonably diminished.

8.5 **Obligations Following Termination**.

8.5.1 Termination or expiration of this Agreement shall not relieve either party from any liability that, at the time of such termination or expiration, has already accrued to the other party, including without limitation any of MannKind's purchases of Product Materials that cannot be cancelled without penalty or reasonably used for any other purpose.

9. **GENERAL PROVISIONS**

9.1 **Disputes/Governing Law/Jury Trial Waiver.** Disputes arising out of this Agreement shall be treated in accordance with Article 14 of the License Agreement. 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 the New York General Obligation Law. The United Nations Convention on Contracts for the International Sale of Goods shall not be applicable to this Agreement. **Each party hereto waives, to the extent permitted by applicable law, any right it may have to a trial by jury in respect to any litigation directly or indirectly arising out of, under or in connection with this Agreement.**

9.2 **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, pandemic or outbreak of contagious disease, 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 whose performance is affected by 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.

9.3 **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.

9.4 **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.

9.5 **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.

9.6 **Severability.** If 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.

9.7 **Entire Agreement.** This Agreement, the License Agreement, the Cap-Ex Letter Agreement and the Quality Agreement constitute the entire agreement between the parties relating to the subject matter hereof and thereof and supersede and cancel all previous express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof and thereof. Each of the parties acknowledges and agrees that in entering into this Agreement, and the documents referred to in it, it does not rely on, and shall have no remedy in respect of, any statement, representation, warranty or understanding (whether negligently or innocently made) of any Person (whether party to this Agreement or not) other than as expressly set out in this Agreement, the License Agreement or the Quality Agreement. Nothing in this clause shall, however, operate to limit or exclude any liability for fraud.

9.8 **Notices.** Any legal notice related to this Agreement will be sent by electronic mail to the party intended as a recipient of such notice at the email address indicated below. A party receiving such notice by email shall reply to such email to acknowledge receipt within 2 business days of receiving such notice, provided that an automatic acknowledgement from such receiving party’s email system shall not constitute such acknowledgement. If the party sending such notice does not receive acknowledgement within such 2-business day period, the party sending such notice shall send such notice by overnight express mail (e.g., Fed-Ex, UPS), with delivery acknowledgement, or by courier service, to the postal

address listed below for such party, and such notice shall be deemed to have been received by such party on the business day after such notice was received.

If to United Therapeutics:

Email: **[***]**, with cc to: **[***]**

Postal: **[***]**
with copy to:

[***]

If to MannKind:

Email: **[***]**

Postal: **[***]**

9.9 **Assignment.** This Agreement shall not be assigned nor otherwise transferred, nor may any rights 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 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, upon providing written notice of such assignment or transfer to such non-assigning party. 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 purported assignment of this Agreement in contravention to this section 9.9 shall be null and void.

9.10 **No Partnership or Joint Venture.** Nothing in this Agreement or any action which may be taken pursuant to its terms is intended, or shall be deemed, to establish a joint venture or partnership between 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.

9.11 **Interpretation.** The terms that are defined in this Agreement may be used in the singular or the plural, as the context requires. “Days” means calendar days, unless otherwise specified. Headings are intended only for reference purposes. This Agreement will be interpreted and performed in the English language.

9.12 **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.

9.13 **Inference of MannKind's Obligations With Respect to Approved Suppliers.** The terms "MannKind shall" or "MannKind will" or the like, shall be deemed to be followed by the words "or MannKind's designated Approved Supplier will" or "or "MannKind's designated Approved Supplier shall" or "MannKind shall require that its designated Approved Supplier shall" or the like, with respect to MannKind's Manufacturing and Supply obligations herein.

[Signature page follows]

UNITED THERAPEUTICS CORPORATION	MANNKIND CORPORATION
By:/s/ Patrick Poisson	By:/s/ Joe Kocinsky
Name:Patrick Poisson	Name:Joe Kocinsky
Title:EVP, Technical Operations	Title: Chief Technology Officer

APPENDIX A
PRODUCT AND SEMI-FINISHED PRODUCT DESCRIPTIONS AND SPECIFICATIONS

[***]

APPENDIX B
PRICE AND PRICE ADJUSTMENTS

[***]

APPENDIX C
CARTRIDGE MANUFACTURING CAPACITY

[***]

APPENDIX D
APPROVED SUPPLIERS

[***]

APPENDIX E
STAFFING PAYMENTS

[***]

APPENDIX F
INSURANCE RESPONSIBILITIES AND REQUIREMENTS

A. MannKind's Insurance Responsibilities.
MannKind shall be responsible for obtaining and maintaining at all times during the effective term of this Agreement all risk property insurance covering the Facility, and all equipment used to manufacture Product and Semi-Finished Product at the Facility other than the Expansion Equipment. MannKind shall additionally be responsible for insuring any Product Materials other than API, and any Semi-Finished Product prior to quality release of such Semi-Finished Product by United Therapeutics.

B. United Therapeutics' Insurance Responsibilities.
United Therapeutics shall be responsible for obtaining and maintaining at all times during the effective term of this Agreement all risk property insurance covering the Expansion Equipment, API stored at the Facility, Semi-Finished Product from the time of quality release by United Therapeutics onward, and all Product.

C. Insurance Requirements.
At all times during the effective term of this Agreement and for five years thereafter, each party shall each maintain, at such party's own cost and expense, the following insurance coverages:

(i) **[***]**

(ii) **[***]**

(iii) **[***]**

(iv) **[***]** and

(v) any other insurance required to comply with any Applicable Laws.

Each party shall procure the foregoing coverages from insurance companies of recognized financial responsibility reasonably acceptable to the other party. Additionally, each party shall provide the other party with a certificate of insurance evidencing the coverages required by this Appendix F, upon execution of the CTA, and following each anniversary of the Effective Date, in each instance at the request of the other party.

Exhibit 10.2

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT MANNKIND CORPORATION TREATS AS PRIVATE OR CONFIDENTIAL.

FIRST AMENDMENT

TO

COMMERCIAL SUPPLY AGREEMENT

This amendment is effective the last date signed by a party, 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.

WHEREAS, the parties to this amendment entered into a Commercial Supply Agreement effective as of August 12, 2021 (as amended from time to time, the "**Agreement**"), and the parties now wish to amend the Agreement as set forth below.

NOW, THEREFORE, in consideration of the terms and conditions specified herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereby agree as follows:

1. **AMENDMENT**.

   a. The second sentence of Section 1.11 (*Cost of Goods*) is hereby amended and replaced with the following sentence:

   In addition, COGs will include an annual facility utilization expense (or rent) of $**[***]** (increasing to $**[***]** on December 1, 2021 and thereafter) per square foot for the portion of the Facility allocated to activities under this Agreement; provided, however, that such facility utilization expense shall not be subject to the Margin.

   b. Section 8.1 (*Term*) of the Agreement is hereby amended and restated in its entirety as follows:

   8.1 Term. The term of this Agreement (the "**Term**") shall begin on the Effective Date and continue until December 31, 2031. This Agreement shall thereafter be automatically renewed for two-year renewal terms (each such period a "**Renewal Term**") unless: (a) United Therapeutics provides notice to MannKind at least 24 months in advance of such renewal that United Therapeutics does not wish to renew this Agreement; or (b) MannKind provides notice to United Therapeutics at least 48 months in advance of such renewal that MannKind does not wish to renew this Agreement

2. **GENERAL.** All terms of the Agreement that are not specifically modified by this amendment remain in full force and effect. The parties may execute this amendment in counterparts, each of which is deemed an original for all purposes, and which together will constitute the same instrument. The parties may execute this amendment by electronic means (electronic signature through generally recognized e-signature vendors), by scanned pdfs of wet-ink signed documents, or by return of originals.

* **

Signature page follows

IN WITNESS WHEREOF, the parties have caused this amendment to be signed by their duly authorized representatives as of the date indicated below.

UNITED THERAPEUTICS CORPORATION

By:/s/ Patrick Poisson

Name:Patrick Poisson

Title:EVP, Technical Operations

Date:October 15, 2021

MANNKIND CORPORATION

By:/s/ Joe Kocinsky

Name:Joe Kocinsky

Title:Chief Technology Officer

Date:October 16, 2021

Exhibit 10.3

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT MANNKIND CORPORATION TREATS AS PRIVATE OR CONFIDENTIAL.

PURCHASE AND SALE AGREEMENT

Between

MANNKIND CORPORATION

"Seller"

and

1 CASPER, LLC

"Buyer"

with Escrow Instructions for

FIRST AMERICAN TITLE INSURANCE COMPANY

"Escrow Holder"

PROPERTY NAME: 1 CASPER STREET

LOCATION: DANBURY, CONNECTICUT

EXHIBITS

PURCHASE AND SALE AGREEMENT

This **PURCHASE AND SALE AGREEMENT** (as the same may be amended, modified, or supplemented from time to time in accordance with the terms hereof, this "**Agreement**"), dated effective for all purposes as of September 23, 2021, is by and between **MANNKIND CORPORATION**, a Delaware corporation ("**Seller**"), and **1 CASPER, LLC**, a Delaware limited liability company (together with its successors and/or assigns, collectively, "**Buyer**").

ARTICLE I
CERTAIN DEFINITIONS

Section 1.1 Definitions. The parties hereby agree that the following terms shall have the meanings hereinafter set forth, such definitions to be applicable equally to the singular and plural forms, and to the masculine and feminine forms, of such terms:

"**Access Agreement**" means that certain Access Agreement executed as of July 1, 2010, by and among Seller, Wyeth LLC, and Wyeth Holdings Corporation (Wyeth LLC and Wyeth Holdings Corporation are collectively referred to herein as "**Wyeth**"), recorded in the Official Records as Document No. 003950680045, Book 2105, Pages 300-344.

"**Access and Remediation Agreement**" means that certain Access and Remediation Agreement in substantially the form attached as **Exhibit M** hereto.

"**Affiliate**" means any Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with Buyer or Seller, as the case may be. For the purposes of this definition, "control" means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise, and the terms "controlling" and "controlled" have the meanings correlative to the foregoing.

"**Agreement**" shall have the meaning set forth in the preamble.

"**Approval Notice**" shall have the meaning set forth in Section 3.2(c).

"**BSA**" shall have the meaning set forth in Section 6.1(l).

"**Business Day**" shall mean any day other than a Saturday, Sunday or other day on which banks are authorized or required by applicable law to be closed in the States of Connecticut, California, New York or Florida.

"**Buyer**" shall have the meaning set forth in the preamble.

"**Buyer Parties**" means, collectively, Buyer, any Affiliates of Buyer, and their actual and potential investors, lenders, representatives, contractors (including, without limitation, any engineers, architects, bankers, contractors and other professionals), employees and agents of Buyer or any Affiliate of Buyer.

"**Buyer's Certificate**" shall have the meaning set forth in Section 9.4(h).

"**Buyer-Seller Lease**" means that certain Lease Agreement between Buyer and Seller in the form attached hereto as **Exhibit N** and to be entered into and dated as of the Closing Date, whereby Seller shall lease all of the Property from Buyer.

"**CERCLA**" shall have the meaning set forth in the definition of "Environmental Laws."

"**Changed Condition**" shall have the meaning set forth in Section 6.5.

"**Claims**" means any and all losses, damages, claims, causes of action, liens, judgments, damages, costs and expenses, including reasonable third-party attorneys' fees and court costs.

"**Close of Escrow**" shall have the meaning set forth in Section 9.2(a).

"**Closing**" shall have the meaning set forth in Section 9.2(a).

"**Closing Date**" means the date that is thirty (30) days from the Effective Date; provided, however, that Buyer shall have one (1) option to extend the Closing Date for a period of fifteen (15) days upon depositing in escrow with Escrow Holder (on or prior to the date that is thirty (30) days from the Effective Date) an additional deposit in the amount of $500,000.00, which amount shall be a part of the Deposit (resulting in a total Deposit of $1,500,000.00) and shall be credited against the Purchase Price at the Closing and otherwise held in accordance with the terms herein.

"**Closing Document**" shall have the meaning set forth in Section 3.2(f).

"Closing Statement" shall have the meaning set forth in Section 9.5(a).

"Closing Tax Year" shall have the meaning set forth in Section 9.8.

"**Code**" shall have the meaning set forth in Section 5.4.

"**Costs**" shall have the meaning set forth in Section 11.8.

"**CT Transfer Act**" means the Connecticut Property Transfer Act as codified at Connecticut General Statutes §§ 22a-134 et seq., as amended.

"**CT Transfer Act Filings**" means the applicable forms, reports and documents, including for example, a Form III (Real Estate), and an accompanying Environmental Condition Assessment Form and Fee Payment Form to be filed with DEEP within ten (10) days of the Closing, to the extent required for compliance with the CT Transfer Act.

"**Deed**" shall have the meaning set forth in Section 9.3(a).

"**DEEP**" shall mean the Connecticut Department of Energy and Environmental Protection.

"**Deposit**" shall have the meaning set forth in Section 2.3.

"**Disapproval Notice**" shall have the meaning set forth in Section 3.2(c).

"**Disclosure Items**" shall mean those items set forth on **Exhibit C** attached hereto.

"**Due Diligence Activities**" shall have the meaning set forth in Section 3.2(b).

"**Due Diligence Contingency**" shall have the meaning set forth in Section 3.2(a).

"**Due Diligence Items**" shall have the meaning set forth in Section 3.1(a).

"**Due Diligence Period**" shall mean the period from the Effective Date until 12:00 p.m. Eastern time on the fourth (4th) Business Day following the Effective Date.

"**Effective Date**" means the date this Agreement is executed and delivered by the last of Buyer and Seller.

"**Environmental Laws**" means, to the extent applicable, the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended ("**CERCLA**"), 42 U.S.C. §9601 et seq.; the Toxic Substance Control Act, 15 U.S.C. §2601 et seq.; the Hazardous Materials Transportation Act, 49 U.S.C. §5101 et seq.; the Resource Conservation and Recovery Act, 42 U.S.C. §6901, et seq.; the Clean Water Act, 33 U.S.C. §1251 et seq.; the Safe Drinking Water Act, 42 U.S.C. §300f et seq.; the Clean Air Act, 42 U.S.C. §7401 et seq.; Federal Water Pollution Control Act, 33 U.S.C. §§ 1251 et seq.; Clean Air Act, 42 U.S.C. §§ 7401 et seq.; Emergency Planning and Community Right-To-Know Act, 42 U.S.C. §§ 11001 et seq.; Occupational Safety and Health Act, 29 U.S.C. §§ 65 et seq.; Connecticut General Statutes § 22a, including, without limitation, §§ 22a-134 to 22a-134e, and all other applicable federal, state and local laws governing the environment as in effect on the Effective Date, together with their implementing regulations, guidelines, rules or orders as of the Effective Date, and all state, regional, county, municipal and other local laws, regulations, ordinances, rules or orders that are equivalent or similar to the federal and state laws recited above or that purport to regulate Hazardous Materials.

