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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

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 0-26301

United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

Delaware	52-1984749
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1040 Spring Street, Silver Spring, MD	20910
(Address of Principal Executive Offices)	(Zip Code)

(301) 608-9292
(Registrant's Telephone Number, Including Area Code)
(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 exchange on which registered
Common Stock, par value $0.01 per share	UTHR	Nasdaq Global Select Market

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

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

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

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

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

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

The number of shares outstanding of the issuer's common stock, par value $.01 per share, as of July 27, 2022 was 45,516,299.

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements
Consolidated Balance Sheets
(In millions, except share data)

	June 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 795.2	$ 894.8
Marketable investments	1,460.0	1,035.9
Accounts receivable, no allowance for 2022 and 2021	173.4	198.7
Inventories, net	89.9	93.8
Other current assets	165.8	100.4
Total current assets	2,684.3	2,323.6
Marketable investments	1,641.9	1,649.9
Goodwill and other intangible assets, net	44.6	44.6
Property, plant, and equipment, net	791.4	780.9
Deferred tax assets, net	275.3	261.9
Other non-current assets	105.8	108.2
Total assets	**$ 5,543.3**	**$ 5,169.1**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 196.6	$ 174.6
Share tracking awards plan	95.3	102.4
Other current liabilities	39.6	28.4
Total current liabilities	331.5	305.4
Line of credit	800.0	800.0
Other non-current liabilities	93.4	104.8
Total liabilities	1,224.9	1,210.2
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $.01, 10,000,000 shares authorized, no shares issued	—	—
Common stock, par value $.01, 245,000,000 shares authorized, 72,109,175 and 71,727,021 shares issued, and 45,489,959 and 45,107,805 shares outstanding at June 30, 2022 and December 31, 2021, respectively	0.7	0.7
Additional paid-in capital	2,291.5	2,245.4
Accumulated other comprehensive loss	(65.5)	(23.0)
Treasury stock, 26,619,216 shares at June 30, 2022 and December 31, 2021	(2,579.2)	(2,579.2)
Retained earnings	4,670.9	4,315.0
Total stockholders' equity	4,318.4	3,958.9
Total liabilities and stockholders' equity	**$ 5,543.3**	**$ 5,169.1**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Operations
(In millions, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
Revenues:				
Net product sales	$ 466.9	$ 446.5	$ 918.8	$ 825.6
Other	—	—	10.0	—
Total revenues	466.9	446.5	928.8	825.6
Operating expenses:				
Cost of product sales	29.7	37.2	55.6	60.2
Research and development	93.9	74.3	162.9	378.0
Selling, general, and administrative	141.5	112.8	220.5	230.0
Total operating expenses	265.1	224.3	439.0	668.2
Operating income	201.8	222.2	489.8	157.4
Interest income	6.8	4.0	11.1	8.7
Interest expense	(6.2)	(4.7)	(10.9)	(9.3)
Other (expense) income, net	(51.8)	(2.7)	(29.0)	94.5
Impairments of investments in privately-held companies	—	(2.3)	(1.7)	(2.3)
Total other (expense) income, net	(51.2)	(5.7)	(30.5)	91.6
Income before income taxes	150.6	216.5	459.3	249.0
Income tax expense	(34.6)	(43.9)	(103.4)	(48.1)
Net income	**$ 116.0**	**$ 172.6**	**$ 355.9**	**$ 200.9**
Net income per common share:				
Basic	**$ 2.56**	**$ 3.85**	**$ 7.86**	**$ 4.49**
Diluted	**$ 2.41**	**$ 3.65**	**$ 7.43**	**$ 4.28**
Weighted average number of common shares outstanding:				
Basic	**45.4**	**44.8**	**45.3**	**44.7**
Diluted	**48.1**	**47.3**	**47.9**	**46.9**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income (In millions)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
Net income	$ 116.0	$ 172.6	$ 355.9	$ 200.9
Other comprehensive loss:				
Defined benefit pension plan:				
Actuarial gain arising during period, net of tax	—	—	0.2	0.2
Amortization of prior service cost included in net periodic pension cost, net of tax	0.2	0.2	0.3	0.3
Total defined benefit pension plan, net of tax	0.2	0.2	0.5	0.5
Unrealized loss on available-for-sale securities, net of tax	(11.4)	(2.0)	(43.0)	(4.9)
Other comprehensive loss, net of tax	(11.2)	(1.8)	(42.5)	(4.4)
Comprehensive income	**$ 104.8**	**$ 170.8**	**$ 313.4**	**$ 196.5**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Stockholders' Equity (In millions)

	Three Months Ended June 30, 2022 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, April 1, 2022	71.9	$ 0.7	$ 2,254.2	$ (54.3)	$(2,579.2)	$4,554.9	$ 4,176.3
Net income	—	—	—	—	—	116.0	116.0
Unrealized losses on available-for-sale securities	—	—	—	(11.4)	—	—	(11.4)
Defined benefit pension plan	—	—	—	0.2	—	—	0.2
Exercise of stock options	0.2	—	23.9	—	—	—	23.9
Share-based compensation	—	—	13.4	—	—	—	13.4
Balance, June 30, 2022	**72.1**	**$ 0.7**	**$ 2,291.5**	**$ (65.5)**	**$(2,579.2)**	**$4,670.9**	**$ 4,318.4**

	Three Months Ended June 30, 2021 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, April 1, 2021	71.4	$ 0.7	$ 2,173.2	$ (16.8)	$(2,579.2)	$3,867.5	$ 3,445.4
Net income	—	—	—	—	—	172.6	172.6
Unrealized losses on available-for-sale securities	—	—	—	(2.0)	—	—	(2.0)
Defined benefit pension plan	—	—	—	0.2	—	—	0.2
Restricted stock units (**RSUs**) withheld for taxes	—	—	(0.2)	—	—	—	(0.2)
Exercise of stock options	0.1	—	10.8	—	—	—	10.8
Share-based compensation	—	—	12.7	—	—	—	12.7
Balance, June 30, 2021	**71.5**	**$ 0.7**	**$ 2,196.5**	**$ (18.6)**	**$(2,579.2)**	**$4,040.1**	**$ 3,639.5**

	Six Months Ended June 30, 2022 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, January 1, 2022	71.7	$ 0.7	$ 2,245.4	$ (23.0)	$(2,579.2)	$ 4,315.0	$ 3,958.9
Net income	—	—	—	—	—	355.9	355.9
Unrealized losses on available-for-sale securities	—	—	—	(43.0)	—	—	(43.0)
Defined benefit pension plan	—	—	—	0.5	—	—	0.5
Shares issued under employee stock purchase plan (**ESPP**)	—	—	3.3	—	—	—	3.3
RSUs withheld for taxes	—	—	(11.1)	—	—	—	(11.1)
Common stock issued for RSUs vested	0.1	—	—	—	—	—	—
Exercise of stock options	0.3	—	28.2	—	—	—	28.2
Share-based compensation	—	—	25.7	—	—	—	25.7
Balance, June 30, 2022	**72.1**	**$ 0.7**	**$ 2,291.5**	**$ (65.5)**	**$(2,579.2)**	**$ 4,670.9**	**$ 4,318.4**

	Six Months Ended June 30, 2021 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, January 1, 2021	71.1	$ 0.7	$ 2,148.7	$ (14.2)	$(2,579.2)	$ 3,839.2	$ 3,395.2
Net income	—	—	—	—	—	200.9	200.9
Unrealized losses on available-for-sale securities	—	—	—	(4.9)	—	—	(4.9)
Defined benefit pension plan	—	—	—	0.5	—	—	0.5
Shares issued under ESPP	0.1	—	2.8	—	—	—	2.8
RSUs withheld for taxes	—	—	(10.4)	—	—	—	(10.4)
Common stock issued for RSUs vested	0.1	—	—	—	—	—	—
Exercise of stock options	0.2	—	28.3	—	—	—	28.3
Share-based compensation	—	—	27.1	—	—	—	27.1
Balance, June 30, 2021	**71.5**	**$ 0.7**	**$ 2,196.5**	**$ (18.6)**	**$(2,579.2)**	**$ 4,040.1**	**$ 3,639.5**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows (In millions)