"**Escrow Holder"** means First American Title Insurance Company, with an address of 2777 Summer Street, Stamford, CT 06905, Attention: **[***]**.

"**EUR**" means an "environmental use restriction" as defined in Conn. Gen. Stat. § 22a-133n.

"**Excluded Claim**" shall have the meaning set forth in Section 3.2(i).

"**Excluded Property**" means (a) any documents, materials or information which are subject to attorney/client, work product or similar privilege, which constitute attorney communications, or which are subject to a confidentiality agreement or that Seller is legally required to not disclose, (b) all cash on hand or on deposit in any operating account or other account maintained in connection with the ownership, operation or management of the Real Property, (c) all Trade Fixtures, (d) furniture and equipment located on the Real Property (other than Fixtures), (e) all other personal property placed in the Real Property by Seller and used in connection with Seller's trade or business, (f) any licenses, permits and authorizations presently or hereafter issued to or for the benefit of Seller or its Affiliates in connection with Seller's operation as a going concern, (g) any intangible property whatsoever related to Seller or its Affiliates as a going concern, and (h) any Intellectual Property whatsoever owned or licensed by Seller or its Affiliates.

"**Fixtures**" means Personal Property which is located at and affixed to the Real Property, and any replacement thereof as of the Closing Date.

"**Governmental Entity**" means the various federal, state and local governmental and quasi-governmental bodies or agencies having jurisdiction over Seller, the Real Property or any portion thereof.

"**Hazardous Materials**" means (a) hazardous wastes, hazardous materials, hazardous substances, hazardous constituents, toxic substances or related materials, whether solids, liquids or gases, including, but not limited to, substances defined as "hazardous wastes," "hazardous materials," "hazardous substances," "toxic substances," "pollutants," "contaminants," "radioactive materials", "toxic pollutants", or other similar designations in, or otherwise subject to regulation under the Environmental Laws; and (b) any other substances, constituents or wastes subject to Environmental Law, now or hereafter in effect, including but not limited to (A) petroleum, (B) refined petroleum products, (C) waste oil, (D) waste aviation or motor vehicle fuel and their byproducts, (E) asbestos, (F) lead in water, paint or elsewhere, (G) radon, (H) Polychlorinated Biphenyls (PCBs), (I) urea formaldehyde, (J) volatile organic compounds (VOC), (K) total petroleum hydrocarbons (TPH), (L) benzine derivative (BTEX), and (M) petroleum byproduct.

"Improvements" means the buildings, structures and appurtenances located on the Land.

"**Indemnification Cap**" shall have the meaning set forth in Section 6.2.

"Independent Consideration" shall have the meaning set forth in Section 2.4.

"**Intellectual Property**" means with respect to any Person, collectively, (a) all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret, (b) any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and all goodwill connected with and symbolized by such trademarks, (c) all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same, (d) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how and operating manuals, (e) any and all source code, (f) any and all design rights which may be available to such Person, (g) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified herein, and (h) all amendments, renewals and extensions of any of the foregoing.

"**Known Environmental Condition**" means any Hazardous Materials at, on, under or migrating to or from the Property as of the Closing as described or referenced in the Due Diligence Items, Disclosure Items or in reports or other documents on file with the DEEP, or otherwise publicly available, including any Pre-Existing Environmental Conditions or Post-Sale Environmental Conditions (as those terms are defined in the Access Agreement) that exist as of the Closing.

"**Known Misrepresentation**" shall have the meaning set forth in Section 6.5.

"**Land"** means those certain parcels of land and appurtenances thereto more particularly described on attached **Exhibit A** and which are commonly known as 1 Casper Street, Danbury, CT 06810.

"**Leases**" means all unexpired leases, subleases, licenses, occupancy agreements, and any other agreements, written or oral, for the use, possession, or occupancy of any portions of the Real Property or otherwise relating thereto, as of the Closing Date, together with any renewals, extensions, amendments, modifications or supplements thereto and guarantees thereof and all prepaid rent, tenant security deposits and other deposits, if any, thereunder; provided, however, the Leases shall not include the Buyer-Seller Lease.

"**LEP**" shall have the meaning set forth in Section 2.7(f).

"Licenses and Permits" means, collectively, all licenses, permits approvals, density rights, development rights, certificates, consents, exemptions, decisions, actions, approvals, variances, entitlements, certificates of occupancy, dedications, sewer rights, subdivision maps and entitlements now or hereafter issued, approved or granted by any Governmental Entity in connection with the Real Property, including, without limitation, all curb cut and street opening permits required for vehicular access to and from the Real Property, together with all renewals and modifications thereof, in each case to the extent assignable.

"**Memorandum of ROFR**" means a Memorandum of Right of First Refusal in substantially the form attached as **Exhibit E** hereto.

"**OFAC**" means the U.S. Department of the Treasury's Office of Foreign Assets Control.

"**OFAC List**" means any list of prohibited countries, individuals, organizations and entities that is administered or maintained by OFAC, including: (i) Section 1(b), (c) or (d) of Executive Order No. 13224 (September 23, 2001) issued by the President of the United States (Executive Order Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism), any related enabling legislation or any other similar executive orders; (ii) the List of Specially Designated Nationals and Blocked Persons maintained by OFAC, and/or on any other similar list maintained by OFAC pursuant to any authorizing statute, executive order or regulation; or (iii) a "Designated National" as defined in the Cuban Assets Control Regulations, 31 C.F.R. Part 515.

"**Official Records**" means the office of the Town Clerk of Danbury, Connecticut.

"**Omnibus Assignment**" shall have the meaning set forth in Section 9.3(e).

"**Owner's Affidavit**" shall have the meaning set forth in Section 9.3(k).

"**Patriot Act**" shall have the meaning set forth in Section 6.1(l).

"**Permitted Exceptions**" means and includes all of the following: (a) such state of facts as would be disclosed by a physical inspection of the Property, (b) the lien of taxes and assessments not yet due and payable, (c) any exclusions from coverage set forth in the jacket of any Owner's Policy of Title Insurance or any standard printed exceptions (except to the extent removable upon Seller's delivery of the Owner's Affidavit), (d) any matters arising from any document or instrument delivered

in connection with the transfer contemplated hereby (including without limitation the Deed and the Memorandum of ROFR, which shall be recorded as of the Closing), (e) any exceptions caused by Buyer, its agents, representatives or employees, (f) any exceptions approved or deemed approved in writing by Buyer, (g) any matters appearing in the Title Commitment and approved or deemed approved by Buyer, (h) the anticipated EURs substantially in the form attached as **Exhibit L**, (i) any exceptions arising from matters disclosed on attached **Exhibit C** ("**Disclosure Items**") that are approved or deemed approved during the Due Diligence Period, and (j) matters shown on Schedule B to **Exhibit F** attached hereto or disclosed on the Survey. In no event shall Permitted Exceptions be deemed to include any of Seller's Required Removal Items.

"**Person**" means any individual, partnership, corporation, limited liability company, limited liability partnership, trust or other entity.

"**Property**" means all of Seller's rights, title and interests in and to the Real Property, and all of Seller's right, title and interest in and to all tangible and intangible assets solely relating to the Real Property, including, without limitation, (a) all warranties, claims, and causes of action, (b) all claims and causes of action arising out of or in connection with the Real Property after the Closing Date (but excluding any claims or causes of action of Seller after the Closing arising from its rights under this Agreement or any documents to be delivered at the Closing), (c) the Licenses and Permits, (d) signage rights, utility and development rights and privileges, (e) site plans, surveys, environmental and other physical reports, plans and specifications pertaining to the foregoing; and (f) all licenses, covenants and other rights appurtenant to the Land, including Seller's right, title and interest in and to all development, density and similar rights, rights-of-way, open or proposed streets, alleys, easements, strips or gores of land adjacent to, in front of, abutting, or adjoining the Land, provided, however, that "Property" shall not include the Excluded Property.

"Purchase Price" shall have the meaning set forth in Section 2.2.

"Real Property" means the Land, the Improvements and the Fixtures.

"**Reporting Person**" shall have the meaning set forth in Section 5.4(a).

"**ROFR**" means a Right of First Refusal Agreement in substantially the form attached as **Exhibit D** hereto.

"**Seller**" shall have the meaning set forth in the preamble.

"**Seller Indemnified Party**" or "**Seller Indemnified Parties**" shall have the meaning set forth in Section 3.2(b)(viii).

"**Seller's Certificate**" shall have the meaning set forth in Section 9.3(j).

"**Seller's Required Removal Items**" shall have the meaning set forth in Section 4.1.

"**SRO**" means a self-regulatory organization.

"**Substantial Damage**" shall have the meaning set forth in Section 10.1(c)(i).

"**Survey**" means a new ALTA survey of the Land and Improvements.

"**Surviving Obligations**" means any obligations of Buyer or Seller hereunder that expressly state they will survive termination of this Agreement.

"**Taking**" shall have the meaning set forth in Section 10.3.

"**Title Commitment**" shall have the meaning set forth in Section 4.1.

"**Title Company**" means First American Title Insurance Company, with an address of 2777 Summer Street, Stamford, CT 06905, Attention: **[***]**.

"**Title Documents**" shall have the meaning set forth in Section 4.1.

"**Title Policy**" shall have the meaning set forth in Section 4.5.

"**Trade Fixture**" means a piece of equipment placed on the Real Property which is used in Seller's trade or business.

"**Transaction Costs**" shall have the meaning set forth in Section 5.1.

"**Transfer Act Work**" shall have the meaning set forth in Section 2.7(d).

"**Transfer Tax Forms**" shall have the meaning set forth in Section 9.3(g).

"**United Therapeutics Buildout**" means (a) construction of a lab sample preparation area, which construction work is in progress as of the date hereof, and (b) the following build-out within the existing shell and core of the Improvements to accommodate an expansion of Seller's contract manufacturing capacity at the Property: (i) an approximately 5,000-7,000 square foot cold chain (refrigerated) warehouse, and (ii) approximately 10,000-15,000 square foot area for a spray drying train and a filling and packaging system for pharmaceutical manufacturing, which work is expected to commence in the fourth calendar quarter of 2021 or first calendar quarter of 2022. For clarity, the United Therapeutics Buildout includes any modifications to the building systems and Fixtures as necessary or appropriate to complete such alterations.

"**Unsafe Conditions**" shall have the meaning set forth in Section 10.1(b).

Section 1.2 Rules of Construction. Article and section captions used in this Agreement are for convenience only and shall not affect the construction of this Agreement. All references to "Article" or "Section" without reference to a document other than this Agreement, are intended to designate articles and sections of this Agreement, and the words "herein," "hereof," "hereunder," and other words of similar import refer to this Agreement as a whole and not to any particular article or section, unless specifically designated otherwise. The use of the term "including" means in all cases "including but not limited to," unless specifically designated otherwise. No rules of construction against the drafter of this Agreement shall apply in any interpretation or enforcement of this Agreement, any documents or certificates executed pursuant hereto, or any provisions of any of the foregoing.

ARTICLE II
PURCHASE AND SALE AGREEMENT; PURCHASE PRICE

Section 2.1 **Purchase and Sale Agreement**. Seller agrees to sell, transfer, assign and convey to Buyer, and Buyer agrees to purchase, accept and assume, subject to the terms and conditions stated herein, all of Seller's right, title and interest in and to the Property.

Section 2.2 **Purchase Price**. Buyer shall pay Seller the purchase price ("**Purchase Price**") in immediately available funds at Closing. The Purchase Price shall be equal to the sum of One Hundred Two Million Two Hundred Fifty Thousand and 00/100 United States Dollars (US$102,250,000.00). The Purchase Price, together with such other funds as may be necessary to pay Buyer's required payments hereunder, subject to closing adjustments, shall be deposited with the Escrow Holder on or before 3:00 p.m. Eastern Time on the Closing Date in accordance with this Agreement. The Purchase Price shall be paid to Seller upon satisfaction of all conditions precedent to the Closing as described herein.

Section 2.3 **Deposit**. Within one (1) business day of the Effective Date, Buyer shall deposit in escrow with Escrow Holder a deposit in the amount of One Million and 00/100 United States Dollars (US$1,000,000.00) (together with any interest earned thereon, the "**Deposit**"). All sums constituting the Deposit shall be held in an interest-bearing account as directed by Buyer, and interest accruing thereon shall be held for the account of the party entitled to the benefit of the Deposit pursuant to this Agreement. If the sale of the Property as contemplated hereunder is consummated, the Deposit plus interest accrued thereon shall be credited against the Purchase Price. If Buyer delivers a Disapproval Notice during the Due Diligence Period, then Buyer shall be deemed to have elected to terminate this Agreement under Section 3.2(c) in which event this Agreement shall automatically terminate and the parties shall have no further obligation to each other, except for any Surviving Obligations. Following such termination, Escrow Holder shall return to Buyer the Deposit. If Seller defaults under this Agreement or the sale of the Property is not consummated because of the failure of any condition precedent set forth in Section 9.2(c) (except in the event that such condition precedent was not satisfied because of a default by Buyer under this Agreement, without any default of Seller), then the Deposit plus interest accrued thereon shall immediately be returned to Buyer. If the sale is not consummated solely because of Buyer's default hereunder (including without limitation Buyer's failure to deliver any of the items required pursuant to Section 9.4), then the Deposit shall be paid to and retained by Seller as liquidated damages as Seller's sole remedy pursuant to Section 5.2 below.

Section 2.4 **[Intentionally Deleted]**

Section 2.5 **Indivisible Economic Package**. Buyer has no right to purchase, and Seller has no obligation to sell, less than all of the Property, it being the express agreement and understanding of Buyer and Seller that, as a material inducement to Seller and Buyer to enter into this Agreement, Buyer has agreed to purchase, and Seller has agreed to sell, all of the Property, subject to and in accordance with the terms and conditions hereof.

Section 2.6 **Right of First Refusal**. At Closing, Buyer and Seller shall enter into the ROFR and cause a duly executed and acknowledged Memorandum of ROFR to be recorded in the Official Records.

Section 2.7 CT Transfer Act Provisions.

(a) The parties acknowledge that Wyeth is currently performing environmental investigation and remediation at the Property pursuant to the CT Transfer Act and the Access Agreement and that such environmental investigation and remediation being performed by Wyeth will continue after the Closing. The parties further acknowledge that Seller and Wyeth entered into the Access Agreement and that the Access Agreement is binding upon successors and assigns.

(b) The parties agree that the Land is an "establishment" as defined by the CT Transfer Act and that consummation of the transaction contemplated by this Agreement will trigger the requirements of the CT Transfer Act. To the extent required by the CT Transfer Act, Seller shall (i) prepare the CT Transfer Act Filings; (ii) provide drafts of the CT Transfer Act Filings to Buyer at least five (5)[1] days prior to the Closing for Buyer's review and comment; and (iii) file the fully executed and notarized CT Transfer Act Filings with the DEEP within ten (10) days of the Closing along with the DEEP required filing fee.

(c) Seller agrees to sign the CT Transfer Act Filings as the "Transferor" and have Seller or an Affiliate sign the relevant CT Transfer Act Filings as the "Certifying Party" (as those terms are defined in the CT Transfer Act). Buyer agrees to sign the CT Transfer Act Filings as the "Transferee" (as defined in the CT Transfer Act) and cooperate with Seller in order to permit the timely and complete submittal of the CT Transfer Act Filings to DEEP.

(d) As between Seller and Buyer, Seller agrees to perform in good faith the obligations of the "Certifying Party" under the CT Transfer Act. Buyer agrees that Seller and Wyeth may satisfy their obligations under the CT Transfer Act in order to meet the industrial/commercial (as opposed to residential) criteria established pursuant to the CT Transfer Act and Connecticut Remediation Standard Regulations, R.C.S.A. §§ 22a-133k-1 through 3, as amended (**"Transfer Act Work"**

[1] NTD: We will endeavor to provide sooner, but in light of a 30 day sign and close window, providing the Transfer Act filing 10 days prior to the closing would only give the environmental consultant about two weeks to prepare the draft submittal, which is tight.

). For the avoidance of doubt, Seller and Wyeth shall have the ability to use any and all risk-based or other remedial alternatives in performing the Transfer Act Work that are: (1) permitted pursuant to the Access Agreement; or (2) do not negatively affect the continued use of the Property for industrial or commercial purposes and do not have ongoing costs or monitoring obligations (except for such ongoing costs or monitoring obligations that are (a) the responsibility of Wyeth pursuant to the Access Agreement, (b) assumed in writing by Seller or a third party affiliated with Seller, or (c) agreed to in advance by Buyer in writing, such agreement not to be unreasonably denied), including, but not limited to, the use of institutional and engineering controls such as: (i) prohibition on disturbance of soil rendered inaccessible by pavement or clean fill; (ii) prohibition on the disturbance or demolition of buildings or structures, which may be used to render the soil below a building or structure inaccessible or environmentally isolated; and (iii) the anticipated EURs shown on **Exhibit L**.[2]

(e) Buyer agrees to fully and timely cooperate with Seller in connection with Seller's and Wyeth's performance of the Transfer Act Work, which cooperation shall include, without limitation, providing access to the Property pursuant to the terms of the Access Agreement between Seller and Wyeth and an Access and Remediation Agreement between Seller and Buyer in substantially the form attached as **Exhibit M** hereto. Buyer further covenants and agrees to, post-Closing: (i) provide and sign any and all documentation required of the "owner" of the Property in connection with any EURs proposed by Seller or Wyeth in connection with the Transfer Act Work; (ii) upon request by Seller, obtain at Buyer's sole cost and expense and provide to Seller a subordination agreement with respect to any proposed EUR for any easements or other interests in the Land that first arise as of or subsequent to the Closing; (iii) cooperate in good faith with Seller and Wyeth in connection with obtaining subordination agreements (or amended easements) from any third parties that have an easement or other interest in the Land prior to the Closing (e.g., Eversource, Trikilco, LLC, the City of Danbury), which easement or interest could be impacted by the anticipated EURs shown on **Exhibit L**; and (iv) not interfere with the Transfer Act Work being performed by or on behalf of Seller or Wyeth, unless required to do so pursuant to Environmental Law.

(f) Seller shall have completed its obligations under the CT Transfer Act upon the earlier to occur of: (i) if DEEP has retained oversight of the investigation and remediation, DEEP's written determination and approval that the Property has been remediated in accordance with the CT Transfer Act; or, (ii) if the oversight of the investigation and remediation has been delegated to a Connecticut Licensed Environmental Professional (**"LEP"**), (A) the receipt by Seller of a so-called "No Audit Letter" or "No Further Audit Letter" or equivalent from DEEP after receipt of Seller's LEP's final "Verification", (B) the completion of any DEEP audit of said "Verification," or (C) the expiration of any applicable statutory audit timeframe provided for under the CT Transfer Act.

(g) The provisions of this Section 2.7 shall survive Closing and the delivery of the Closing Documents.

ARTICLE III
DUE DILIGENCE ITEMS

Section 3.1 Due Diligence Items.

(a) On or prior to the Effective Date, Seller has delivered to Buyer, or made available to Buyer for inspection via online due diligence data room relating to the Property, the items described on attached **Exhibit B** (the "**Due Diligence Items**

[2] NTD: Changes here are to make the language consistent with the latest version of the negotiated Access and Remediation Agreement.

"); provided, however, that Seller was and is not obligated to deliver any Excluded Property to Buyer or make any Excluded Property available for its review. Buyer acknowledges that any and all documents actually in such data room have been made available to Buyer. In addition to such items in the data room, Seller shall make available to Buyer (by electronic means) such other documents in Seller's possession or control which relate to the Property, other than the Excluded Property, which Buyer shall reasonably request.

(b) All documents, materials, and information furnished to or made available to Buyer pursuant to this Section 3.1 are being furnished or made available to Buyer for information purposes only and without any representation or warranty by Seller with respect thereto, express or implied, except that, to Seller's actual knowledge, they are in all material respects true, correct and complete originals or copies of the version of such materials Seller has in its files, and except as may otherwise be expressly set forth in Article VI and elsewhere in this Agreement and any other document delivered at Closing by Seller to Buyer, and as limited by Section 6.2, and all such documents, materials, and information are expressly understood by Buyer to be subject to the confidentiality provisions of Section 3.2(e).

Section 3.2 Due Diligence Inspection.

(a) Due Diligence Review. Buyer's obligation to purchase the Property is conditioned upon Buyer's review and approval, prior to the expiration of the Due Diligence Period and in Buyer's sole discretion, for any reason or no reason, of all matters pertaining to the physical, structural, electrical, mechanical, soil, drainage, environmental, economic, tenancy, zoning, land use and other governmental compliance matters and conditions respecting the Property, including without limitation the Due Diligence Items, all as provided in this Section 3.2(a). All references herein to the "**Due Diligence Contingency**" shall refer to the conditions benefiting Buyer that are described in this Section 3.2.

(b) Entry. Following the Effective Date and continuing until the Closing or earlier termination of this Agreement, Seller shall provide the Buyer Parties with reasonable access to the Property in accordance with the terms and conditions of this (b) in order for Buyer to investigate the Property and the physical conditions thereof, including without limitation such non-invasive environmental, engineering and economic feasibility inspections and testing as Buyer may elect (the "**Due Diligence Activities**"). In connection with the foregoing, Buyer and Seller each agree that the provisions of this (b) shall supersede any prior access agreements made by Buyer in favor of Seller as of the date of this Agreement including, without limitation, that certain Entry and Indemnity Agreement dated February 16, 2021, by and between Seller and Buyer. Such access, investigation, inspections, tests and discussions shall be on the following terms and conditions:

(i) Buyer shall pay for all inspections and tests ordered by Buyer.

(ii) In connection with any entry by the Buyer Parties onto the Property:

A. Buyer shall give Seller not less than twenty-four (24) hours written notice (which notice may be given by e-mail) of the date and time of a desired Due Diligence Activity by a Buyer Party, together with a general description of the Due Diligence Activity to be conducted. Any such entry on to the Property shall be conducted during Seller's regular business hours; provided, however, that, in the event a Buyer Party requires access to the Property for conducting any Due Diligence Activities during hours outside Seller's regular business hours (e.g., evenings or

weekends), such access may be granted to Buyer Party, subject to Seller's consent, which consent shall not be unreasonably withheld, conditioned or delayed. Seller shall have the right to have a representative present during any visits to or inspections of the Property by a Buyer Party. Seller shall use reasonable efforts to make a representative available in connection therewith.

B. The Buyer Parties shall not enter any building located on the Property unless (1) Buyer has provided prior notice of such entry as required by (b) (ii)(A) above, (ii) Seller consents to such entry (and the date and time therefor), not to be unreasonably withheld or delayed, (iii) a Seller-authorized representative escorts the applicable Buyer Party within such building(s) at all times, and (iv) the applicable Buyer Party follows all of Seller's safety and security protocols for entry into such building(s). Seller may restrict entry into areas on the Property as is reasonably necessary for Seller's safety and security protocols, or to avoid disruption to Seller's business activities on the Property.

(iii) Buyer's rights under this Section 3.2 shall include the right to conduct non-invasive physical inspections of the Property, including, without limitation, surveys, physical assessments, so-called "Phase I" environmental site assessments, lead-based paint surveys, asbestos surveys or other non-invasive environmental inspections with respect to the Property, subject to the terms and conditions of this Agreement; provided, however, that such right shall in every instance be expressly subject to the condition that Buyer or its Affiliates shall be responsible for all payments or other financial obligations owed to the parties engaged by Buyer or its Affiliates to perform such non-invasive physical inspections. Notwithstanding anything in this Agreement to the contrary, any invasive physical inspections of the Property proposed to be conducted by Buyer, including without limitation so-called "Phase II" environmental site assessments or other environmental inspections or sampling with respect to the Property, shall require Seller's prior written consent, which may be withheld in Seller's sole and absolute discretion. In the event Buyer requests Seller's consent to an invasive physical inspection of the Property (e.g., soil or groundwater sampling), Buyer shall submit to Seller such materials as shall fairly summarize, in reasonable detail, the scope of the work intended to be performed. Buyer or its Affiliates shall be responsible for all payments or other financial obligations owed to the parties engaged by Buyer to perform such invasive physical inspections of the Property that may be approved by Seller.

(iv) Prior to and during any entry on the Property, Buyer shall secure and maintain at Buyer's expense (or cause the relevant independent contractor hired by Buyer to enter on the Property to secure and maintain at that independent contractor's expense) the following policies of insurance, which are to include coverage of Buyer, its agents', employees' and contractors' activities at the Property: comprehensive general liability insurance (including property damage, bodily injury, personal injury, and contractual liability coverage) in amounts of One Million Dollars ($1,000,000) per occurrence and Two Million Dollars ($2,000,000) annual aggregate. The policies of insurance described in the preceding sentence shall name Seller as an additional insured. Buyer shall deliver certificates of insurance evidencing the insurance policies described in this (b)(iv) to Seller prior to the first entry on the Property by a Buyer Party. Any environmental contractor of Buyer which conducts environmental inspections of the Property shall, in addition to the insurance required of Buyer's agents

described above, also provide evidence of environmental liability insurance of not less than One Million Dollars ($1,000,000).

(v) Buyer shall promptly repair any damage to the Property caused by a Buyer Party's entry or testing and restore the Property to its condition prior to such testing, at Buyer's sole cost and expense; provided, however, that Buyer will have no obligation to restore any damage to the extent caused by Seller's gross negligence or misconduct or to repair or restore any latent condition discovered by a Buyer Party. Until restoration is compete, Buyer will take commercially reasonable steps to cause any conditions on the Property created by Buyer's or Buyer Party's testing to not interfere with the normal operation of the Property or create any dangerous conditions on the Property. Buyer shall not commit or suffer to be committed, any waste upon the Property. No Buyer Party may construct, erect or place on the Property any monuments or permanent improvements upon the Property.

(vi) Buyer shall conduct the Due Diligence Activities in accordance with all applicable laws and, if required by applicable laws, under the supervision of Governmental Entities having jurisdiction over the Due Diligence Activities.

(vii) Buyer agrees to keep and maintain the Property free and clear of all labor liens, mechanics and materialmen liens, or other clouds, encumbrances and charges occurring as a result of any act done, suffered or committed or indebtedness incurred by a Buyer Party.

(viii) Buyer hereby indemnifies, protects, defends and holds harmless Seller, its Affiliates, their directors, officers, employees, agents, successors and assigns (collectively, the "**Seller Indemnified Parties**", and each a "**Seller Indemnified Party**") from and against any and all Claims that any Seller Indemnified Party suffers or incurs as a result of a Buyer Party's entry or conduct upon the Property or performance of any Due Diligence Activity pursuant to this Agreement; provided, however, that the foregoing indemnity shall not extend to protect the Seller Indemnified Parties from any pre-existing liabilities for matters merely discovered by a Buyer Party, including, without limitation, a Known Environmental Condition, or any Claims due to or arising from Seller's gross negligence or misconduct.

(ix) Seller is not an insurer of Buyer's person or property. To the maximum extent allowed by applicable laws, Seller shall not be liable to Buyer for any bodily injury or property damage suffered by any Buyer Party as a result of a Buyer Party's entry or conduct upon the Property or performance of any Due Diligence Activity pursuant to this Agreement, except to the extent arising from Seller's gross negligence or willful misconduct. Buyer acknowledges and agrees that Buyer, by electing to exercise its rights of access hereunder, shall be deemed to have assumed all risk of loss of personal injury or property damage to any Buyer Party as a result of a Buyer Party's entry or conduct upon the Property or performance of any Due Diligence Activity pursuant to this Agreement, except to the extent arising from Seller's gross negligence or willful misconduct.

The provisions of this (b) shall survive the termination of this Agreement and delivery of the Deed.

(c) Approval of Condition of Property. If, prior to the expiration of the Due Diligence Period, based upon such review, examination or inspection, Buyer determines in its sole and absolute discretion that it no longer intends to acquire the Property, then Buyer shall promptly notify Seller of

such determination in writing (a "**Disapproval Notice**," which may be given by email), whereupon this Agreement, and the obligations of the parties to purchase and sell the Property hereunder, shall terminate. If, however, on or before the expiration of the Due Diligence Period, Buyer determines that the foregoing matters are acceptable to Buyer and that it intends to proceed with the acquisition of the Property, then Buyer shall promptly notify Seller of such determination in writing (an "**Approval Notice**," which may be by email), which Approval Notice will establish satisfaction or waiver of the Due Diligence Contingency. If Buyer fails to deliver either a Disapproval Notice or an Approval Notice to Seller on or before the expiration of the Due Diligence Period, Buyer shall be deemed to have approved of all of the foregoing matters as if it had delivered an Approval Notice and this Agreement will continue in full force and effect.

(d) Satisfaction of Due Diligence Contingency. If the Due Diligence Contingency is not satisfied on or before the end of the Due Diligence Period, Buyer shall have the right to terminate this Agreement and obtain the refund of the Deposit and interest accrued thereon, and neither party shall have any further obligation to or rights against the other except for the Surviving Obligations. Notwithstanding the foregoing, in the event of a breach or default by Seller in the performance of any of its obligations under this Agreement, then in addition to the refund of the Deposit and all interest accrued thereon to Buyer, Buyer shall have all of its rights and remedies pursuant to Section 5.1.

(e) Confidentiality. Buyer agrees that (i) any Due Diligence Items and information provided by Seller to Buyer or the Buyer Parties in the conduct of its Due Diligence Activity or that was posted to the diligence website, and (ii) the results of any inspections of the Property conducted by Buyer pursuant to this Agreement, shall be treated as "Confidential Information" subject to (and as defined in) that certain Non-Disclosure and Confidentiality Agreement dated as of February 10, 2021, between Seller, Buyer and Raymond James & Associates, the terms of which are incorporated herein by reference in full.