	Six Months Ended June 30,	
	2022	2021
	(Unaudited)	
Cash flows from operating activities:		
Net income	$ 355.9	$ 200.9
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	25.2	24.9
Share-based compensation expense	44.4	69.2
Impairments of investments in privately-held companies	1.7	2.3
Intangible asset impairment charges	—	113.4
Impairments of property, plant, and equipment	—	17.0
Realized gain on sale of equity securities	—	(91.9)
Other	34.6	(3.0)
Changes in operating assets and liabilities:		
Accounts receivable	25.3	(16.1)
Inventories	1.1	0.8
Accounts payable and accrued expenses	13.1	2.2
Other assets and liabilities	(85.6)	(81.7)
Net cash provided by operating activities	415.7	238.0
Cash flows from investing activities:		
Purchases of property, plant, and equipment	(30.5)	(26.9)
Deposits	—	(7.8)
Purchases of available-for-sale investments	(1,008.1)	(869.4)
Maturities of available-for-sale investments	510.4	694.9
Sales of available-for-sale investments	—	45.1
Sales of investments in equity securities	—	108.9
Net cash used in investing activities	(528.2)	(55.2)
Cash flows from financing activities:		
Proceeds from line of credit	800.0	—
Repayment of line of credit	(800.0)	—
Payments of debt issuance costs	(7.5)	—
Proceeds from the exercise of stock options	28.2	28.3
Proceeds from the issuance of stock under ESPP	3.3	2.8
RSUs withheld for taxes	(11.1)	(10.4)
Net cash provided by financing activities	12.9	20.7
Net (decrease) increase in cash and cash equivalents	**$ (99.6)**	**$ 203.5**
Cash and cash equivalents, beginning of period	894.8	738.7
Cash and cash equivalents, end of period	**$ 795.2**	**$ 942.2**
Supplemental cash flow information:		
Cash paid for interest	**$ 9.4**	**$ 8.1**
Cash paid for income taxes	**$ 138.1**	**$ 85.4**
Non-cash investing and financing activities:		
Non-cash additions to property, plant, and equipment	**$ 12.6**	**$ 3.3**

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements
June 30, 2022 (Unaudited)

1. Organization and Business Description

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening conditions. On September 30, 2021, we converted to a Delaware public benefit corporation, with the express public benefit purpose to provide a brighter future for patients through (a) the development of novel pharmaceutical therapies; and (b) technologies that expand the availability of transplantable organs.

We have approval from the U.S. Food and Drug Administration (**FDA**) to market the following therapies: Tyvaso® (treprostinil) Inhalation Solution (**Tyvaso**), Tyvaso DPI™ (treprostinil) Inhalation Powder (**Tyvaso DPI**), Remodulin® (treprostinil) Injection (**Remodulin**), Orenitram® (treprostinil) Extended-Release Tablets (**Orenitram**), Unituxin® (dinutuximab) Injection (**Unituxin**), and Adcirca® (tadalafil) Tablets (**Adcirca**). We also derive revenues outside the United States from sales of Tyvaso, Remodulin, and Unituxin.

As used in these notes to our consolidated financial statements, unless the context otherwise requires, the terms "**we**", "**us**", "**our**", and similar terms refer to United Therapeutics Corporation and its consolidated subsidiaries.

2. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (**SEC**) for interim financial information. Accordingly, they do not include all of the information required by U.S. generally accepted accounting principles for complete financial statements. These consolidated financial statements should be read in conjunction with our audited consolidated financial statements and the accompanying notes to our consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on February 24, 2022.

In our management's opinion, the accompanying consolidated financial statements contain all adjustments, including normal, recurring adjustments, necessary to fairly present our financial position as of June 30, 2022 and December 31, 2021, our statements of operations, comprehensive income, and stockholders' equity for the three- and six-month periods ended June 30, 2022 and 2021, and our statements of cash flows for the six-month periods ended June 30, 2022 and 2021. Interim results are not necessarily indicative of results for an entire year.

Recently Issued Accounting Standards

Accounting Standards Adopted During the Period

None.

Accounting Standards Not Yet Adopted

None.

3. Investments

Marketable Investments

Available-for-Sale Debt Securities

Available-for-sale debt securities are recorded at fair value, with the portion of the unrealized gains and losses that are not credit-related included as a component of *accumulated other comprehensive loss* in stockholders' equity, until realized. Available-for-sale debt securities consisted of the following (in millions):

As of June 30, 2022	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 2,594.5	$ 0.6	$ (49.5)	$ 2,545.6
Corporate debt securities	566.4	0.1	(14.4)	552.1
Total	**$ 3,160.9**	**$ 0.7**	**$ (63.9)**	**$ 3,097.7**
Reported under the following captions in our consolidated balance sheets:				
Cash and cash equivalents				$ 44.8
Current marketable investments				1,411.0
Non-current marketable investments				1,641.9
Total				**$ 3,097.7**

As of December 31, 2021	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 2,178.9	$ 2.0	$ (7.3)	$ 2,173.6
Corporate debt securities	482.5	0.6	(2.0)	481.1
Total	**$ 2,661.4**	**$ 2.6**	**$ (9.3)**	**$ 2,654.7**
Reported under the following captions in our consolidated balance sheets:				
Cash and cash equivalents				$ 39.3
Current marketable investments				965.5
Non-current marketable investments				1,649.9
Total				**$ 2,654.7**

The following tables present gross unrealized losses and fair value for those available-for-sale debt securities that were in an unrealized loss position as of June 30, 2022 and December 31, 2021, aggregated by investment category and length of time that the individual securities have been in a continuous loss position (in millions):

	Less than 12 months		12 months or longer		Total	
As of June 30, 2022	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government and agency securities	$ 2,251.7	$ (48.2)	$ 44.7	$ (1.3)	$ 2,296.4	$ (49.5)
Corporate debt securities	509.4	(14.0)	8.3	(0.4)	517.7	(14.4)
Total	**$ 2,761.1**	**$ (62.2)**	**$ 53.0**	**$ (1.7)**	**$ 2,814.1**	**$ (63.9)**

	Less than 12 months		12 months or longer		Total	
As of December 31, 2021	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government and agency securities	$ 1,729.9	$ (7.3)	$ —	$ —	$ 1,729.9	$ (7.3)
Corporate debt securities	352.3	(2.0)	—	—	352.3	(2.0)
Total	**$ 2,082.2**	**$ (9.3)**	**$ —**	**$ —**	**$ 2,082.2**	**$ (9.3)**

At June 30, 2022 and December 31, 2021, we held 373 and 251 available-for-sale debt securities, respectively, that were in an unrealized loss position. In assessing whether the decline in fair value at June 30, 2022 of any of these securities resulted from a credit loss, we reviewed the credit ratings for each security and consulted with the investment managers regarding the ability to hold the security until maturity. We believe that these unrealized losses are a direct result of the current interest rate environment and do not represent an indication of credit loss. We do not intend to sell the investments in unrealized loss positions prior to their maturity and it is not more likely than not that we will be required to sell these investments before recovery of their amortized cost basis. There were no impairments due to credit loss on our available-for-sale debt securities during the three and six months ended June 30, 2022 and 2021.

The following table summarizes the contractual maturities of available-for-sale debt securities (in millions). Actual maturities may differ from contractual maturities because the issuers of certain of these debt securities have the right to call the securities or prepay their obligations under the securities with or without penalties.

	As of June 30, 2022	
	Amortized Cost	Fair Value
Due within one year	$ 1,470.8	$ 1,455.8
Due in one to three years	1,690.1	1,641.9
Total	**$ 3,160.9**	**$ 3,097.7**

Investments in Equity Securities with Readily Determinable Fair Values

We held investments in equity securities with readily determinable fair values of $49.0 million and $70.4 million as of June 30, 2022 and December 31, 2021, respectively, which are included in *current marketable investments* in our consolidated balance sheets. Changes in the fair value of publicly-traded equity securities are recorded in our consolidated statements of operations within *other (expense) income, net*. Refer to Note 4—*Fair Value Measurements*.

During the first quarter of 2021, we sold our investment in a publicly-traded company. We received $108.9 million in cash from the sale of the investment and realized a gain of $91.9 million. The gain was recorded within *other (expense) income, net* in our consolidated statements of operations for the six months ended June 30, 2021.

Investments in Privately-Held Companies

As of June 30, 2022 and December 31, 2021, we maintained non-controlling equity investments in privately-held companies of $29.4 million and $31.1 million, respectively, in the aggregate. We measure these investments using the measurement alternative because the fair values of these investments are not readily determinable. Under this alternative, the investments are measured at cost, less any impairment, and adjusted for any observable price changes. We include our investments in privately-held companies within *other non-current assets* in our consolidated balance sheets. These investments are subject to a periodic impairment review and, if impaired, the investment is measured and recorded at fair value in accordance with ASC 820, *Fair Value Measurements*.

During the first quarter of 2022, we identified an indicator of impairment for one of these companies. We evaluated this investment for impairment and recognized an impairment charge of $1.7 million. This impairment charge was recorded within *impairments of investments in privately-held companies* in our consolidated statements of operations for the six months ended June 30, 2022.