(f) AS-IS. Buyer hereby acknowledges that except as is otherwise expressly provided in this Agreement and subject to Seller's representations and warranties expressly set forth herein, or in any document executed by Seller (in favor of Buyer or its assignee, as opposed to Title Company or other third parties) pursuant hereto, including the other documents delivered upon the Closing (each such document, a "**Closing Document**"), it is relying upon its own inspections, investigations and analyses of the Property in entering into this Agreement and, except as otherwise provided in this Agreement or in any Closing Document, and subject to Seller's covenants, representations and warranties expressly set forth herein and in any Closing Document, is not relying in any way upon any representations, statements, agreements, warranties, studies, reports, descriptions, guidelines or other information or material furnished by Seller or its representatives, whether oral or written, express or implied, of any nature whatsoever regarding any such matters including without limitation as to the following:

(i) The condition, value, nature, or quality of the Property, including any construction on the Property and any materials or systems incorporated into the Property.

(ii) The soil, water or geology relating to the Property.

(iii) Any income to be derived from the Property.

(iv) The suitability of the Property for any activities or uses which Buyer may wish to conduct on or relating to the Property.

(v) The zoning or developability of the Property.

(vi) Compliance of the Property or its operation with any law, ordinance, rule, regulation, or the status of any permits or approvals relating to or required in connection with the Property, including without limitation the Americans with Disabilities Act, 42 U.S.C. §12101 et seq. (or any successor statute or similar state and local laws).

(vii) The presence or absence of any Hazardous Materials on or about the Property or in the vicinity of the Property or the compliance of the Property with Environmental Laws.

Buyer specifically acknowledges and agrees that, to the extent Seller has made or in the future makes any information (including without limitation the Due Diligence Items) regarding any aspect of the Property available to Buyer, Seller has done or will be doing so only as an accommodation to Buyer and that, except as expressly provided elsewhere in this Agreement and in any Closing Document, and subject to Seller's express covenants, representations and warranties in this Agreement and the Closing Documents, Seller has not made, is not making, and shall make no representation or warranty of any nature concerning the accuracy or completeness of Seller's files or concerning the authenticity, source, accuracy or completeness of any information contained in them or furnished or to be furnished by Seller to Buyer (including without limitation the Due Diligence Items). As to certain of the materials furnished to Buyer from Seller's files, Buyer specifically acknowledges that they have been prepared by third parties with whom Seller has no privity and Buyer acknowledges and agrees that no warranty or representation, express or implied, has been made, nor shall any be deemed to have been made, to Buyer either by Seller or by any third parties that prepared the materials in question, except as otherwise provided in this Agreement and in any Closing Document and subject to Seller's express representations and warranties in this Agreement and the Closing Documents. Except as otherwise provided in this Agreement, in any Closing Document and subject to the Excluded Claims, Buyer waives any claim of any nature against Seller if any information, conclusion, projection, or other statement of any nature contained in any of those materials should prove not to be true, complete or accurate for any reason. By its execution of this Agreement, Buyer acknowledges and agrees that a material inducement to Seller's decision to sell the Property to Buyer at the Purchase Price provided in this Agreement was Buyer's agreement to conduct its own feasibility studies and purchase the Property in an "AS-IS" condition, subject to the express covenants, representations and warranties of Seller set forth in this Agreement or in any Closing Document. By its waiver of the Due Diligence Contingency, Buyer acknowledges that it has had full access to the Property and a full opportunity to inspect and investigate each and every aspect of the Property, except as limited by the provisions of Section 3.2(b), either independently or through agents of Buyer's choosing, and, subject to the express covenants, representations and warranties of Seller set forth in this Agreement or in any Closing Document, shall accept the Property in its condition as of the Closing.

(g) No Liability for Information. BUYER REPRESENTS THAT IT IS A KNOWLEDGEABLE, EXPERIENCED AND SOPHISTICATED BUYER OF REAL ESTATE, AND THAT IT IS RELYING SOLELY ON THE EXPRESS REPRESENTATIONS AND WARRANTIES OF SELLER MADE IN THIS AGREEMENT AND ANY OTHER CLOSING DOCUMENT, ITS OWN EXPERTISE, AND THAT OF BUYER'S CONSULTANTS IN PURCHASING THE PROPERTY. ANY INFORMATION PROVIDED OR TO BE PROVIDED WITH RESPECT TO THE PROPERTY IS SOLELY FOR BUYER'S CONVENIENCE AND WAS OR WILL BE OBTAINED FROM A VARIETY OF SOURCES. SELLER HAS NOT MADE ANY INDEPENDENT INVESTIGATION OR VERIFICATION OF SUCH INFORMATION AND MAKES NO (AND EXPRESSLY DISCLAIMS ALL) REPRESENTATIONS AS TO THE ACCURACY OR COMPLETENESS OF SUCH INFORMATION (EXCEPT TO THE EXTENT EXPRESSLY SET FORTH IN THIS AGREEMENT AND THE CLOSING DOCUMENTS). EXCEPT TO THE EXTENT EXPRESSLY SET FORTH IN THIS AGREEMENT AND THE CLOSING DOCUMENTS AND THE EXCLUDED CLAIMS, SELLER SHALL NOT BE LIABLE FOR ANY MISTAKES, OMISSIONS, MISREPRESENTATION OR ANY FAILURE TO INVESTIGATE THE PROPERTY NOR SHALL SELLER BE BOUND IN ANY MANNER BY ANY VERBAL OR WRITTEN STATEMENTS, REPRESENTATIONS, APPRAISALS, ENVIRONMENTAL ASSESSMENT REPORTS, OR OTHER INFORMATION PERTAINING TO THE PROPERTY OR THE OPERATION THEREOF, FURNISHED BY (A) SELLER, (B) ANY PARTNERSHIP, LIMITED LIABILITY COMPANY, CORPORATION, TRUST OR OTHER ENTITY THAT HAS OR ACQUIRES A DIRECT OR INDIRECT INTEREST IN SELLER, (C) ANY DIRECT OR INDIRECT MEMBER, MANAGER, MANAGING MEMBER, PARTNER, ADVISOR, TRUSTEE, BENEFICIARY, DIRECTOR, OFFICER, SHAREHOLDER, EMPLOYEE, PARTICIPANT, REPRESENTATIVE OR AGENT IN OR OF SELLER OR OF ANY ENTITY THAT HAS OR ACQUIRES A DIRECT OR INDIRECT INTEREST IN SELLER, OR (D) ANY REAL ESTATE BROKER, AGENT, OR OTHER PERSON OR ENTITY ACTING ON SELLER'S BEHALF. EXCEPT TO THE EXTENT EXPRESSLY SET FORTH IN THIS AGREEMENT AND THE CLOSING DOCUMENTS, BUYER WILL ACQUIRE THE PROPERTY SOLELY ON THE BASIS OF ITS OWN PHYSICAL AND FINANCIAL EXAMINATIONS, REVIEWS AND INSPECTIONS AND THE TITLE INSURANCE PROTECTION AFFORDED BY THE TITLE POLICY. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT OR THE CLOSING DOCUMENTS (INCLUDING, WITHOUT LIMITATION, SELLER'S REPRESENTATIONS AND WARRANTIES HEREIN AND THEREIN), SELLER SPECIFICALLY DISCLAIMS, AND NEITHER IT NOR ANY OTHER PERSON IS MAKING, ANY REPRESENTATION, WARRANTY OR ASSURANCE WHATSOEVER TO BUYER AND NO WARRANTIES OR REPRESENTATIONS OF ANY KIND OR CHARACTER, EITHER EXPRESS OR IMPLIED, ARE MADE BY SELLER OR RELIED UPON BY BUYER WITH RESPECT TO THE STATUS OF TITLE TO OR THE MAINTENANCE, REPAIR, CONDITION, DESIGN OR MARKETABILITY OF THE PROPERTY, OR ANY PORTION THEREOF, INCLUDING BUT NOT LIMITED TO (i) ANY IMPLIED OR EXPRESS WARRANTY OF MERCHANTABILITY, (ii) ANY IMPLIED OR EXPRESS WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, (iii) ANY IMPLIED OR EXPRESS WARRANTY

OF CONFORMITY TO MODELS OR SAMPLES OF MATERIALS, (iv) ANY RIGHTS OF BUYER UNDER APPROPRIATE STATUTES TO CLAIM DIMINUTION OF CONSIDERATION, (v) ANY CLAIM BY BUYER FOR DAMAGES BECAUSE OF DEFECTS, WHETHER KNOWN OR UNKNOWN, WITH RESPECT TO THE IMPROVEMENTS OR THE PERSONAL PROPERTY, AND (vi) THE FINANCIAL CONDITION OR PROSPECTS OF THE PROPERTY, IT BEING THE EXPRESS INTENTION OF SELLER AND BUYER THAT, EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE PROPERTY WILL BE CONVEYED AND TRANSFERRED TO BUYER IN ITS PRESENT CONDITION AND STATE OF REPAIR, “AS IS” AND “WHERE IS”, WITH ALL FAULTS. BUYER, WITH BUYER'S COUNSEL, HAS FULLY REVIEWED THE DISCLAIMERS, RELEASES AND WAIVERS SET FORTH IN THIS AGREEMENT, AND UNDERSTANDS THE SIGNIFICANCE AND EFFECT THEREOF. BUYER ACKNOWLEDGES AND AGREES THAT THE DISCLAIMERS, RELEASES, WAIVERS AND OTHER

AGREEMENTS SET FORTH HEREIN ARE AN INTEGRAL PART OF THIS AGREEMENT, AND THAT SELLER WOULD NOT HAVE AGREED TO SELL THE PROPERTY TO BUYER FOR THE PURCHASE PRICE WITHOUT THE DISCLAIMERS, RELEASES, WAIVERS AND OTHER AGREEMENTS SET FORTH IN THIS AGREEMENT.

(h) Release by Buyer. Notwithstanding any other provisions contained herein, or in any Closing Document, to the contrary (including, without limitation, any language providing for survival of certain provisions hereof or thereof), Buyer hereby acknowledges and agrees that (a) prior to Closing, Buyer's sole recourse in the event of a breach by Seller under this Agreement only shall be as set forth in Section 5.1 hereof, and (b) Seller shall, upon consummation of Closing, be deemed to have satisfied and fulfilled all of Seller's covenants, indemnities, and obligations contained in this Agreement which do not expressly survive Closing and the documents delivered pursuant hereto, and Seller shall have no further liability to Buyer or otherwise with respect to this Agreement, the Property, the transfers contemplated hereby, or any documents delivered pursuant hereto, except to the extent of any obligation or liability Seller may expressly have under this Agreement or the Closing Documents or with respect to any Excluded Claim. Except for the Excluded Claims or as otherwise provided in this Agreement and any of the Closing Documents, Buyer hereby waives its right to recover from, and fully and irrevocably releases Seller and its Indemnified Parties from any and all Claims that it may now have or hereafter acquire against any Seller or any of the Indemnified Parties arising from or related to any defects, errors, omissions or other conditions, latent or otherwise, affecting the Property, any Hazardous Materials affecting the Property, and any right of contribution or private right that Buyer may now or hereafter acquire against Seller with respect to the Property under Environmental Laws and in the regulations adopted and publications promulgated pursuant to such Environmental Laws (as such laws and regulations may be amended, supplemented or replaced from time to time).

(i) Excluded Claims. Notwithstanding anything to the contrary contained in this Section 3.2 or elsewhere in this Agreement, the parties acknowledge and agree that the waivers and releases by Buyer set forth in this Section 3.2 or elsewhere in this Agreement or any Closing Document shall not apply to, limit or affect, and the released Claims shall expressly not include, any Claims resulting or arising from any of the following (each, an "**Excluded Claim**") (i) a breach or inaccuracy of any representation or warranty of Seller set forth in this Agreement or any of the Closing Documents or a breach of any Seller covenant set forth in this Agreement that expressly survives the Closing or in a Closing Document, (ii) Seller's fraud, intentional misrepresentation, or intentional omission, (iii) third party tort claims arising prior to the Closing Date, (iv) the Surviving Obligations of Seller including all of Seller's indemnity obligations set forth in this Agreement, and any obligations arising under any of the Closing Documents that expressly survive the Closing, or (v) obligations or matters under the Buyer-Seller Lease.

(j) Survival. The provisions of Sections 3.2(f)-(i) shall survive the Closing or any earlier termination of this Agreement and delivery of the Deed.

ARTICLE IV
TITLE AND SURVEY

Section 4.1 Title to Real Property. Buyer has obtained or will obtain (a) a commitment to issue an owner's policy of title insurance with respect to the Property issued by the Title Company in favor of Buyer (the "**Title Commitment**"), and (b) copies of all recorded documents referred to on

Schedule B of the Title Commitment as exceptions to coverage (the "**Title Documents**"). As of the Effective Date, Buyer has approved the exceptions to title shown on Schedule B to **Exhibit F** attached hereto and the matters disclosed on the Survey, and the same shall be deemed Permitted Exceptions.

Section 4.2 Certain Exceptions to Title. Notwithstanding anything to the contrary in this Agreement, Seller will be obligated to remove or cure on or before the Closing, in each case, exceptions to title to the Property which are (a) mortgage liens or other monetary liens affecting the Property (except to the extent created by or arising from the acts or omissions of a Buyer Party) and which shall include, without limitation, the mortgage lien in favor of MidCap Financial Trust, (b) mechanics' and materialmen's liens affecting the Property (except to the extent created by or arising from the acts or omissions of a Buyer Party), (c) code violations and other violations with respect to the Property that can be satisfied by payment of a liquidated amount or bonding, (d) encumbrances that have been placed against the Property by, through or under Seller after the date of this Agreement without Buyer's prior written consent (other than in connection with the anticipated EURs shown on **Exhibit L**), (e) so called "standard" exceptions that can be removed from the Title Policy by Seller's delivery of the Owner's Affidavit, and (f) tax liens for real property taxes and assessments which are due and payable or any judgment liens (the liens described in clauses (a) through (f) are collectively referred to as, "**Seller's Required Removal Items**"). It is understood and agreed that the marketability of title herein required to be conveyed by Seller shall be determined in accordance with the Standards of Title of the Connecticut Bar Association now in effect (the "**Title Standards**") and Sections 47-33b through 47-33l of the Connecticut General Statutes, amended (the "**Connecticut Marketable Record Title Act**"). It is also agreed that any and all defects in or encumbrances against the title which come within the scope of said Title Standards or the Connecticut Marketable Record Title Act shall not constitute a valid objection on the part of Buyer if such Title Standards or the Connecticut Marketable Record Title Act do not recommend that any corrective or curative action is necessary in circumstances substantially similar to those presented by such encumbrance or lien, provided that (i) Seller furnishes any affidavits or other instruments which may be required by the applicable Title Standards or the Connecticut Marketable Record Title Act, as applicable, and (ii) the Title Company will issue a commitment to provide the Title Policy (as defined below) at standard rates without exception for such item or insuring against loss or damage arising therefrom. Where the Connecticut Marketable Record Title Act and the Standards of Title conflict or are found to be inconsistent, the Connecticut Marketable Record Title Act shall control. Notwithstanding anything to the contrary contained herein, on or before Closing, Seller shall provide the Title Company with any documentation, including, without limitation, any commercially reasonable indemnity agreements in favor of the Title Company with respect to the United Therapeutics Buildout as may be reasonably necessary for the Title Company to provide the Title Policy and to insure Buyer's lender's interest in the policy, without any exceptions related to the United Therapeutics Buildout; provided, however, that, if the Title Policy includes a general exception for mechanic's liens, Seller shall also provide a commercially reasonable indemnity agreement in favor of Buyer with respect to mechanics liens related to the United Therapeutics Buildout.

Section 4.3 [Reserved].

Section 4.4 Additional Title Matters. In the event that the Title Commitment is amended or supplemented by the Title Company to include new exceptions not created by or arising from the acts or omissions of a Buyer Party, its Affiliates or any of their respective agents, contractors, employees or licensees, and any such new exceptions do not appear on the Title Commitment

delivered to Buyer dated as of March 9, 2021, then Buyer shall have five (5) Business Days following Buyer's receipt of any such amended or supplemented Title Commitment to notify Seller of its disapproval of any such exceptions disclosed in the amended or supplemented Title Commitment. In the event any such exception is not included within Seller's Required Removal Items and Seller is unwilling to commit to remove any such exceptions objected to by Buyer prior to Closing, Buyer may terminate this Agreement by delivering notice thereof in writing to Seller by the earlier to occur of (i) the Close of Escrow or (ii) five (5) Business Days after Seller's written notice to Buyer of Seller's unwillingness to eliminate any one or more of such title exceptions. If Buyer terminates this Agreement pursuant to its rights set forth in the preceding sentence, the Deposit shall be promptly returned to Buyer by Escrow Holder and, if any such new exceptions were executed and recorded by Buyer, Seller shall reimburse Buyer for its Transaction Costs (as hereinafter defined), and neither party shall have any further obligations under this Agreement, except that if such new exception arises solely as a result of a default by Seller under this Agreement, then notwithstanding the foregoing, Buyer shall be entitled to all rights and remedies provided in this Agreement upon the occurrence of a default by Seller.

Section 4.5 **Title Insurance**. At Closing, and as a condition thereto for Buyer's benefit, the Title Company shall issue to Buyer or be irrevocably committed to issue to Buyer a standard coverage ALTA owner's form title policy (the "**Title Policy**"), in the amount of the Purchase Price, insuring that fee simple title to the Real Property is vested in Buyer subject only to the Permitted Exceptions and in accordance with the Connecticut Marketable Record Title Act. Buyer shall be entitled to request that the Title Company provide extended coverage and/or such endorsements (or amendments) to the Title Policy as Buyer may reasonably require, provided that (a) the premium for such extended coverage and/or endorsements (or amendments) requested by Buyer shall be at no cost to, and shall impose no additional liability (except for the delivery of the Owner's Affidavit and any other documents Seller expressly agrees to execute) on, Seller, and (b) unless specifically included by Buyer as a requirement in Buyer's Title Notice, Buyer's obligations under this Agreement shall not be conditioned upon Buyer's ability to obtain such extended coverage and/or endorsements and, if Buyer is unable to obtain such extended coverage and/or endorsements, Buyer shall nevertheless be obligated to proceed to close the transaction contemplated by this Agreement without reduction of or set off against the Purchase Price.

ARTICLE V
REMEDIES AND DEPOSIT INSTRUCTIONS

Section 5.1 **Seller Default**. If the sale of the Property is not consummated due to the permitted termination of this Agreement by Buyer as expressly provided in this Section 5.1 or due to the failure of a condition precedent set forth in Section 9.2(c) (except in the event that such condition precedent was not satisfied because of a default by Buyer under this Agreement), the Deposit shall be returned to Buyer, Seller shall reimburse Buyer for Buyer's actual reasonable out-of-pocket, third party costs and fees incurred by Buyer in connection with the transaction contemplated by this Agreement not to exceed a total aggregate amount of One Hundred Fifty Thousand and 00/Dollars ($150,000.00) (the "**Transaction Costs**") and Buyer will have no liability hereunder except for the Surviving Obligations. If the sale of the Property is not consummated due to a breach or default by Seller in the performance of any of its obligations under this Agreement, Buyer shall be entitled, as its sole and exclusive remedy, either: (a) to terminate this Agreement and receive the return of the Deposit, together with a reimbursement to Buyer for its Transaction Costs, whereupon the parties shall be released from all further obligations under this Agreement, except the Surviving Obligations;

or (b) to enforce specific performance of the sale of the Property pursuant to this Agreement. Buyer shall be deemed to have elected to terminate this Agreement and receive back the Deposit and a reimbursement of the Transaction Costs as set forth hereinabove if Buyer fails to file suit for specific performance against Seller in a court prescribed by Section 11.4 hereof, on or before sixty (60) days following the date upon which Closing was to have occurred (and Seller shall not be obligated to reimburse the Transaction Costs until Buyer has so elected or been deemed to have so elected). Notwithstanding the foregoing, nothing contained herein shall limit Buyer's remedies at law, in equity or as herein provided in the event Seller shall convey or encumber all or any interest in the Property to or in favor of a party other than Buyer in violation of the terms hereof. Except in connection with a claim brought under the preceding sentence, each of Seller and Buyer hereby waives any claim for special, punitive, or consequential damages with respect to this Agreement. Nothing in this Section 5.1 shall be deemed to limit a party's right to recover reasonable third-party attorneys' fees pursuant to Section 11.8.

Section 5.2 BUYER DEFAULT; LIQUIDATED DAMAGES. IF THE SALE IS NOT CONSUMMATED SOLELY DUE TO A DEFAULT BY BUYER HEREUNDER OR DUE TO THE FAILURE OF A CONDITION PRECEDENT SET FORTH IN SECTION 9.2(B) (EXCEPT IN THE EVENT THAT SUCH CONDITION PRECEDENT WAS NOT SATISFIED BECAUSE OF A DEFAULT BY SELLER UNDER THIS AGREEMENT), THEN SELLER SHALL RETAIN THE DEPOSIT AS LIQUIDATED DAMAGES, WHICH RETENTION SHALL OPERATE TO TERMINATE THIS AGREEMENT AND RELEASE BUYER FROM ANY AND ALL LIABILITY HEREUNDER EXCEPT FOR THE SURVIVING OBLIGATIONS. THE PARTIES HAVE AGREED THAT SELLER'S ACTUAL DAMAGES, IN THE EVENT OF A FAILURE TO CONSUMMATE THIS SALE SOLELY DUE TO BUYER'S DEFAULT, WOULD BE EXTREMELY DIFFICULT OR IMPRACTICABLE TO DETERMINE. BUYER DESIRES TO LIMIT THE AMOUNT OF DAMAGES FOR WHICH BUYER MIGHT BE LIABLE SHOULD THE CLOSING NOT OCCUR AS A RESULT OF BUYER'S DEFAULT UNDER THIS AGREEMENT. BUYER AND SELLER WISH TO AVOID THE COSTS AND LENGTHY DELAYS WHICH WOULD RESULT IF SELLER FILED A LAWSUIT TO COLLECT ITS DAMAGES FOR THE FAILURE OF THE CLOSING DUE TO BUYER'S DEFAULT UNDER THIS AGREEMENT. AFTER NEGOTIATION, THE PARTIES HAVE AGREED THAT, CONSIDERING ALL THE CIRCUMSTANCES EXISTING ON THE EFFECTIVE DATE, THE AMOUNT OF THE DEPOSIT IS A REASONABLE ESTIMATE OF THE DAMAGES THAT SELLER WOULD INCUR IN SUCH EVENT. BY PLACING THEIR INITIALS BELOW, EACH PARTY SPECIFICALLY CONFIRMS THE ACCURACY OF THE STATEMENTS MADE ABOVE AND THE FACT THAT EACH PARTY WAS REPRESENTED BY COUNSEL WHO EXPLAINED, AT THE TIME THIS AGREEMENT WAS MADE, THE CONSEQUENCES OF THIS LIQUIDATED DAMAGES PROVISION. NOTHING IN THIS SECTION 5.2 SHALL BE DEEMED TO LIMIT SELLER'S RIGHT TO RECOVER REASONABLE THIRD-PARTY ATTORNEYS' FEES PURSUANT TO SECTION 11.8 BELOW.

Section 5.3 Escrow Instructions. The Escrow Holder joins in this Agreement to evidence its agreement to act in accordance with the terms and conditions of this Agreement. Further, the following provisions shall control with respect to the rights, duties and liabilities of the Escrow Holder.

(a) The Escrow Holder acts hereunder as a depository only and is not responsible or liable in any manner whatsoever for the (i) sufficiency, correctness, genuineness or validity of any written instrument, notice or evidence of a party's receipt of any instruction or notice which is received by the Escrow Holder, or (ii) identity or authority of any person executing such instruction notice or evidence.

(b) The Escrow Holder shall have no responsibility hereunder except for the performance by it in good faith of the acts to be performed by it hereunder, and the Escrow Holder shall have no liability except for its own willful misconduct or gross negligence.

(c) The Escrow Holder shall be reimbursed on an equal basis by Buyer and Seller for any reasonable expenses incurred by the Escrow Holder arising from a dispute with respect to the amount held in escrow, including the cost of any legal expenses and court costs incurred by the Escrow Holder, should the Escrow Holder deem it necessary to retain an attorney with respect to the disposition of the amount held in escrow.

(d) In the event of a dispute between the parties hereto with respect to the disposition of the amount held in escrow, the Escrow Holder shall be entitled, at its own discretion, to deliver such amount to an appropriate court of law pending resolution of the dispute.

(e) The Escrow Holder shall invest the amount in escrow in accounts which are federally insured or which invest solely in government securities and shall be applied in accordance with the terms of this Agreement. Interest earned thereon shall be added to the funds deposited by Buyer.

Section 5.4 Designation of Reporting Person. In order to assure compliance with the requirements of Section 6045 of the Internal Revenue Code of 1986, as amended (for purposes of this Section 5.4, the "**Code**"), and any related reporting requirements of the Code, the parties hereto agree as follows:

(a) Provided the Escrow Holder shall execute a statement in writing (in form and substance reasonably acceptable to the parties hereunder) pursuant to which it agrees to assume all responsibilities for information reporting required under Section 6045(e) of the Code, Seller and Buyer shall designate the Escrow Holder as the person to be responsible for all information reporting under Section 6045(e) of the Code (the "**Reporting Person**"). If the Escrow Holder refuses to execute a statement pursuant to which it agrees to be the Reporting Person, Seller and Buyer shall agree to appoint another third party as the Reporting Person.

(b) Seller and Buyer hereby agree:

(i) to provide to the Reporting Person all information and certifications regarding such party, as reasonably requested by the Reporting Person or otherwise required to be provided by a party to the transaction described herein under Section 6045 of the Code; and

(ii) to provide to the Reporting Person such party's taxpayer identification number and a statement (on Internal Revenue Service Form W-9 or an acceptable substitute form, or on any other form the applicable current or future Code sections and regulations might require and/or any form requested by the Reporting Person), signed under penalties of perjury, stating that the taxpayer identification number supplied by such party to the Reporting Person is correct.

Each party hereto agrees to retain this Agreement for not less than four (4) years from the end of the calendar year in which the Closing occurred, and to produce it to the Internal Revenue Service upon a valid request therefor.

ARTICLE VI
REPRESENTATIONS AND WARRANTIES OF SELLER

Section 6.1 Representations and Warranties of Seller. Subject to the provisions of Section 6.2, Seller makes the following representations and warranties with respect to the Property:

(a) Status. Seller is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and is qualified to transact business in the State of Connecticut.

(b) Authority. The execution and delivery of this Agreement (and all ancillary documents delivered pursuant hereto including, without limitation, the Closing Documents) by Seller and the performance of its obligations hereunder and thereunder have been or will be duly authorized by all necessary action on the part of Seller, and this Agreement constitutes the legal, valid and binding obligation of Seller, subject to equitable principles and principles governing creditors' rights generally.

(c) Non-Contravention. Except as set forth on attached **Exhibit C**, the execution and delivery of this Agreement by Seller and the consummation of the transactions by Seller contemplated hereby or in the other Closing Documents will not (i) violate any judgment, order, injunction, decree, regulation or ruling of any court or Governmental Entity or (ii) conflict with, result in a breach of, or constitute a default under the organic documents of Seller, any note or other evidence of indebtedness, any mortgage, deed of trust or indenture, or any lease or other material agreement or instrument to which Seller is a party or by which Seller may be bound.

(d) Suits and Proceedings. Except as set forth on attached **Exhibit C**, there are no legal actions, suits or similar proceedings at law, in equity, or otherwise pending and served or, to Seller's actual knowledge, threatened in writing against Seller (with respect to the Property, as opposed to actions against Seller as a going concern) or the Property which would be reasonably likely to adversely affect, individually or in the aggregate, (i) the ability of Seller to perform its obligations hereunder, or (ii) the ownership or operation of the Property.

(e) Non-Foreign Entity. Seller is not a “foreign person” or “foreign corporation” as those terms are defined in the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

(f) Consents. Except as set forth on attached **Exhibit C**, no consent, waiver, approval or authorization is required from any Person (that has not already been obtained) in connection with the execution and delivery of this Agreement by Seller or the performance by Seller of the transactions contemplated hereby.

(g) Condemnation. Seller has not received any written notice of any pending or contemplated condemnation or action in eminent domain from a Governmental Entity with respect to all or part of the Property.

(h) Bankruptcy. Seller has not (i) commenced a voluntary case, or had entered against it a petition, for relief under any federal bankruptcy act or any similar petition, order or decree under any federal or state law or statute relative to bankruptcy, insolvency or other relief for debtors, (ii) caused, suffered or consented to the appointment of a receiver, trustee, administrator, conservator, liquidator or similar official in any federal, state or foreign judicial or non-judicial proceedings, to hold, administer and/or liquidate all or substantially all of its property, or (iii) made an assignment for the benefit of creditors.

(i) Governmental Notices. Except as set forth on attached **Exhibit C**, Seller has not received written notice from any Governmental Entity of (i) any pending or threatened zoning, building, fire, or health code violations or violations of other governmental requirements or regulations with respect to the Property that have not previously been corrected, (ii) violations with respect to the Title Documents that have not previously been corrected, or (iii) violation of any applicable laws, ordinances, rules, requirements, regulations or codes of any governmental agency, body or subdivision thereof bearing on the Property.

(j) Leases and Occupancy Agreements; Contracts. Except as set forth on attached **Exhibit C** and except for the Access Agreement and the other agreements disclosed in the Official Records, there are no Leases or other agreements for occupancy or any property management contracts, real property service contracts, construction contracts, reciprocal easement agreements, or any other contracts related to the leasing, subleasing, ownership, operation, maintenance, construction or development of any part of the Real Property to which Seller is a party, or, to Seller's knowledge, to which any other Person is a party, which would be binding on Buyer after Closing.