During the second quarter of 2021, we observed an indicator of impairment for our investment in two of these companies. We evaluated these investments for impairment and recognized impairment charges of $2.3 million in the aggregate. These impairment charges were recorded within *impairments of investments in privately-held companies* in our consolidated statements of operations.

Variable Interest Entity

Unconsolidated Variable Interest Entity

In November 2019, we entered into a supply agreement with an affiliate of DEKA Research & Development Corporation (**DEKA**) to manufacture and supply the Remunity® Pump to us. Under the terms of the supply agreement, we reimburse all of the affiliate's costs to manufacture and supply the Remunity Pump. We determined that the affiliate is a variable interest entity as we are the primary customer of the affiliate and the affiliate currently relies on our reimbursement of its costs to sustain its operations. We have determined we are not the primary beneficiary of the affiliate as we do not have the power to direct or control its significant activities related to the manufacturing of medical devices. Accordingly, we have not consolidated the affiliate's results of operations and financial position with ours. As of June 30, 2022 and December 31, 2021, our consolidated balance sheets included $10.4 million and $10.6 million of assets, respectively, related to the supply agreement. As of June 30, 2022 and December 31, 2021, our consolidated balance sheets included a $2.5 million and $2.0 million liability, respectively, for our obligation to reimburse costs related to the supply agreement. While the terms of the supply agreement expose us to various future risks of

loss given our responsibility to reimburse all costs incurred by the affiliate to manufacture and supply the Remunity Pump, we believe that our maximum exposure to loss as of June 30, 2022 as a result of our involvement with the affiliate is $10.4 million, the amount of assets related to the supply agreement noted above.

4. Fair Value Measurements

We account for certain assets and liabilities at fair value and classify these assets and liabilities within the fair value hierarchy (Level 1, Level 2, or Level 3). Our *other current assets* and *other current liabilities* have fair values that approximate their carrying values.

Assets and liabilities subject to fair value measurements are as follows (in millions):

	As of June 30, 2022			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds[1]	$ 216.7	$ —	$ —	$ 216.7
Time deposits[1]	150.3	—	—	150.3
U.S. government and agency securities[2]	—	2,545.6	—	2,545.6
Corporate debt securities[2]	—	552.1	—	552.1
Equity securities[3]	49.0	—	—	49.0
Contingent consideration[4]	—	—	0.6	0.6
Total assets	**$ 416.0**	**$ 3,097.7**	**$ 0.6**	**$ 3,514.3**
Liabilities				
Contingent consideration[5]	—	—	21.5	21.5
Total liabilities	**$ —**	**$ —**	**$ 21.5**	**$ 21.5**

	As of December 31, 2021			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds[1]	$ 516.7	$ —	$ —	$ 516.7
U.S. government and agency securities[2]	—	2,173.6	—	2,173.6
Corporate debt securities[2]	—	481.1	—	481.1
Equity securities[3]	70.4	—	—	70.4
Contingent consideration[4]	—	—	1.2	1.2
Total assets	**$ 587.1**	**$ 2,654.7**	**$ 1.2**	**$ 3,243.0**
Liabilities				
Contingent consideration[5]	—	—	20.8	20.8
Total liabilities	**$ —**	**$ —**	**$ 20.8**	**$ 20.8**

(1) Included in *cash and cash equivalents* in our consolidated balance sheets.

(2) Included in *cash and cash equivalents* and *current* and *non-current marketable investments* in our consolidated balance sheets. Refer to Note 3—*Investments—Marketable Investments—Available-for-Sale Debt Securities* for further information. The fair value of these securities is principally measured or corroborated by trade data for identical securities for which related trading activity is not sufficiently frequent to be considered a Level 1 input or comparable securities that are more actively traded.

(3) Included in *current marketable investments* in our consolidated balance sheets. The fair value of these securities is based on quoted market prices for identical instruments in active markets. During the three and six months ended June 30, 2022, we recognized $47.1 million and $21.4 million of net unrealized losses, respectively, on these securities. During the three and six months ended June 30, 2021, we recognized $1.3 million of net unrealized losses and $95.5 million of net unrealized and realized gains in the aggregate, respectively, on these securities. We recorded these gains and losses in our consolidated statements of operations within *other (expense) income, net*. Refer to Note 3—*Investments—Marketable Investments—Investments in Equity Securities with Readily Determinable Fair Values*.

(4) Included in *other non-current assets* in our consolidated balance sheets. We estimated the fair value of contingent consideration using a Monte Carlo simulation. The Monte Carlo simulation incorporates Level 3 inputs including price volatility of peer company stocks and the probability of completing certain milestones during a specified period of time. The fair value of our contingent consideration assets decreased by $0.6 million from December 31, 2021 to June 30, 2022. The loss was recorded within *other (expense) income, net* in our consolidated statements of operations.

(5) Included in *other current* and *other non-current liabilities* in our consolidated balance sheets. The fair value of our contingent consideration obligations has been estimated using probability-weighted discounted cash flow models (**DCFs**). The DCFs incorporate

Level 3 inputs, including estimated discount rates, that we believe market participants would consider relevant in pricing and the projected timing and amount of cash flows, which are estimated and developed, in part, based on the requirements specific to each acquisition agreement. The fair value of our contingent consideration liabilities increased by $0.7 million from December 31, 2021 to June 30, 2022. The associated expense was recorded within *research and development* in our consolidated statements of operations.

Fair Value of Financial Instruments

The carrying amounts of *cash and cash equivalents*, *accounts receivable*, *accounts payable*, and *accrued expenses* approximate fair value because of their short maturities. The fair values of our marketable investments and contingent consideration are reported above within the fair value hierarchy. Refer to Note 3—*Investments*. The carrying value of our debt is a reasonable estimate of the fair value of the outstanding debt based on the variable interest rate of the debt.

5. Inventories

Inventories are stated at the lower of cost (first-in, first-out method) or net realizable value and consist of the following, net of reserves (in millions):

	June 30, 2022	December 31, 2021
Raw materials	$ 19.4	$ 17.6
Work-in-progress	30.2	31.9
Finished goods	40.3	44.3
Total inventories	**$ 89.9**	**$ 93.8**

6. Goodwill and Other Intangible Assets

Goodwill and other intangible assets comprise the following (in millions):

	As of June 30, 2022			As of December 31, 2021		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	$ 28.0	$ —	$ 28.0	$ 28.0	$ —	$ 28.0
Other intangible assets:						
Technology, patents, and trade names	6.7	(5.6)	1.1	6.7	(5.6)	1.1
In-process research and development[1] [2]	15.5	—	15.5	15.5	—	15.5
Total	**$ 50.2**	**$ (5.6)**	**$ 44.6**	**$ 50.2**	**$ (5.6)**	**$ 44.6**

(1) In March 2021, we decided to discontinue the U.S. development of Trevyent®, due to written comments provided by the FDA in February 2021. The FDA provided these written comments following a meeting between us and the FDA to discuss our planned resubmission of our new drug application (**NDA**) for Trevyent in light of a complete response letter issued by the FDA in April 2020. We determined these FDA comments to be a potential indicator of impairment of our in-process research and development (**IPR&D**) asset related to Trevyent and fully impaired the $107.3 million IPR&D asset during the first quarter of 2021. The impairment charge was recorded within *research and development* in our consolidated statements of operations for the six months ended June 30, 2021.

(2) In January 2021, we decided to discontinue our research and development efforts related to biomechanical lungs. As a result of the decision, we fully impaired the IPR&D asset related to these efforts, which had a carrying value of $6.1 million, during the first quarter of 2021. The impairment charge was recorded within *research and development* in our consolidated statements of operations for the six months ended June 30, 2021.

7. Property, Plant, and Equipment

Property, plant, and equipment (**PP&E**) consists of the following (in millions):

	June 30, 2022	December 31, 2021
Land and land improvements	$ 134.0	$ 132.6
Buildings, building improvements, and leasehold improvements	619.2	612.7
Buildings under construction	76.6	55.1
Furniture, equipment, and vehicles	325.9	322.9
Subtotal	1,155.7	1,123.3
Less—accumulated depreciation	(364.3)	(342.4)
Property, plant, and equipment, net	**$ 791.4**	**$ 780.9**

In 2019, we completed construction of a new cell culture and purification facility. During the first quarter of 2021, we decided to repurpose this facility to produce autologous cells that we intend to use to cellularize lung scaffolds for clinical studies. The decision to repurpose this facility was an indicator of impairment of the facility which we evaluated during the first quarter of 2021. Based on our impairment assessment, we recorded an $11.6 million impairment charge for equipment that was disposed of when we repurposed this facility during the first quarter of 2021. During the six months ended June 30, 2021, we recorded $17.0 million of PP&E impairment charges in the aggregate, of which $15.5 million was recorded within *research and development* in our consolidated statements of operations and $1.5 million was recorded within *selling, general, and administrative* in our consolidated statements of operations. We did not record any PP&E impairment charges during the six months ended June 30, 2022.

We entered into a commercial supply agreement (**Supply Agreement**) with MannKind Corporation (**MannKind**), under which MannKind is responsible for manufacturing and supplying Tyvaso DPI to us on a cost-plus basis. Unless earlier terminated, the initial term of the Supply Agreement continues until December 31, 2031 and will thereafter be renewed automatically for additional, successive two-year terms unless either party provides notice of non-renewal. We determined that the Supply Agreement contains certain lease components and have elected the expedient to combine lease and non-lease components as a single lease component. All payment obligations under the Supply Agreement are variable in nature and we incurred costs of $7.5 million and $13.9 million thereunder during the three and six months ended June 30, 2022, respectively.

8. Debt

2022 Credit Agreement

In March 2022, we entered into a credit agreement (the **2022 Credit Agreement**) with Wells Fargo Bank, National Association (**Wells Fargo**), as administrative agent and a swingline lender, and various other lender parties, which provides for: (1) an unsecured revolving credit facility of up to $1.2 billion; and (2) a second unsecured revolving credit facility of up to $800.0 million (which facilities may, at our request, be increased by up to $500.0 million in the aggregate subject to obtaining commitments from existing or new lenders for such increase and other conditions). The facilities will mature five years after the closing date of the 2022 Credit Agreement on March 31, 2027, subject to the lenders' ability to extend the maturity date by one year if we request such an extension in accordance with the terms of the 2022 Credit Agreement, up to a maximum of two such extensions.

At our option, amounts borrowed under the 2022 Credit Agreement bear interest at either an adjusted Term Secured Overnight Finance Rate (**Term SOFR**) or a fluctuating base rate, in each case, plus an applicable margin determined on a quarterly basis based on our consolidated ratio of total indebtedness to EBITDA (as calculated in accordance with the 2022 Credit Agreement). To date, we have elected to calculate interest on the outstanding balance at an adjusted Term SOFR plus an applicable margin.

On March 31, 2022, we borrowed $800.0 million under the 2022 Credit Agreement, and used the funds to repay outstanding indebtedness under the 2018 Credit Agreement as discussed below under *2018 Credit Agreement*.

As of June 30, 2022 and December 31, 2021, our outstanding aggregate principal balance under the 2022 Credit Agreement and the 2018 Credit Agreement, respectively, was $800.0 million, all of which was classified as a non-current liability because we do not intend to repay any portion of this amount within one year.

The 2022 Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of June 30, 2022, we were in compliance with these covenants. Lung Biotechnology PBC is our only subsidiary that guarantees our obligations under the 2022 Credit Agreement though, from time to time, one or more of our other subsidiaries may be required to guarantee our obligations.

In connection with the 2022 Credit Agreement, we capitalized debt issuance costs of $7.5 million, which are being amortized to *interest expense* over the contractual term of the 2022 Credit Agreement. As of June 30, 2022, $3.2 million was recorded in *other current assets* and $12.1 million in *other non-current assets* in our consolidated balance sheets.

The interest expense reported in our consolidated statements of operations for the three and six months ended June 30, 2022 and 2021 related to our borrowings under the 2022 Credit Agreement and 2018 Credit Agreement.

2018 Credit Agreement

In June 2018, we entered into a credit agreement (the **2018 Credit Agreement**) with Wells Fargo, as administrative agent and a swingline lender, and various other lender parties, providing for: (1) an unsecured revolving credit facility of up to $1.0 billion; and (2) a second unsecured revolving credit facility of up to $500.0 million.

On March 31, 2022, we terminated the 2018 Credit Agreement and entered into the 2022 Credit Agreement. We repaid in full all our obligations under the 2018 Credit Agreement in connection with the termination of the 2018 Credit Agreement and our entry into the 2022 Credit Agreement. There were no penalties associated with the early termination of the 2018 Credit Agreement.

9. Share-Based Compensation

As of June 30, 2022, we have two shareholder-approved equity incentive plans: the United Therapeutics Corporation Amended and Restated Equity Incentive Plan (the **1999 Plan**) and the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (the **2015 Plan**). The 2015 Plan provides for the issuance of up to 11,500,000 shares of our common stock pursuant to awards granted under the 2015 Plan, which includes 500,000 shares added pursuant to an amendment and restatement of the 2015 Plan approved by our shareholders in June 2022. No further awards will be granted under the 1999 Plan. We also have one equity incentive plan, the United Therapeutics Corporation 2019 Inducement Stock Incentive Plan (the **2019 Inducement Plan**), that has not been approved by our shareholders, as permitted by the Nasdaq Stock Market rules. The 2019 Inducement Plan was approved by our Board of Directors in February 2019 and provides for the issuance of up to 99,000 shares of our common stock under awards granted to newly-hired employees. Currently, we grant equity-based awards to employees and members of our Board of Directors in the form of stock options and restricted stock units (**RSUs**) under the 2015 Plan, and we may grant RSUs to newly-hired employees under the 2019 Inducement Plan. Refer to the sections entitled *Stock Options* and *RSUs* below.

We previously issued awards under the United Therapeutics Corporation Share Tracking Awards Plan (**2008 STAP**) and the United Therapeutics Corporation 2011 Share Tracking Awards Plan (**2011 STAP**). We refer to the 2008 STAP and the 2011 STAP collectively as the **STAP** and awards outstanding under either of these plans as **STAP awards**. Refer to the section entitled *STAPs* below. We discontinued the issuance of STAP awards in June 2015.

In 2012, our shareholders approved the United Therapeutics Corporation Employee Stock Purchase Plan (**ESPP**), which is structured to comply with Section 423 of the Internal Revenue Code. Refer to the section entitled *ESPP* below.

The following table reflects the components of share-based compensation expense recognized in our consolidated statements of operations (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Stock options	$ 5.6	$ 5.7	$ 11.1	$ 14.0
RSUs	7.4	6.5	13.7	12.2
STAP awards	52.1	16.4	18.7	42.1
ESPP	0.4	0.5	0.9	0.9
Total share-based compensation expense before tax	**$ 65.5**	**$ 29.1**	**$ 44.4**	**$ 69.2**

Stock Options

We estimate the fair value of stock options using the Black-Scholes-Merton valuation model, which requires us to make certain assumptions that can materially impact the estimation of fair value and related compensation expense. The assumptions used to estimate fair value include the price of our common stock, the expected volatility of our common stock, the risk-free interest rate, the expected term of stock option awards, and the expected dividend yield.

The following weighted average assumptions were used in estimating the fair value of stock options granted to employees during the six months ended June 30, 2022 and 2021:

	June 30, 2022	June 30, 2021
Expected term of awards (in years)	6.0	6.0
Expected volatility	32.3 %	32.7 %
Risk-free interest rate	2.1 %	1.1 %
Expected dividend yield	— %	— %

A summary of the activity and status of stock options under our equity incentive plans during the six-month period ended June 30, 2022 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2022	7,317,978	$ 126.73		
Granted	17,619	178.82		
Exercised	(240,873)	117.35		
Forfeited/canceled	(2,500)	130.48		
Outstanding at June 30, 2022	**7,092,224**	**$ 127.17**	**4.1**	**$ 769.3**
Exercisable at June 30, 2022	**5,696,950**	**$ 125.80**	**3.9**	**$ 625.8**
Unvested at June 30, 2022	**1,395,274**	**$ 132.79**	**4.9**	**$ 143.5**

The weighted average fair value of a stock option granted during each of the six-month periods ended June 30, 2022 and June 30, 2021 was $63.07 and $54.63, respectively. These stock options have an aggregate grant date fair value of $1.1 million and $0.8 million, respectively. The total grant date fair value of stock options that vested during the six-month periods ended June 30, 2022 and June 30, 2021 was $14.6 million and $49.7 million, respectively.

Total share-based compensation expense related to stock options is recorded as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of product sales	$ —	$ —	$ —	$ 0.1
Research and development	—	0.2	0.1	0.4
Selling, general, and administrative	5.6	5.5	11.0	13.5
Share-based compensation expense before taxes	5.6	5.7	11.1	14.0
Related income tax benefit	(0.2)	(0.2)	(0.3)	(0.5)
Share-based compensation expense, net of taxes	**$ 5.4**	**$ 5.5**	**$ 10.8**	**$ 13.5**

As of June 30, 2022, unrecognized compensation cost related to stock options was $15.7 million. Unvested outstanding stock options as of June 30, 2022 had a weighted average remaining vesting period of 0.9 years.