(k) Environmental. Except as set forth on attached **Exhibit C**, Seller has not received written notice from any Governmental Entity or third party concerning (i) a violation, or alleged violation, of any applicable Environmental Laws with respect to the Property, (ii) any existing, pending, or threatened investigation or inquiry of Seller or the Property by any Governmental Entity, other than Wyeth's ongoing requirements under the CT Transfer Act, or (iii) any remedial obligations with respect to Seller or the Property under any Environmental Laws, other than Wyeth's ongoing obligations under the CT Transfer Act. Seller has not given or received any written notices of default under the Access Agreement and no claims for indemnification have been made pursuant to the Access Agreement.

(l) Patriot Act. Seller is in compliance with all applicable anti-money laundering and anti-terrorist laws, regulations, rules, executive orders and government guidance, including the reporting, record keeping and compliance requirements of the Bank Secrecy Act ("**BSA**"), as amended by The International Money Laundering Abatement and Financial Anti-Terrorism Act of 2001, Title III of the USA PATRIOT Act (the "**Patriot Act**"), and other authorizing statutes, executive orders and regulations administered by OFAC, and related Securities and Exchange Commission, SRO or other agency rules and regulations, and has policies, procedures, internal controls and systems that are reasonably designed to ensure such compliance.

(m) OFAC. None of: (i) Seller, any Affiliate of Seller nor any Person controlled by Seller; nor (ii) to the actual of knowledge of Seller, after making due inquiry, any Person who owns a controlling interest in or otherwise controls Seller; nor (iii) to the best of Seller's knowledge, after making due inquiry, any Person otherwise having a direct or indirect beneficial interest (other than with respect to an interest in a publicly traded entity) in Seller; nor (iv) any Person for whom Seller

is acting as agent or nominee in connection with this investment, is a country, territory, Person, organization, or entity named on an OFAC List, nor is a prohibited country, territory, Person, organization, or entity under any economic sanctions program administered or maintained by OFAC.

(n) Due Diligence Items. The Due Diligence Items delivered to Buyer are in all material respects true, correct and complete originals or copies of the versions of the Due Diligence Items that Seller has in its files and Seller uses with respect to the operation of the Property. Seller has not received written notice from any Person that any information in the Due Diligence Items was not true, accurate or complete when provided to Seller.

Section 6.2 Limited Liability. The representations and warranties of Seller set forth in this Agreement, together with Seller's liability for the breach of any covenant set forth herein, will survive the Closing for a period expiring on the date that is nine (9) months after the Closing (unless Buyer has given written notice to Seller of a breach of any such representation or warranty (specifying the specific claim and breach) prior to the expiration of the nine (9) month period following Closing, in which event Buyer's right to recover amounts from Seller for such noticed breach of a representation or warranty shall survive such period). Buyer will not have any right to bring any action against Seller as a result of any untruth or inaccuracy of such representations and warranties unless and until the aggregate amount of all liability and losses arising out of any such untruth or inaccuracy exceeds $100,000.00 (the "**Basket**") in which event Buyer may claim indemnification for the full amount of such claim(s) up to the Indemnification Cap (as defined below), and Seller's liability for any untruth or inaccuracy of such representations and warranties shall not exceed, in the aggregate, $5,000,000.00 (the "**Indemnification Cap**"); it being understood and agreed, however, that such Basket and Indemnification Cap shall not apply to but shall expressly exclude Seller liabilities under Section 9.5 (Prorations and Closing Costs), and Section 9.8 (Tax Protests; Tax Refunds and Credits). Seller shall have no liability with respect to any of Seller's representations, warranties and covenants herein if, prior to the Closing, Buyer has actual knowledge or Buyer obtains actual knowledge (within the meaning of Section 6.3) of any breach of a representation, warranty or covenant of Seller herein (from whatever source, including, without limitation, as a result of Buyer's due diligence or as a result of written disclosure by Seller or Seller's agents and employees) that contradicts any of Seller's representations and warranties herein, and Buyer nevertheless consummates the transaction contemplated by this Agreement. The provisions of this Section 6.2 shall survive the Closing or any earlier termination of this Agreement and delivery of the Deed.

Section 6.3 Knowledge Parties.

(a) If a representation, warranty or other statement is made in this Agreement or in any document or instrument to be delivered at Closing pursuant to this Agreement, on the basis of the "knowledge," "actual knowledge" or "best of knowledge" (or similar phrases) of Seller then such representation, warranty or other statement is made based on the actual, current, conscious express awareness of facts or other information of Steven Binder and David Thomson, as distinguished from implied, imputed and/or constructive knowledge, as of the Effective Date and as of any time thereafter up to and including the Closing, and without undertaking any special inquiry or investigation by such person(s). Seller represents and warrants that such persons are the most knowledgeable employees of Seller with respect to (i) the representations and warranties made by Seller under this Agreement, (ii) the Property, and (iii) the transaction contemplated by this Agreement. Seller is not under a duty of inquiry or investigation in order to make any such representation, warranty or other statement.

(b) If a representation, warranty or other statement is made in this Agreement or in any document or instrument to be delivered at Closing pursuant to this Agreement, on the basis of the "knowledge," "actual knowledge" or "best of knowledge" (or similar phrases) of Buyer then such representation, warranty or other statement is made based on the actual, current, conscious express awareness of facts or other information of Christopher Brewer, as distinguished from implied, imputed and/or constructive knowledge, as of the Effective Date and as of any time thereafter up to and including the Closing, and without undertaking any special inquiry or investigation by such person(s). In all events, Buyer shall be deemed to have actual knowledge of the Due Diligence Materials that are in the diligence data room described in Section 3.1(a). Buyer represents and warrants to Seller that such individuals are the persons most knowledgeable in connection with the representations and warranties made by Buyer under this Agreement. Buyer is not under a duty of inquiry or investigation in order to make any such representation, warranty or other statement.

Section 6.4 Liability of Representations and Warranties. The parties acknowledge that the individuals named above are named solely for the purpose of defining and narrowing the scope of Seller's and Buyer's knowledge, as applicable, and not for the purpose of imposing any liability on or creating any duties running from such individuals to the counterparty under this Agreement, as applicable. Each of Seller and Buyer covenants that it will bring no action of any kind against such individuals, as applicable, or related to or arising out of these representations and warranties.

Section 6.5 Notice of Breaches of Representations and Warranties. Seller shall promptly notify Buyer in writing of any changed condition, receipt of notice or documentation, or acquired actual knowledge, that would cause any material inaccuracy of any representation or warranty of Seller contained herein (any such changed condition, received notice or documentation or acquired knowledge being defined as a "**Changed Condition**"). Buyer shall promptly notify Seller in writing of any material inaccuracy in any representation or warranty of Seller contained herein of which Buyer obtains actual knowledge (within the meaning of Section 6.3) prior to the Close of Escrow ("**Known Misrepresentation**"). Within five (5) Business Days after either notification in writing by Seller to Buyer of any such Changed Condition or notification by Buyer to Seller of any Known Misrepresentation, Seller, at Seller's own option and expense, may elect by written notice to Buyer to remedy the Changed Condition or Known Misrepresentation such that Seller's representations have no material inaccuracy, and the Closing Date may be extended for up to ten (10) calendar days after the scheduled Closing Date in order for Seller to effectuate such remedy. If Seller does not elect to effectuate such remedy so as to cause Seller's representations to have no material inaccuracy, or if Seller so elects but then fails to complete such remedy within such ten (10) day period, then Buyer may elect, by written notice to Seller given at any time thereafter, to terminate this Agreement, in which event (i) neither Buyer nor Seller shall have any further obligation under this Agreement, except for the Surviving Obligations, (ii) the Deposit shall be promptly returned to Buyer by Escrow Holder and Seller shall reimburse Buyer for its Transaction Costs, and (iii) if such Changed Condition resulted from Seller's intentional acts and was not cured by Seller pursuant to the provisions above, then Seller shall be in breach of a material obligation under this Agreement and Buyer shall have the remedies set forth in Section 5.1. If, notwithstanding Seller's election not to effectuate such remedy (or Seller's failure to complete such remedy within such ten (10) day period), Buyer elects to consummate the purchase of the Property, Seller shall not be liable to Buyer as a result of any inaccuracy in any representation or warranty of Seller contained herein that results from such Changed Condition or Known Misrepresentation identified in any such written notice from one party to the other.

ARTICLE VII
REPRESENTATIONS AND WARRANTIES OF BUYER

Section 7.1 Buyer's Representations and Warranties. Buyer represents and warrants to Seller the following:

(a) Status. Buyer is a limited liability company duly organized or formed, validly existing and in good standing under the laws of the State of Delaware and is qualified to transact business in the State of Connecticut.

(b) Authority. The execution and delivery of this Agreement and the performance of Buyer's obligations hereunder have been or will be duly authorized by all necessary action on the part of Buyer and this Agreement constitutes the legal, valid and binding obligation of Buyer, subject to equitable principles and principles governing creditors' rights generally.

(c) Non-Contravention. The execution and delivery of this Agreement by Buyer and the consummation by Buyer of the transactions contemplated hereby will not violate any judgment, order, injunction, decree, regulation or ruling of any court or Governmental Entity or conflict with, result in a breach of, or constitute a default under the organic documents of Buyer, any note or other evidence of indebtedness, any mortgage, deed of trust or indenture, or any lease or other material agreement or instrument to which Buyer is a party or by which it is bound.

(d) Consents. No consent, waiver, approval or authorization is required from any Person (that has not already been obtained or, in the case of authorization by Buyer and its direct and indirect members, will be obtained prior to the Closing) in connection with the execution and delivery of this Agreement by Buyer or the performance by Buyer of the transactions contemplated hereby.

(e) Bankruptcy. Buyer has not (i) commenced a voluntary case, or had entered against it a petition, for relief under any federal bankruptcy act or any similar petition, order or decree under any federal or state law or statute relative to bankruptcy, insolvency or other relief for debtors, (ii) caused, suffered or consented to the appointment of a receiver, trustee, administrator, conservator, liquidator or similar official in any federal, state or foreign judicial or non-judicial proceeding, to hold, administer and/or liquidate all or substantially all of its property, or (iii) made an assignment for the benefit of creditors.

(f) Patriot Act. Buyer is in compliance with all applicable anti-money laundering and anti-terrorist laws, regulations, rules, executive orders and government guidance, including the reporting, record keeping and compliance requirements of the BSA, as amended by The International Money Laundering Abatement and Financial Anti-Terrorism Act of 2001, Title III of the Patriot Act, and other authorizing statutes, executive orders and regulations administered by OFAC, and related Securities and Exchange Commission, SRO or other agency rules and regulations, and has policies, procedures, internal controls and systems that are reasonably designed to ensure such compliance.

(g) OFAC. None of: (i) Buyer, any direct Affiliate of Buyer nor any Person controlled by Buyer; nor (ii) to the best of knowledge of Buyer, after making due inquiry, any Person who owns a controlling interest in or otherwise controls Buyer; nor (iii) to the best of knowledge of Buyer, after making due inquiry, if Buyer is a privately held entity, any Person otherwise having a direct or indirect beneficial interest (other than with respect to an interest in a publicly traded entity) in Buyer; nor (iv) any Person for whom Buyer is acting as agent or nominee in connection with this investment, is

a country, territory, Person, organization, or entity named on an OFAC List, nor is a prohibited country, territory, Person, organization, or entity under any economic sanctions program administered or maintained by OFAC.

ARTICLE VIII
INTERIM OPERATING COVENANTS

Section 8.1 **Buyer-Seller Lease**. The parties acknowledge and agree that, pursuant and subject to the terms of the Buyer-Seller Lease, Seller, as tenant thereunder, shall occupy the Property from and after Closing without interruption. Seller shall have no obligation to remove any personal property or otherwise vacate or discontinue use of the Property upon or after Closing, or to make repairs or improvements to the Property before, upon or following Closing, except as expressly provided in this Agreement or in the Buyer-Seller Lease.

Section 8.2 **Operation of Property**. Seller shall, from and after the Effective Date up to and including the Closing Date, maintain and repair the Property in substantially the same condition as the Property exists as of the Effective Date, reasonable wear and tear and the United Therapeutics Buildout excepted. Furthermore, from and after the Effective Date up to and including the Closing Date, Seller shall comply with all covenants, conditions, restrictions, easements, rights of way and other rights of third parties relating to the Property. Seller hereby covenants that, from the Effective Date up to and including the Closing Date, without the express prior written consent of Buyer, which may be granted or withheld in Buyer's sole discretion, Seller shall not grant or otherwise create or consent to the creation of any easement, restriction, lien, assessment or encumbrance respecting the Property, including without limitation, any lease or license.

Section 8.3 **Insurance**. From and after the Effective Date to the Closing Date, Seller shall carry and maintain in full force and effect, at its sole cost and expense, the policies now in effect, including, without limitation, any fire and extended coverage insurance policies (or substitute policies in equal or greater amounts).

Section 8.4 **Transfers**. From and after the Effective Date to the Closing Date, Seller shall not sell, assign or transfer any interest or option in any portion of the Property, except in connection with the proposed EURs shown on **Exhibit L**.

Section 8.5 **Alterations**. Except for the United Therapeutics Buildout, from and after the Effective Date to the Closing Date, Seller shall not make or permit any capital improvements (or other improvements and alterations which would require Buyer's consent as "Landlord" under the Buyer-Seller Lease) to any portion of the Property, without the express written consent of Buyer.

Section 8.6 **New Contracts**. Seller is not party to and will not enter into any service, supply, equipment rental and/or other service contracts related to the operation of the Property or other contract that will be an obligation affecting the Property subsequent to Closing, except (i) contracts expressly approved by Buyer or entered into in the ordinary course of business that are terminable without cause and without the payment of any termination penalty on not more than thirty (30) days' prior notice, (ii) contracts that the Seller is either required or permitted to maintain in its own name under the terms of the Buyer-Seller Lease and are not binding on Buyer or the Property, and (iii) design, engineering, construction and similar contracts necessary for the United Therapeutics Buildout.

ARTICLE IX
CLOSING AND CONDITIONS

Section 9.1 Escrow Instructions. Upon execution of this Agreement, the parties hereto shall deposit an executed counterpart of this Agreement with the Escrow Holder, and this Agreement shall serve as escrow instructions to the Escrow Holder as the escrow holder for consummation of the purchase and sale contemplated hereby. Seller and Buyer agree to execute such reasonable additional and supplementary escrow instructions as may be appropriate to enable the Escrow Holder to comply with the terms of this Agreement; provided, however, that in the event of any conflict between the provisions of this Agreement and any supplementary escrow instructions, the terms of this Agreement shall control.

Section 9.2 Closing.