Stock option exercise data is summarized below (dollars in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Number of options exercised	202,314	80,650	240,873	213,439
Cash received	$ 23.9	$ 10.8	$ 28.2	$ 28.3
Total intrinsic value of options exercised	$ 21.2	$ 4.7	$ 24.3	$ 9.4

RSUs

Each RSU entitles the recipient to one share of our common stock upon vesting. We measure the fair value of RSUs using the stock price on the date of grant. Share-based compensation expense for RSUs is recorded ratably over their vesting period.

A summary of the activity with respect to, and status of, RSUs during the six-month period ended June 30, 2022 is presented below:

	Number of RSUs	Weighted Average Grant Date Fair Value
Unvested at January 1, 2022	390,539	$ 129.76
Granted	295,268	187.20
Vested	(182,552)	120.80
Forfeited/canceled	(16,831)	153.60
Unvested at June 30, 2022	**486,424**	**$ 167.16**

Total share-based compensation expense related to RSUs is recorded as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of product sales	$ 0.6	$ 0.5	$ 1.2	$ 1.0
Research and development	2.8	2.2	4.8	4.0
Selling, general, and administrative	4.0	3.8	7.7	7.2
Share-based compensation expense before taxes	7.4	6.5	13.7	12.2
Related income tax benefit	(1.8)	(1.6)	(3.3)	(2.9)
Share-based compensation expense, net of taxes	**$ 5.6**	**$ 4.9**	**$ 10.4**	**$ 9.3**

As of June 30, 2022, unrecognized compensation cost related to the grant of RSUs was $70.6 million. Unvested outstanding RSUs as of June 30, 2022 had a weighted average remaining vesting period of 3.1 years.

STAPs

STAP awards convey the right to receive in cash an amount equal to the appreciation of our common stock, which is measured as the increase in the closing price of our common stock between the dates of grant and exercise. STAP awards expire on the tenth anniversary of the grant date, and in most cases, they vest in equal increments on each anniversary of the grant date over a four-year period. We discontinued the issuance of STAP awards in June 2015.

The aggregate STAP liability balance was $95.3 million and $102.4 million at June 30, 2022 and December 31, 2021, respectively, all of which was classified as a current liability in our consolidated balance sheets.

Estimating the fair value of STAP awards requires the use of certain inputs that can materially impact the determination of fair value and the amount of compensation expense we recognize. Inputs used in estimating fair value include the price of our common stock, the expected volatility of the price of our common stock, the risk-free interest rate, the expected term of STAP awards, and the expected dividend yield. The fair value of the STAP awards is measured at the end of each financial reporting period because the awards are settled in cash.

The table below includes the weighted average assumptions used to measure the fair value of the outstanding STAP awards:

	June 30, 2022	June 30, 2021
Expected term of awards (in years)	1.1	1.4
Expected volatility	34.0 %	31.2 %
Risk-free interest rate	2.8 %	0.2 %
Expected dividend yield	— %	— %

The closing price of our common stock was $235.64 and $179.41 on June 30, 2022 and June 30, 2021, respectively. The closing price of our common stock was $216.08 on December 31, 2021.

A summary of the activity and status of STAP awards during the six-month period ended June 30, 2022 is presented below:

	Number of Awards	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2022	1,093,560	$ 123.89		
Granted	—	—		
Exercised	(326,893)	106.99		
Forfeited/canceled	(354)	148.82		
Outstanding at June 30, 2022	**766,313**	**$ 131.09**	**2.2**	**$ 80.1**
Exercisable at June 30, 2022	**756,313**	**$ 132.12**	**2.2**	**$ 78.3**
Unvested at June 30, 2022	**10,000**	**$ 52.57**	**0.4**	**$ 1.8**

Share-based compensation expense recognized in connection with STAP awards is as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of product sales	$ 1.9	$ 0.8	$ 0.7	$ 1.9
Research and development	11.5	2.3	5.5	6.6
Selling, general, and administrative	38.7	13.3	12.5	33.6
Share-based compensation expense before taxes	52.1	16.4	18.7	42.1
Related income tax benefit	(10.5)	(2.6)	(3.9)	(7.5)
Share-based compensation expense, net of taxes	**$ 41.6**	**$ 13.8**	**$ 14.8**	**$ 34.6**

Cash paid to settle STAP exercises during the six-month periods ended June 30, 2022 and June 30, 2021 was $25.7 million and $42.2 million, respectively.

ESPP

The ESPP provides eligible employees with the right to purchase shares of our common stock at a discount through elective accumulated payroll deductions at the end of each offering period. Eligible employees may contribute up to 15 percent of their base salary, subject to certain annual limitations as defined in the ESPP. The purchase price of the shares is equal to the lower of 85 percent of the closing price of our common stock on either the first or last trading day of a given offering period. In addition, the ESPP provides that no eligible employee may purchase more than 4,000 shares during any offering period. The ESPP expires in June 2032 and limits the aggregate number of shares that can be issued under the ESPP to 3.0 million.

10. Earnings Per Common Share

Basic earnings per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period, adjusted for the potential dilutive effect of our outstanding stock options, RSUs, and shares issuable under the ESPP, as if they were vested and exercised.

The components of basic and diluted earnings per common share comprised the following (in millions, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Numerator:				
Net income	$ 116.0	$ 172.6	$ 355.9	$ 200.9
Denominator:				
Weighted average outstanding shares — basic	45.4	44.8	45.3	44.7
Effect of dilutive securities[1]:				
Stock options, RSUs, and ESPP	2.7	2.5	2.6	2.2
Weighted average shares — diluted[2]	**48.1**	**47.3**	**47.9**	**46.9**
Net income per common share:				
Basic	$ 2.56	$ 3.85	$ 7.86	$ 4.49
Diluted	$ 2.41	$ 3.65	$ 7.43	$ 4.28
Stock options and RSUs excluded from calculation[2]	**—**	**—**	**—**	**0.1**

(1) Calculated using the treasury stock method.

(2) The common shares underlying certain stock options and RSUs have been excluded from the computation of diluted earnings per share because their impact would be anti-dilutive.

11. Income Taxes

Our effective income tax rate (**ETR**) for the six months ended June 30, 2022 and 2021 was 23 percent and 19 percent, respectively. Our ETR for the six months ended June 30, 2022 increased compared to the ETR for the six months ended June 30, 2021 primarily due to an increase in the valuation allowance in the current period compared to a decrease in the prior period.

We record interest and penalties related to uncertain tax positions as a component of income tax expense. As of June 30, 2022 and December 31, 2021, our total liability for unrecognized tax benefits, including related interest, was approximately $4.4 million and $3.9 million, respectively. The total amount of unrecognized tax benefits relating to our tax positions is subject to change based on future events and it is reasonably possible that the balance could change significantly over the next 12 months. Given the uncertainty of future events, we are unable to reasonably estimate the range of possible adjustments to our unrecognized tax benefits.

12. Segment Information

We operate as one operating segment with a focus on the development and commercialization of products to address the unmet needs of patients with chronic and life-threatening conditions. Our Chief Executive Officer, as our chief operating decision maker, manages and allocates resources to the operations of our company on a consolidated basis. This enables our Chief Executive Officer to assess our overall level of available resources and determine how best to deploy these resources across functions, therapeutic areas, and research and development projects in line with our long-term company-wide strategic goals.

Net product sales, cost of product sales, and gross profit for each of our commercial products were as follows (in millions):

	Three Months Ended June 30,					
2022	**Tyvaso[1]**	**Remodulin[2]**	**Orenitram**	**Unituxin**	**Adcirca**	**Total**
Net product sales	$ 201.0	$ 132.0	$ 79.0	$ 44.5	$ 10.4	$ 466.9
Cost of product sales	6.5	8.6	6.4	3.5	4.7	29.7
Gross profit	**$ 194.5**	**$ 123.4**	**$ 72.6**	**$ 41.0**	**$ 5.7**	**$ 437.2**
2021						
Net product sales	$ 153.8	$ 139.8	$ 76.2	$ 53.1	$ 23.6	$ 446.5
Cost of product sales	9.7	8.4	3.8	5.0	10.3	37.2
Gross profit	**$ 144.1**	**$ 131.4**	**$ 72.4**	**$ 48.1**	**$ 13.3**	**$ 409.3**

	Six Months Ended June 30,					
2022	**Tyvaso[1]**	**Remodulin[2]**	**Orenitram**	**Unituxin**	**Adcirca**	**Total**
Net product sales	$ 373.0	$ 263.7	$ 161.8	$ 100.1	$ 20.2	$ 918.8
Cost of product sales	12.7	15.8	11.6	6.8	8.7	55.6
Gross profit	**$ 360.3**	**$ 247.9**	**$ 150.2**	**$ 93.3**	**$ 11.5**	**$ 863.2**
2021						
Net product sales	$ 276.8	$ 270.0	$ 148.6	$ 97.0	$ 33.2	$ 825.6
Cost of product sales	12.8	16.6	7.9	8.6	14.3	60.2
Gross profit	**$ 264.0**	**$ 253.4**	**$ 140.7**	**$ 88.4**	**$ 18.9**	**$ 765.4**

(1) Net product sales and cost of product sales include both the drug product and the respective inhalation devices for both Tyvaso and Tyvaso DPI.

(2) Net product sales and cost of product sales include sales of infusion devices, such as the Remunity Pump.

Geographic revenues are determined based on the country in which our customers (distributors) are located. Total revenues from external customers by geographic area are as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
United States	$ 440.4	$ 411.7	$ 850.2	$ 766.0
Rest of World[1]	26.5	34.8	78.6	59.6
Total[1]	**$ 466.9**	**$ 446.5**	**$ 928.8**	**$ 825.6**

(1) Includes other revenue of $10.0 million for the six months ended June 30, 2022, reflecting an up-front payment from an international distributor.

We recorded revenue from three distributors in the United States that exceeded ten percent of total revenues. Revenue from these three distributors as a percentage of total revenues is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Distributor 1	51 %	48 %	49 %	50 %
Distributor 2	31 %	29 %	30 %	27 %
Distributor 3	9 %	11 %	10 %	11 %

13. Litigation

Sandoz Antitrust Litigation

On April 16, 2019, Sandoz Inc. (**Sandoz**) and its marketing partner RareGen, LLC (now known as Liquidia PAH, LLC, a subsidiary of Liquidia Corporation) (**RareGen**), filed a complaint in the U.S. District Court for the District of New Jersey against us and Smiths Medical ASD, Inc. (**Smiths Medical**), alleging that we and Smiths Medical engaged in anticompetitive conduct in connection with

plaintiffs' efforts to launch their generic version of Remodulin. In particular, the complaint alleged that we and Smiths Medical unlawfully impeded competition by entering into an agreement to produce CADD-MS®3 cartridges specifically for the delivery of subcutaneous Remodulin for our patients, without making these cartridges available for the delivery of Sandoz's generic version of Remodulin. On March 30, 2020, the plaintiffs filed an amended complaint to add a count alleging that we breached our earlier patent settlement agreement with Sandoz by refusing to grant Sandoz access to cartridges purchased for our patients.

Smiths Medical was dismissed from the case in November 2020, based on a settlement resolving the disputes between the plaintiffs and Smiths Medical. As part of this settlement, Smiths Medical paid the plaintiffs $4.25 million, disclosed and made available to the plaintiffs certain specifications and other information related to the MS-3 cartridges, and granted to the plaintiffs a non-exclusive, royalty-free license in the United States to Smiths Medical's patents and copyrights associated with the MS-3 cartridges and certain other information related to the MS-3 pumps and cartridges.

On March 30, 2022, the court granted our motion for summary judgment with respect to all claims brought by the plaintiffs except the breach of contract claim. As a result, all antitrust claims, all claims under state competition laws, and the common law tortious interference claim have been resolved in our favor. These were the only claims in the case that gave rise to any potential for trebling of damages, punitive damages, and/or the award of attorneys' fees. The court also denied plaintiffs' request for injunctive relief.

The court granted Sandoz's motion for summary judgment with respect to Sandoz's breach of contract claim. The issue of what, if any, damages Sandoz is entitled to based on the contract claim will proceed to trial. RareGen has no claim for breach of contract and, as a result, has no remaining claims in the litigation. The case will now proceed to trial with respect to damages under the breach of contract claim. The court has not yet set a date for trial. The parties will have the right to appeal the summary judgment decisions upon entry of final judgment following the trial.

We intend to continue to vigorously defend this litigation. Among other things, we believe that plaintiffs, who were on notice that Smiths Medical would discontinue the CADD MS-3 delivery system, failed to fulfill their duty to properly mitigate their exposure as a result of such discontinuation, thereby causing the alleged damages for which they are suing us. However, due to the uncertainty inherent in any litigation, we cannot guarantee that an adverse outcome will not result. Any litigation of this nature could involve substantial cost, and an adverse outcome could result in substantial monetary damages. We currently are not able to reasonably estimate a range of potential losses due to the number of variables that may affect the outcome of the damages trial and any potential appeals, including potential damages amounts sought, the strength of our defenses, the variety of potential legal and factual determinations yet to be made by the court, the rulings that may be subject to appeal, and the inherent unpredictability of any outcome associated with these issues.

Litigation with Liquidia Technologies, Inc.

On March 30, 2020, Liquidia Technologies, Inc. (**Liquidia**) filed two petitions for *inter partes* review (**IPR**) with the Patent Trial and Appeal Board (**PTAB**) of the U.S. Patent and Trademark Office (**USPTO**). In its petitions, Liquidia sought to invalidate U.S. Patent Nos. 9,604,901 (the **'901 patent**) and 9,593,066 (the **'066 patent**), both of which relate to a method of making treprostinil, the active pharmaceutical ingredient in Tyvaso, Tyvaso DPI, Remodulin, and Orenitram. These patents were issued in March 2017 and are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, also known as the Orange Book, for Tyvaso, Tyvaso DPI, Remodulin, and Orenitram. In October 2020, the PTAB declined to institute IPR proceedings on the '066 patent because Liquidia failed to establish a reasonable likelihood of prevailing on any claim relating to the '066 patent. The PTAB instituted IPR proceedings on the '901 patent in October 2020 and issued a final written decision in October 2021. The final written decision found that Liquidia had proven the invalidity of seven of the claims of the '901 patent, but failed to prove the invalidity of two other claims. Each party has the right to appeal this decision until August 16, 2022, and no cancelation of claims takes effect until resolution of any appeals.

In January 2020, Liquidia submitted an NDA to the FDA for approval of Yutrepia, a dry powder inhalation formulation of treprostinil, to treat pulmonary arterial hypertension (**PAH**). This NDA was submitted under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. In November 2021, the FDA granted tentative approval of Liquidia's NDA.

In April 2020, we received a Paragraph IV Certification Notice Letter (**Notice Letter**) from Liquidia, stating that it intends to market Yutrepia before the expiration of all patents listed in the Orange Book for Tyvaso. The Notice Letter states that Liquidia's NDA for Yutrepia contains a Paragraph IV certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of Yutrepia.

On June 4, 2020, we filed a lawsuit in the U.S. District Court for the District of Delaware against Liquidia for infringement of the '901 patent and the '066 patent, both of which expire in December 2028. We filed our lawsuit within 45 days of receipt of notice from Liquidia of its NDA filing. As a result, under the Hatch-Waxman Act, the FDA is precluded by regulation from approving Liquidia's NDA for up to 30 months or until the resolution of the litigation, whichever occurs first. In July 2020, Liquidia filed an answer to our complaint that included counterclaims alleging, among other things, that the patents at issue in the litigation are not valid and will not be infringed by the commercial manufacture, use or sale of Yutrepia.

In July 2020, the USPTO issued a new patent to us related to Tyvaso. The new patent, U.S. Patent No. 10,716,793 (the **'793 patent**), expires in May 2027, and is listed in the Orange Book for Tyvaso. In July 2020, we filed an amended complaint against Liquidia to include a claim for infringement of the '793 patent. The '793 patent relates to a method of administering treprostinil via inhalation and includes claims covering the dosing regimen used to administer Tyvaso. In August 2020, Liquidia filed an answer to our

amended complaint that repeated its defenses and counterclaims and added new defenses and counterclaims related to the '793 patent. In August 2020, we filed a motion to dismiss Liquidia's invalidity defenses with respect to the '793 patent based on assignor estoppel. The court denied our motion, finding that it was too early in the case to conclusively resolve the issue given the fact-intensive inquiry that is necessary. In December 2021, we filed a stipulation that the '901 patent is not infringed by Liquidia based on the court's claim construction ruling. That stipulation is subject to our right to appeal the court's claim construction at the appropriate time. In January 2022, Liquidia filed a motion for summary judgment arguing that the '901 and '066 patents are invalid based on collateral estoppel due to an earlier decision invalidating a related patent, U.S. Patent No. 8,497,393. The court denied Liquidia's motion for summary judgment.

Trial took place during March 28-31, 2022. No claim or defense was resolved at trial other than Liquidia's indefiniteness defense, and the court entered judgment in our favor on that defense during trial. Post-trial briefing is complete, and we expect the court to issue its decision sometime before the expiration of the 30-month stay in October 2022.

In January 2021, Liquidia filed another petition for IPR with the PTAB. In its petition, Liquidia sought to invalidate the '793 patent. On July 19, 2022, the PTAB issued a final written decision finding all claims of the '793 patent to be unpatentable. We have the right to appeal this decision. We also have the right to request a rehearing, if we choose to do so, before any appeal. Any appeals of the PTAB's final written decision would delay any final outcome. The PTAB's decision does not resolve the ongoing district court litigation, and does not remove the 30-month stay.