(a) **Closing**. The closing hereunder ("**Closing**" or "**Close of Escrow**") shall be held and delivery of all items to be made at the Closing under the terms of this Agreement shall be made through escrow at Escrow Holder's office on the Closing Date. Except as provided in this Agreement, such date may not be extended without the prior written approval of both Seller and Buyer, each in its sole and absolute discretion. At least two (2) Business Days prior to the Closing Date, Buyer shall request that the Escrow Holder prepare and deliver to Buyer and Seller a preliminary closing statement (the "**Closing Statement**"). On the Closing Date, Buyer shall deposit in escrow with the Escrow Holder the Purchase Price (subject to adjustments described in Section 9.5), together with all other costs and amounts to be paid by Buyer at the Closing pursuant to the terms of this Agreement, by Federal Reserve wire transfer of immediately available funds to an account to be designated by the Escrow Holder. No later than 3:00 p.m. Eastern Time on the Closing Date and provided all conditions to Closing set forth in Section 9.2(c) have been satisfied, or waived or deemed waived by Buyer, (a) Buyer will cause the Escrow Holder to (i) pay to Seller by Federal Reserve wire transfer of immediately available funds to an account designated by Seller, the Purchase Price (subject to adjustments described in Section 9.5), less any costs or other amounts to be paid by Seller at Closing pursuant to the terms of this Agreement, and (ii) pay all appropriate payees the other costs and amounts to be paid by Buyer at Closing pursuant to the terms of this Agreement and (b) to otherwise pay to the appropriate payees out of the proceeds of Closing payable to Seller all costs and amounts to be paid by Seller at Closing pursuant to the terms of this Agreement.

(b) **Seller Closing Conditions**. It shall be a condition precedent to Seller's obligation to sell the Property that:

(i) all of Buyer's representations and warranties contained in or made pursuant to this Agreement shall be true and correct in all material respects as of the Closing Date;

(ii) there shall be no material breach of Buyer's covenants and obligations set forth in this Agreement; and

(iii) Buyer shall have delivered the items described in Section 9.4 to Seller or to Escrow Holder, as applicable.

It is understood and agreed that Seller may waive any such condition precedent in Seller's sole and absolute discretion. In the event any such condition is not timely satisfied (except in the event that such condition precedent was not satisfied because of a default by Seller under this Agreement) or

waived by Seller, then the same shall be a material breach of this Agreement by Buyer and Seller shall have the remedies set forth in Section 5.2. Buyer hereby covenants that it shall exercise reasonable and diligent efforts to cause the conditions set forth in this Section 9.2(b) and the condition set forth in Section 9.2(c)(iv) below to be fully satisfied by the Closing Date.

(c) **Buyer Closing Conditions**. The following shall each constitute a condition precedent to Buyer's obligation to consummate the Closing hereunder:

(i) all of Seller's representations and warranties contained in or made pursuant to this Agreement shall be true and correct in all material respects as of the Closing Date;

(ii) there shall be no material breach of Seller's covenants and obligations set forth in this Agreement;

(iii) Seller shall have delivered the items described in Section 9.3 to Buyer or to Escrow Holder;

(iv) the Title Company shall be unconditionally committed to issue the Title Policy (subject only to the payment of the premium, satisfaction of all requirements set forth in the Title Commitment, delivery by Buyer to the Title Company of all documents and instruments requested by the Title Company from Buyer and payment of all other amounts specified in this Agreement to be paid by Buyer) showing no exceptions other than the Permitted Exceptions;

(v) Subject to Section 10.1, the Property shall be in substantially the same condition as it existed on the Effective Date, subject to ordinary wear and tear and the United Therapeutics Buildout; and

(vi) There shall not have been any material adverse change with respect to the financial condition or operations of the Seller.

It is understood and agreed that Buyer may waive any such condition precedent in Buyer's sole and absolute discretion; and Buyer’s failing to terminate this Agreement prior to the Closing shall be deemed to constitute Buyer’s waiver of such conditions precedents; provided, however, nothing set forth herein shall constitute a waiver of Buyer's post-Closing remedies for any Changed Condition of which Buyer did not have actual knowledge (within the meaning of Section 6.3) prior to the Closing. In the event any such condition is not timely satisfied (except in the event that such condition precedent was not satisfied because of a default by Buyer under this Agreement) or waived by Buyer, then Buyer shall have the right to terminate this Agreement by written notice to Seller and Escrow Holder, in which event, Buyer shall be entitled to the immediate return of the Deposit and all interest accrued thereon; provided, however, that, to the extent, any of the condition precedents set forth in sub-sections (i), (ii), (iii), (v) and (vi), is not satisfied, Buyer shall also receive a reimbursement of its Transaction Costs. Seller hereby covenants that it shall exercise reasonable and diligent efforts to cause the conditions set forth in this Section 9.2(c) to be fully satisfied by the Closing Date.

Section 9.3 Seller's Closing Documents and Other Items. At or before Closing, Seller shall deposit into escrow the following items:

(a) a duly executed and acknowledged Special Warranty Deed in the form of attached **Exhibit F** (the "**Deed**");

(b) two (2) duly executed counterparts of the Buyer-Seller Lease and one (1) duly executed and acknowledged counterpart of a memorandum of the Buyer-Seller Lease;

(c) two (2) duly executed counterparts of the ROFR and one (1) duly executed and acknowledged Memorandum of ROFR;

(d) Intentionally deleted

(e) two (2) duly executed counterparts of an Omnibus Assignment and Assumption Agreement in the form of attached **Exhibit H** (the "**Omnibus Assignment**");

(f) an affidavit pursuant to Section 1445(b)(2) of the Code, on which Buyer is entitled to rely, that Seller (or, if Seller is a disregarded entity for federal income tax purposes, the person treated as the owner of the Property for such purposes) is not a "foreign person" within the meaning of Section 1445(f)(3) of the Code;

(g) a duly executed counterpart of the CT Transfer Act Filings with Seller signing as "Transferor" and Seller or an Affiliate signing as "Certifying Party" along with the appropriate DEEP filing fee;

(h) a duly completed and signed real estate conveyance tax return for the Property (the "**Transfer Tax Forms**");

(i) documentation to establish to Buyer's reasonable satisfaction and the Title Company's satisfaction the due authority of Seller's disposition of the Property and Seller's delivery of the documents required to be delivered by Seller pursuant to this Agreement (including, but not limited to, the organizational documents of Seller, as they may have been amended from time to time, resolutions of Seller and incumbency certificates of Seller);

(j) a duly executed certificate, stating that each of the representations and warranties of Seller set forth in this Agreement are, as of the Closing Date, true and accurate in all material respects, duly authorized and executed by Seller, in the form of attached **Exhibit I** (the "**Seller's Certificate**");

(k) a duly executed title affidavit in the form of **Exhibit K** (the "**Owner's Affidavit**");

(l) two (2) duly executed counterparts of the Access and Remediation Agreement;

(m) a counterpart signature to the Closing Statement executed by Seller; and

(n) such other documents as may be reasonably required by the Title Company or as may be agreed upon by Seller and Buyer to consummate the purchase of the Property as expressly contemplated by this Agreement.

Section 9.4 Buyer's Closing Documents and Other Items. At or before Closing, Buyer shall deposit into escrow the following items:

(a) the balance of the Purchase Price and such additional funds as are necessary to close this transaction;

(b) two (2) duly executed counterparts of the Buyer-Seller Lease and one (1) duly executed and acknowledged counterpart of a memorandum of the Buyer-Seller Lease;

(c) two (2) duly executed counterparts of the ROFR and one (1) duly executed and acknowledged Memorandum of ROFR;

(d) two (2) duly executed counterparts of the Omnibus Assignment;

(e) documentation to establish to Seller's reasonable satisfaction the due authority of Buyer's acquisition of the Property and Buyer's delivery of the documents required to be delivered by Buyer pursuant to this Agreement (including, but not limited to, the organizational documents of Buyer, as they may have been amended from time to time, resolutions of Buyer and incumbency certificates of Buyer);

(f) a duly executed counterpart of the CT Transfer Act Filings with Buyer signing as "Transferee";

(g) if applicable, signed Transfer Tax Forms;

(h) a duly executed certificate, stating that each of the representations and warranties of Buyer set forth in this Agreement are, as of the Closing Date, true and accurate in all material respects, duly authorized and executed by Buyer, in the form of attached **Exhibit J** (the "**Buyer's Certificate**");

(i) two (2) duly executed counterparts of the Access and Remediation Agreement;

(j) a counterpart signature to the Closing Statement executed by Buyer; and

(k) such other documents as may be reasonably required by the Title Company or as may be agreed upon by Seller and Buyer to consummate the purchase of the Property as contemplated by this Agreement.

Section 9.5 Prorations and Closing Costs.

(a) Real estate and personal property taxes, utilities and all other proratable items shall remain the responsibility of Seller pursuant to the Buyer-Seller Lease and all payments of the same that may be due and payable as of Closing shall remain Seller's responsibility; provided, however, that solely for accounting purposes, all such proratable items paid by Seller upon Closing but attributable to amounts accruing on and after of 12:01 a.m. Eastern Time on the Closing Date shall be credited to Seller's obligation to pay such expenses as the "tenant" under the Buyer-Seller Lease.

(b) Seller shall pay (i) one-half of the Escrow Holder's escrow and settlement fees, (ii) all state and municipal conveyance taxes unless otherwise exempt, (iii) intentionally omitted, (iv) fees for the release of Seller's Required Removal Items, and (v) any additional costs and charges customarily charged to sellers in accordance with the closing customs and practices of the Fairfield County Bar Association, other than those costs and charges specifically required to be paid by Buyer

hereunder. Buyer shall pay (A) one-half of the Escrow Holder's escrow and settlement fees, (B) intentionally omitted, (C) the costs for all title insurance search fees and commitment fees, and all premiums for the Title Policy and any endorsements thereto, (D) the costs of preparing the Survey or otherwise conforming the Survey to the requirements for issuance of such Title Policy, (E) the cost of all third party studies and reports obtained by Buyer in connection with Buyer's inspections and investigations, and (F) any additional costs and charges customarily charged to buyers in accordance with the closing customs and practices of the Fairfield County Bar Association, other than those costs and charges specifically required to be paid by Seller hereunder.

Section 9.6 Brokers. Buyer represents and warrants to Seller that, other than Raymond James & Associates (whose commission shall be payable by Buyer pursuant to a separate written agreement), it did not employ or use any broker or finder to arrange or bring about this transaction, and that there are no claims or rights for brokerage commissions or finder's fees in connection with the transactions contemplated by this Agreement. Seller represents and warrants to Buyer that, other than Cushman & Wakefield (whose commission shall be payable by Seller pursuant to a separate written agreement), Seller has not employed any broker with respect to this transaction. If any Person, other than Raymond James & Associates, brings a claim for a commission or finder's fee based upon any contact, dealings, or communication with Buyer in connection with the transactions contemplated by this Agreement, then Buyer shall defend Seller from such claim, and shall indemnify Seller and hold Seller harmless from any and all Claims incurred by Seller with respect to the claim. If any Person, other than Cushman & Wakefield, brings a claim for a commission or finder's fee based upon any contact, dealings, or communication with Seller in connection with the transactions contemplated by this Agreement, then Seller shall defend Buyer from such claim, and shall indemnify Buyer and hold Buyer harmless from any and all Claims incurred by Buyer with respect to the claim. The provisions of this Section 9.6 shall survive the Closing or, if the purchase and sale is not consummated, any termination of this Agreement and shall not be subject to the limitation set forth in Section 6.2.

Section 9.7 Expenses. Except as provided in Sections 9.5 and 9.6, each party hereto shall pay its own expenses incurred in connection with this Agreement and the transactions contemplated hereby, including, without limitation in the case of Buyer, all third-party engineering and environmental review costs and all other due diligence costs.

Section 9.8 Tax Protests; Tax Refunds and Credits. Seller shall have the right to control the progress of and to make all decisions with respect to any contest of the real estate taxes and personal property taxes for the Real Property due and payable during all tax years through and including the tax year in which the Closing occurs (the "**Closing Tax Year**"); provided Seller shall keep Buyer reasonably informed regarding the status of any contest with respect to the taxes attributable to such period. To the extent any real estate or personal property tax refunds or credits are received after Closing with respect to the Property and such refunds or credits are attributable to real estate and personal property taxes paid for any tax year prior to and including the Closing Tax Year, Seller shall be entitled to the entirety of such refunds and credits. Any contest of the real estate taxes and personal property taxes for the Property due and payable for all years subsequent to the Closing Tax Year, and any real estate or personal property tax refunds or credits attributable to such period, shall be governed by the terms of the Buyer-Seller Lease.

CASUALTY AND CONDEMNATION

Section 10.1 Casualty. If all or any part of the Property is damaged by fire or other casualty occurring after the Effective Date and prior to Closing, whether or not such damage affects a material part of such Property, then:

(a) Notice. Seller shall provide written notice thereof to Buyer within three (3) days of such fire or casualty.

(b) Assignment of Insurance; Repairs. Subject to the rights in Section 10.1(c)(i) below, neither of the parties shall have the right to terminate this Agreement and the parties shall nonetheless consummate this transaction in accordance with this Agreement, without any abatement of the Purchase Price or any liability or obligation on the part of Seller by reason of said destruction or damage. In such event, Seller shall assign to Buyer and Buyer shall have the right to make a claim for and to retain any casualty insurance proceeds payable under Seller's casualty insurance policies (if any) in effect with respect to the Property on account of said physical damage or destruction. In addition to assigning all rights under and proceeds payable under casualty insurance policies with respect to such damage and destruction, Seller shall also pay to Buyer an amount equal to any "deductible" under such policies. In the event Seller, as a result of such casualty, must remedy unsafe conditions (i) to protect the Property or (ii) to preserve the health and safety of persons or to prevent damage to property, (each an "**Unsafe Condition**"; and collectively the "**Unsafe Conditions**"), and in the event such amount spent by Seller to remedy the Unsafe Condition shall exceed the amount of the deductible on such casualty insurance policy, then Buyer shall deliver such excess amount to Seller, within thirty (30) days of, if and to the extent of, its receipt of any casualty insurance proceeds received on account of such fire or casualty but only to the extent such expense is approved in writing by Buyer prior to Seller incurring such expense, which approval shall not be unreasonably withheld or delayed; provided, however, Seller may elect to bear such expense at its sole cost and expense. Seller need not obtain the consent of Buyer prior to causing the remedy of an Unsafe Condition, provided however, other than an Unsafe Condition, Seller shall not remedy or repair any damage or destruction on account of such fire or casualty without the consent of Buyer, which consent shall not be unreasonably withheld or delayed, and in the event such amount spent by Seller to remedy or repair the condition consented to by Buyer exceeds the amount of the deductible on such casualty insurance policy, then Buyer shall deliver such excess amount to Seller, within thirty (30) days of its receipt of any casualty insurance proceeds received on account of such fire or casualty, but in no event greater than ninety (90) days from the date of such fire or casualty; provided, however, in no event shall Buyer be required to deliver to Seller an amount in excess of the casualty proceeds actually received by Buyer. Notwithstanding the foregoing, should the casualty not have been repaired prior to Closing then any proceeds of insurance with respect to such casualty actually received by Seller shall be handled pursuant to the terms of the Buyer-Seller Lease.

(c) Termination Right. Notwithstanding any of the preceding provisions of this Section 10.1, if Substantial Damage (as defined below) shall occur to the Property by fire or other insured casualty prior to Closing, then:

(i) Buyer shall have the right to terminate this Agreement by giving a written notice of termination to Seller within ten (10) Business Days after Buyer receives a written estimate of the estimated time to repair and cost to repair and/or replace the damage caused by the casualty, obtained pursuant to Section 10.2 below. In the event of any termination by Buyer pursuant to this Section 10.1(c), then the Deposit, together with all interest earned thereon, shall be promptly returned to Buyer by Escrow Holder, and this Agreement shall be

and become null and void, and neither Party shall have any further rights or obligations hereunder, except for the Surviving Obligations. As used in this Section 10.1, "**Substantial Damage**" shall mean such damage that would cost at least Five Million and 00/100 U.S. Dollars (US $5,000,000.00) to repair.

(ii) If Buyer does not timely give Seller notice of a termination pursuant Section 10.1(c)(i), then Buyer shall be deemed to have waived its right contained in Section 10.1(c)(i) to terminate this Agreement, and Buyer's obligations under this Agreement shall remain in effect notwithstanding such casualty.

Section 10.2 Time for Repair. The estimated cost to repair and/or restore and the estimated time to complete such repairs contemplated in Section 10.1 shall be established by estimates obtained by independent contractors retained by Seller, subject to the reasonable approval of Buyer. The Closing Date may be extended up to a maximum extension of ninety (90) calendar days as reasonably required to obtain such estimates, determine the availability and amount of insurance proceeds and give the notices required under this Article X. Seller and Buyer shall cooperate and exercise due diligence to obtain damage estimation and insurance proceeds.

Section 10.3 Condemnation. If, prior to Closing, any part of the Property is taken (other than a temporary Taking or a Taking which does not materially interfere with the use of or access to the Property), or if Seller shall receive an official notice from any Governmental Entity having eminent domain power over all or any part of the Property of its intention to take, by eminent domain proceeding, any material part of the Property (a "**Taking**"), then Buyer shall have the option, exercisable within twenty (20) days after receipt of written notice of such Taking, (and if necessary, Closing Date shall be extended to give the full period to make such election) time being of the essence, to terminate this Agreement by delivering notice thereof to Seller (a copy of such notice of termination shall be given to Escrow Holder), whereupon the Deposit, together with all interest earned thereon, shall be promptly returned to Buyer by Escrow Holder and this Agreement shall be deemed canceled and of no further force or effect, and neither Party shall have any further rights or liabilities against or to the other except for the Surviving Obligations. If a Taking shall occur and Buyer shall fail to terminate this Agreement in a timely fashion, then Buyer and Seller shall consummate this transaction in accordance with this Agreement, without any abatement of the Purchase Price or any liability or obligation on the part of Seller by reason of such Taking; provided, however, Seller shall, subject to the terms of the Buyer-Seller Lease, on the Closing Date, (i) assign and remit to Buyer the full amount of any award or other proceeds of such Taking which may have been collected by Seller as a result of such Taking, or (ii) if no award or other proceeds shall have been collected, deliver to Buyer an assignment of Seller's right to any such award or other proceeds which may be payable to Seller as a result of such Taking. For purposes hereof, a material Taking is the Taking of a portion of the Improvements that materially adversely affects the use of such Improvements by the tenant under the Buyer-Seller Lease, any Taking of ten percent (10%) or more of the Land.

ARTICLE XI
MISCELLANEOUS

Section 11.1 Amendment and Modification. Subject to applicable law, this Agreement may be amended, modified, or supplemented only by a written agreement signed by the party against whom enforcement is sought.

Section 11.2 **Notices**. All notices required or permitted hereunder shall be in writing and shall be served on the parties at the following address(es):

If to Seller: **[***]**

with a copy to: **[***]**

If to Buyer: **[***]**

With a copy to: **[***]**

If to Escrow Holder: **[***]**

Any such notices may be sent by (a) certified mail, return receipt requested, in which case notice shall be deemed delivered upon actual or attempted but refused delivery, (b) a nationally recognized overnight courier, in which case notice shall be deemed delivered upon actual or attempted but refused delivery, (c) personal delivery, in which case notice shall be deemed delivered upon actual or attempted but refused delivery, or (d) Email transmission, in which case notice shall be deemed delivered upon electronic verification that transmission to recipient was completed. The above addresses and Email addresses may be changed by written notice to the other party; provided that no notice of a change of address or Email address shall be effective until actual receipt of such notice.

Section 11.3 **Assignment**. Buyer shall not have the right to assign this Agreement, without the prior written consent of Seller, in its sole and absolute discretion. Notwithstanding the foregoing, Buyer may assign its interests herein (in whole or in part) to an Affiliate upon written notice to Seller (delivered at least three (3) Business Days prior to the scheduled Closing Date), and assumption by such assignee of Buyer's obligations hereunder, provided that such assignment will not relieve the original Buyer of its obligations hereunder until the Closing. This Agreement will be binding upon and inure to the benefit of Seller and Buyer and their respective successors and permitted assigns, and no other party will be conferred any rights by virtue of this Agreement or be entitled to enforce any of the provisions hereof. Whenever a reference is made in this Agreement to Seller or Buyer, such reference will include the successors and permitted assigns of such party under this Agreement.

Section 11.4 **Governing Law and Consent to Jurisdiction. THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF CONNECTICUT, WITHOUT REGARD TO ANY OTHERWISE APPLICABLE PRINCIPLES OF CONFLICTS OF LAWS. ANY ACTION ARISING OUT OF THIS AGREEMENT MUST BE COMMENCED BY BUYER OR SELLER IN THE STATE COURTS OF THE STATE OF CONNECTICUT OR IN U.S. FEDERAL COURTS HAVING JURISDICTION OVER THE STATE OF CONNECTICUT AND EACH PARTY HEREBY CONSENTS TO THE JURISDICTION OF THE ABOVE COURTS IN ANY SUCH ACTION AND TO THE LAYING OF VENUE IN THE STATE OF CONNECTICUT.**

Section 11.5 **Counterparts; Electronic Signatures**. This Agreement may be executed in counterparts, each of which shall be deemed an original, but such counterparts, when taken together, shall constitute one agreement. This Agreement may be executed by a Party's signature transmitted by email, and copies of this Agreement executed and delivered by means of emailed signatures shall have the same force and effect as copies hereof executed and delivered with original signatures. All

parties hereto may rely upon emailed signatures (including signatures in Portable Document Format) as if such signatures were originals. All parties hereto agree that an emailed signature page may be introduced into evidence in any proceeding arising out of or related to this Agreement as if it were an original signature page.

Section 11.6 Entire Agreement. This Agreement and any other document (including, without limitation, non-disclosure agreements executed by Buyer and/or its Affiliates, investors and other related parties with respect to the transactions contemplated by this Agreement) to be furnished pursuant to the provisions hereof embody the entire agreement and understanding of the parties hereto as to the subject matter contained herein. There are no restrictions, promises, representations, warranties, covenants, or undertakings other than those expressly set forth or referred to in such documents. This Agreement and such documents (including, without limitation, non-disclosure agreements executed by Buyer and/or its Affiliates, investors and other related parties with respect to the transactions contemplated by this Agreement) supersede all prior agreements and understandings among the parties with respect to the subject matter hereof.

Section 11.7 Severability. Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction will, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement, or affecting the validity or enforceability of any of the terms or provisions of this Agreement.

Section 11.8 Attorney Fees. If any action is brought by any party to this Agreement to enforce or interpret its terms or provisions, the prevailing party (whether by final judgment or out of court settlement) will be entitled to reasonable third-party attorney fees and costs and expenses of suit incurred in connection with such action prior to and at trial and on any appeal therefrom. Any judgment or order entered in any final judgment shall contain a specific provision providing for the recovery of all costs and expenses of suit, including attorneys' fees (collectively "**Costs**") incurred in enforcing, perfecting and executing such judgment. For the purposes of this paragraph, Costs shall include, without limitation, reasonable third-party attorneys' fees, costs and expenses incurred in (i) postjudgment motions, (ii) contempt proceeding, (iii) garnishment, levy, and debtor and third party examination, (iv) discovery, and (v) bankruptcy litigation.

Section 11.9 Payment of Fees and Expenses. Each party to this Agreement will be responsible for, and will pay, all of its own fees and expenses, including those of its counsel and accountants, incurred in the negotiation, preparation, and consummation of this Agreement and the transaction contemplated hereunder.

Section 11.10 No Joint Venture. Nothing set forth in this Agreement shall be construed to create a joint venture between Buyer and Seller.

Section 11.11 Waiver of Jury Trial. BUYER AND SELLER EACH HEREBY AGREE NOT TO ELECT A TRIAL BY JURY OF ANY ISSUE TRIABLE OF RIGHT BY JURY, AND WAIVES ANY RIGHT TO TRIAL BY JURY FULLY TO THE EXTENT THAT SUCH RIGHT SHALL NOW OR HEREAFTER EXIST WITH REGARD TO THIS AGREEMENT OR ANY CLAIM, COUNTERCLAIM OR OTHER ACTION ARISING IN CONNECTION THEREWITH. THIS WAIVER OF RIGHT TO TRIAL BY JURY IS GIVEN KNOWINGLY AND VOLUNTARILY BY BUYER AND SELLER, AND IS INTENDED TO ENCOMPASS

INDIVIDUALLY EACH INSTANCE AND EACH ISSUE AS TO WHICH THE RIGHT TO TRIAL BY JURY WOULD OTHERWISE ACCRUE. SELLER OR BUYER, AS APPLICABLE, IS HEREBY AUTHORIZED A COPY OF THIS SECTION 11.11 IN ANY PROCEEDING AS CONCLUSIVE EVIDENCE OF THIS WAIVER BY BUYER OR SELLER, AS APPLICABLE. THE PROVISIONS OF THIS SECTION 11.11 SHALL SURVIVE THE CLOSING OR EARLIER TERMINATION OF THIS AGREEMENT.

Section 11.12 Time of Essence. Time is of the essence of this Agreement. If the deadline for performance of any act hereunder shall fall on a day that is not a Business Day, the deadline for such performance shall be deemed to be the next Business Day following such day.

Section 11.13 No Waiver. No waiver of any of the provisions of this Agreement shall be deemed, or shall constitute, a waiver of any other provision, whether or not similar, nor shall any waiver constitute a continuing waiver, nor shall a waiver in any instance constitute a waiver in any subsequent instance. No waiver shall be binding unless executed in writing by the Party making the waiver.

Section 11.14 Not an Offer. The preparation or distribution of drafts hereof by one party to the other shall not be deemed to constitute an offer and this Agreement shall only become binding and enforceable upon execution hereof by both parties.

Section 11.15 No Third Party Beneficiaries. Nothing in this Agreement is intended to benefit any third party, or create any third party beneficiary.

Section 11.16 Exculpation. Notwithstanding anything to the contrary contained in this Agreement, (a) Seller's shareholders, partners, members, the partners or members of such partners or members, the shareholders of such partners or members, and the trustees, officers, directors, employees, agents and security holders of Seller and the partners or members of Seller assume no personal liability for any obligations entered into on behalf of Seller and its individual assets shall not be subject to any claims of any person relating to such obligations, (b) Buyer's shareholders, partners, members, the partners or members of such partners or members, the shareholders of such partners or members, and the trustees, officers, directors, employees, agents and security holders of Buyer and the partners or members of Buyer assume no personal liability for any obligations entered into on behalf of Buyer and their individual assets shall not be subject to any claims of any person relating to such obligations.. The foregoing shall govern any direct and indirect obligations of Seller under this Agreement. The provisions of this Section 11.16 shall survive the Closing or any termination of this Agreement

[**Balance of Page Intentionally Left Blank; signatures follow**]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

SELLER:

MANNKIND CORPORATION,
a Delaware corporation

By: /s/ David Thomson
Name: David Thomson
Title: Executive Vice President
Date: 9/23/21

BUYER:

1 CASPER, LLC,
a Delaware limited liability company

By: /s/ Christopher W. Brewer
Name: Christopher W. Brewer
Title: Authorized Representative
Date: 9/23/21

JOINDER BY ESCROW HOLDER:

The Escrow Holder is executing this Agreement to evidence its agreement to act as escrow agent in accordance with the terms and conditions of this Agreement.

FIRST AMERICAN TITLE INSURANCE COMPANY

By: _____
Name: _____
Its: _____

EXHIBIT A

Description of Land

257090980 v3

EXHIBIT B

List of Due Diligence Items

EXHIBIT B

257090980 v3

EXHIBIT C

Disclosure Items

Any item disclosed in any particular part of this **Exhibit C** and all matters shown on Schedule B to **Exhibit F** attached hereto or disclosed on the Survey will be deemed to be disclosed with respect to any other section and paragraph of Article VI of the Agreement to the extent its relevance or appropriateness is reasonably apparent from the context in which it is presented and to the extent of any cross-references and the like.

This **Exhibit C** and the information and disclosures contained in this **Exhibit C** are intended only to qualify and limit, and otherwise respond to requests for disclosures contained in, the representations and warranties of Seller contained in the Agreement and shall not be deemed to create any covenant. Any description of any document included in this **Exhibit C** is a summary only and is qualified in its entirety by the specific terms of such referenced document.

[to be provided]

EXHIBIT D

Form of Right of First Refusal

257090980 v3

EXHIBIT E

Form of Memorandum of Right of First Refusal

257090980 v3

EXHIBIT F

Form of Deed

257090980 v3

EXHIBIT G

INTENTIONALLY DELETED

EXHIBIT H

Form of Omnibus Assignment and Assumption Agreement

257090980 v3

EXHIBIT I

Form of Seller's Certificate

257090980 v3

EXHIBIT J

Form of Buyer's Certificate

257090980 v3

EXHIBIT K

Form of Title Affidavit

257090980 v3

EXHIBIT L

Anticipated EUR(s)

257090980 v3

EXHIBIT M

Form of Access and Remediation Agreement

257090980 v3

EXHIBIT N

Form of Buyer-Seller Lease

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 E. Castagna, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021 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.

/s/ Michael E. Castagna
Michael E. Castagna
Chief Executive Officer and Director

Date: November 9, 2021

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 B. Binder, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021 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.

/s/ Steven B. Binder
Steven B. Binder
Chief Financial Officer

Date: November 9, 2021

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)[1]

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, 2021, 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) or Rule 15d-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 E. 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.

In Witness Whereof, the undersigned has set his hand hereto as of the 9th day of November, 2021.

/s/ Michael E. Castagna
Michael E. 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)[1]

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, 2021, 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) or Rule 15d-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 B. 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.

In Witness Whereof, the undersigned has set his hand hereto as of the 9th day of November, 2021.

/s/ Steven B. Binder
Steven B. 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.