In June 2021, we filed a motion in the patent case in the U.S. District Court for the District of Delaware to file an amended complaint adding trade secret misappropriation claims against Liquidia and a former Liquidia employee, Dr. Robert Roscigno. The court denied the motion based on a finding that adding the additional claims would impact the case schedule. Thus, we filed those claims as a separate case against Liquidia and Robert Roscigno in North Carolina state court.

We plan to vigorously enforce our intellectual property rights related to Tyvaso.

MSP Recovery Litigation

On July 27, 2020, MSP Recovery Claims, Series LLC; MSPA Claims 1, LLC; and Series PMPI, a designated series of MAO-MSO Recovery II, LLC filed a "Class Action Complaint" against Caring Voices Coalition, Inc. (**CVC**) and us in the U.S. District Court for the District of Massachusetts. The complaint alleged that we violated the federal Racketeer Influenced and Corrupt Organizations act and various state laws by coordinating with CVC when making donations to a PAH fund so that those donations would go towards copayment obligations for Medicare patients taking drugs manufactured and marketed by us. Plaintiffs claim to have received assignments from various Medicare Advantage health plans and other insurance entities that allow them to bring this lawsuit on behalf of those entities to recover allegedly inflated amounts they paid for our drugs. In April 2021, the court granted our motion to transfer the case to the U.S. District Court for the Southern District of Florida. Two members of the putative class, Humana Inc. and UnitedHealthcare Insurance Company, have informed us that they may bring claims directly against us to recover alleged overpayments.

In October 2021, we filed a motion for judgment on the pleadings, seeking to dismiss the plaintiffs' claims in this litigation. On that same day, plaintiffs filed an amended complaint that includes state antitrust claims based on alleged facts similar to those raised by Sandoz and RareGen in the matter described above. The amended complaint added MSP Recovery Claims Series 44, LLC as a plaintiff and Smiths Medical and CVC as defendants. As a result of the amended complaint, the court ruled that our motion for judgment on the pleadings was moot. In December 2021, we filed a motion to dismiss all of the plaintiffs' claims in the amended complaint, including the new antitrust claims. Smiths Medical has also filed a motion to dismiss the plaintiffs' claims against Smiths Medical. On July 21, 2022, the magistrate judge in the case issued a report and recommendation that the court grant both our and Smiths Medical's motions to dismiss without prejudice. The parties have the right to file objections to the report and recommendation by August 4, 2022. The court has set a case schedule with trial commencing in June 2024, if the motions to dismiss are not granted by the court.

We intend to vigorously defend against this lawsuit.

Patent Litigation with ANI Pharmaceuticals, Inc.

In February 2021, we received a Paragraph IV certification notice letter from ANI Pharmaceuticals, Inc. (**ANI**) indicating that ANI submitted an abbreviated new drug application (**ANDA**) to the FDA to market a generic version of Orenitram before the expiration of 11 of our patents. ANI's notice letter stated that the ANDA contains a Paragraph IV certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the proposed product described in ANI's ANDA submission. We responded to the ANI notice letter by filing a lawsuit against ANI in April 2021 in the U.S. District Court for the District of Delaware alleging infringement of each of the 11 patents.

We entered into a settlement agreement with ANI in May 2022, resolving the litigation without any payment obligation by either party. Under the terms of the settlement agreement, ANI is permitted to market its generic version of Orenitram in December 2027 or earlier in some circumstances.

We previously settled litigation with Actavis Laboratories FL, Inc. (**Actavis**) related to its ANDA submitted to the FDA to market a generic version of Orenitram. Under our settlement agreement, Actavis is permitted to market its generic version of Orenitram in June 2027.

340B Program Litigation

We participate in the Public Health Service's 340B drug pricing program (the **340B program**), through which we sell our products at discounted prices to covered entities, including through pharmacies that have contracts with such covered entities (**340B contract pharmacies**). Increasing use of 340B contract pharmacies, coupled with a lack of oversight and transparency, has resulted in increased risks of 340B statutory violations related to the diversion of 340B-purchased drugs to individuals who are not patients of the 340B covered entity, and to prohibited "duplicate discounts" when 340B-purchased drugs are also billed to Medicaid. In November 2020, we notified the U.S. Health Resources and Services Administration (**HRSA**) that we would begin implementing narrowly-tailored 340B contract pharmacy policies with the goal of stemming abuses of the 340B program without upsetting the status quo or creating hardship for covered entities or their patients. At around the same time, a number of other manufacturers also announced their own policies aimed at stemming 340B program abuses.

In December 2020, the U.S. Department of Health and Human Services (**HHS**) General Counsel issued a non-binding Advisory Opinion (the **Advisory Opinion**) concluding that, among other things, pharmaceutical manufacturers are obligated to sell their drugs at the 340B discounted price to an unlimited number of 340B contract pharmacies. In May 2021, HRSA sent a letter to us stating that our 340B contract pharmacy policies violated the 340B statute. HRSA also sent materially similar letters to five other pharmaceutical manufacturers. We responded to that letter by clarifying our policies and requesting additional information from HRSA. To date, HRSA has not responded.

The federal government's pronouncements regarding the use of 340B contract pharmacies have triggered a variety of litigation. In one of those cases, the court concluded that the Advisory Opinion was "legally flawed," and in response HHS withdrew the Advisory Opinion. Notwithstanding the withdrawal of the Advisory Opinion, HRSA has made clear that it is not withdrawing its May 2021 letter to us and the threat of enforcement action.

On June 23, 2021, we commenced litigation against HRSA and HHS in the U.S. District Court for the District of Columbia seeking to vindicate the lawfulness of our 340B program contract pharmacy policies. Despite the litigation, in September 2021, HRSA sent to us, along with the other manufacturers challenging HRSA's 340B interpretation, letters stating that HRSA is referring "this issue to the HHS Office of the Inspector General (**OIG**)" for potential enforcement action. We have not received any communication from the OIG regarding our 340B contract pharmacy policy. Meanwhile, the parties submitted and fully briefed cross-motions for summary judgment, and the court heard oral argument on those motions, and also similar motions in a related case involving Novartis, in October 2021. In November 2021, the court granted our motion for summary judgment in part, and issued a decision holding that the HRSA letters threatening enforcement action "contain legal reasoning that rests upon an erroneous reading of Section 340B." The court explained that "[t]he statute's plain language, purpose, and structure do not prohibit drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies. Nor do they permit all conditions. Accordingly, any future enforcement action must rest on a new statutory provision, a new legislative rule, or a well-developed legal theory that Section 340B precludes the specific conditions at issue here." HRSA and HSS appealed to the U.S. Court of Appeals for the District of Columbia Circuit in December 2021, and the appeal is pending. No date for oral argument has been set.

Litigation involving other manufacturers is also moving forward in parallel with our case, and some of the decisions issued in those cases have reached different conclusions regarding HRSA's and HHS's interpretation of the 340B statute than our case.

We intend to vigorously defend our 340B program contract pharmacy policies.

14. Priority Review Voucher

In December 2020, we entered into an agreement to acquire a rare pediatric disease priority review voucher for $105.0 million. In January 2021, we closed the transaction and expensed the $105.0 million within *research and development* in our consolidated statements of operations for the first quarter of 2021. We redeemed the voucher in connection with our submission of the NDA for Tyvaso DPI in April 2021.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2021 (the **2021 Annual Report**), and our consolidated financial statements and accompanying notes included in *Part I, Item I* of this Quarterly Report on Form 10-Q. All statements in this filing are made as of the date this Quarterly Report on Form 10-Q is filed with the U.S. Securities and Exchange Commission (**SEC**). We undertake no obligation to publicly update or revise these statements, whether as a result of new information, future events or otherwise.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations and other sections of this report contain forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 (the **Exchange Act**) and the Private Securities Litigation Reform Act of 1995. These statements, which are based on our beliefs and expectations about future outcomes and on information available to us through the date this Quarterly Report on Form 10-Q is filed with the SEC, include, among others, statements related to the following:

- The potential impact of the COVID-19 pandemic on our business, results of operations, liquidity, and operations, and our ability to mitigate this potential impact;
- Expectations of revenues, expenses, profitability, cash flows, and growth in the number of patients being treated with our products, including anticipated growth in the number of Tyvaso patients as a result of the expansion of its label to include pulmonary hypertension associated with interstitial lung disease (**PH-ILD**) and anticipated growth in revenues following the recent launch of Tyvaso DPI;
- The sufficiency of our cash on hand to support operations;
- Our ability to obtain financing on terms favorable to us or at all;
- Our ability to obtain and maintain domestic and international regulatory approvals;
- Our ability to maintain attractive pricing for our products, in light of increasing competition, including from generic products, and pressure from government and other payers to decrease the costs associated with healthcare;
- The expected volume and timing of sales of our commercial products, as well as potential future commercial products, including the anticipated effect of various research and development efforts on sales of these products;
- The timing and outcome of clinical studies, other research and development efforts, and related regulatory filings and approvals;
- The outcome of pending and potential future legal and regulatory actions by the U.S. Food and Drug Administration (**FDA**) and other regulatory and government enforcement agencies, and the anticipated duration of regulatory exclusivity for our products;
- The timing and outcome of ongoing litigation, including the lawsuit filed against us by Sandoz, Inc. (**Sandoz**) and Liquidia PAH, LLC (formerly known as RareGen, LLC) (**RareGen**); our patent and trade secret litigation with Liquidia Technologies, Inc. (**Liquidia**) related to its new drug application (**NDA**) for Yutrepia; our litigation with MSP Recovery Claims, Series LLC, and related entities; and our litigation with the U.S. Department of Health and Human Services (**HHS**) and the U.S. Health Resource Services Administration (**HRSA**) related to the Public Health Service's 340B drug pricing program (the **340B program**);
- The impact of competing therapies on sales of our commercial products, including the impact of generic versions of Adcirca and Remodulin; established therapies such as Uptravi; and newly-developed therapies;
- The expectation that we will be able to manufacture sufficient quantities and maintain adequate inventories of our commercial products, through both our in-house manufacturing capabilities and third-party manufacturing sites, and our ability to obtain and maintain related approvals by the FDA and other regulatory agencies;
- The adequacy of our intellectual property protection and the validity and expiration dates of the patents we own or license, as well as the regulatory exclusivity periods for our products;
- The effect of our recent conversion to a Delaware public benefit corporation (**PBC**);
- Any statements that include the words "believe," "seek," "expect," "anticipate," "forecast," "project," "intend," "estimate," "should," "could," "may," "will," "plan," or similar expressions; and
- Other statements contained or incorporated by reference in this report that are not historical facts.

We caution you that these statements are not guarantees of future performance and are subject to numerous evolving risks and uncertainties that we may not be able to accurately predict or assess, and that may cause our actual results to differ materially from anticipated results, including the risks and uncertainties we describe in *Part II, Item 1A—Risk Factors* of this Quarterly Report on Form 10-Q; factors described in our 2021 Annual Report, under the section entitled *Part I, Item 1A—Risk Factors*, and factors described in other cautionary statements, cautionary language, and risk factors set forth in our other filings with the SEC.

Impact of COVID-19 on our Business

We are closely monitoring developments related to the COVID-19 pandemic and are making every effort to ensure we remain focused on the health and well-being of our patients and our employees while maintaining business continuity. It remains difficult to predict what impact this pandemic, and the associated economic impact, will ultimately have on our business. Except as otherwise discussed in this Quarterly Report on Form 10-Q, there have been no material changes to the impact of COVID-19 on our business since the date of our 2021 Annual Report. Please see the discussion of the impact of COVID-19 on our business in our 2021 Annual Report.

For a discussion of the risks to our business associated with COVID-19, please see the risk factor below entitled, *We face risks and uncertainties related to the COVID-19 pandemic, which could significantly disrupt our operations and/or business for an unknown period of time.*

Overview of Marketed Products

We market and sell the following commercial products:

- *Tyvaso*, an inhaled formulation of the prostacyclin analogue treprostinil, approved by the FDA and regulatory authorities in Argentina and Israel to improve exercise ability in patients with pulmonary arterial hypertension (**PAH**). Tyvaso was also approved by the FDA in March 2021 to improve exercise ability in patients with PH-ILD. In May 2022, we also obtained FDA approval of Tyvaso DPI to treat PAH and PH-ILD, and we initiated commercial shipments of Tyvaso DPI to our distributors in June 2022.
- *Remodulin*, a continuously-infused formulation of treprostinil, approved by the FDA for subcutaneous and intravenous administration to diminish symptoms associated with exercise in patients with PAH. Remodulin has also been approved in various countries outside of the United States. In February 2021, we launched U.S. sales of the Remunity Pump, a new subcutaneous delivery system for Remodulin.
- *Orenitram*, a tablet dosage form of treprostinil, approved by the FDA to delay disease progression and improve exercise capacity in PAH patients. In April 2022, an international distributor submitted a marketing approval application for Orenitram to the European Medicines Agency.
- *Unituxin*, a monoclonal antibody approved in the United States, Canada, and Japan for treatment of high-risk neuroblastoma.
- *Adcirca*, an oral PDE-5 inhibitor approved by the FDA to improve exercise ability in PAH patients.

Revenues

Our net product sales consist of sales of the commercial products noted above, together with associated sales of delivery devices (in the case of Remodulin, Tyvaso, and Tyvaso DPI), and up-front and milestone payments by our distributors. We have entered into separate, non-exclusive distribution agreements with Accredo Health Group, Inc. and its affiliates (**Accredo**) and Caremark, L.L.C. (**CVS Specialty**) to distribute Tyvaso, Tyvaso DPI, Remodulin, the Remunity Pump, and Orenitram in the United States, and we have entered into an exclusive distribution agreement with ASD Specialty Healthcare, Inc., an affiliate of AmerisourceBergen Corporation, to distribute Unituxin in the United States. We recently amended our agreements with Accredo and CVS Specialty to include the distribution of Tyvaso DPI. We also sell Tyvaso, Remodulin, and Unituxin to distributors internationally. We sell Adcirca through the pharmaceutical wholesale network of Eli Lilly and Company (**Lilly**). To the extent we have increased the price of any of these products, increases have typically been in the single-digit percentages per year, except for Adcirca, the price of which is set solely by Lilly.

We require our specialty pharmaceutical distributors to maintain reasonable levels of inventory reserves for our treprostinil-based therapies because the interruption of these therapies can be life threatening. Our specialty pharmaceutical distributors typically place monthly orders based on current utilization trends and contractual minimum and maximum inventory requirements. As a result, sales of our treprostinil-based therapies can vary depending on the timing and magnitude of these orders and do not precisely reflect changes in patient demand.

Generic Competition and Challenges to our Intellectual Property Rights

Remodulin—Generic Competition

We settled litigation with Sandoz related to its abbreviated new drug application (**ANDA**) seeking FDA approval to market a generic version of Remodulin and in March 2019, Sandoz announced the availability of its generic product in the United States. We have also entered into similar settlement agreements with other generic companies, some of which have also launched sales of generic versions of Remodulin. Through June 30, 2022, we have seen minimal erosion of Remodulin sales as a result of generic treprostinil competition in the United States. We are currently engaged in litigation with Sandoz and its marketing

partner, RareGen (now a subsidiary of Liquidia Corporation, the parent company for Liquidia), related to the infusion devices used to deliver Remodulin subcutaneously. We understand that generic treprostinil was initially launched by Sandoz/RareGen for use only by intravenous administration. In May 2021, Liquidia announced that Sandoz's generic treprostinil has been made available for subcutaneous use, following FDA clearance of a cartridge that can deliver the product via the Smiths Medical MS-3 pump. See Note 13—*Litigation*, to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

Regulatory authorities in various European countries began approving generic versions of Remodulin in 2018, followed by pricing approvals and launches in most of these countries in 2019 and 2020. As a result, our international Remodulin revenues have come under pressure due to increased competition and a reduction in our contractual transfer price for Remodulin sold by certain international distributors for sales in countries in which the pricing of Remodulin is impacted by the generic competition.

Tyvaso and Orenitram—Potential Future Generic Competition

We also settled litigation with Watson Laboratories, Inc. (**Watson**) and Actavis Laboratories FL, Inc. (**Actavis**) related to their ANDAs seeking FDA approval to market generic versions of Tyvaso and Orenitram, respectively, before the expiration of certain of our U.S. patents. Under the settlement agreements, Watson and Actavis can market their generic versions of Tyvaso and Orenitram in the United States beginning in January 2026 and June 2027, respectively, although they may be permitted to enter the market earlier under certain circumstances. In May 2022, we settled litigation with ANI Pharmaceuticals, Inc. (**ANI**) regarding its ANDA seeking FDA approval to market a generic version of Orenitram. Under the settlement agreements, ANI can market its generic version of Orenitram in the United States beginning in December 2027, although it may be permitted to enter the market earlier under certain circumstances. Competition from these generic companies could reduce our net product sales and profits.

Liquidia—Yutrepia

We are engaged in patent litigation with Liquidia concerning three patents related to Tyvaso. The litigation is proceeding in parallel in two fora: (1) federal district court; and (2) the Patent Trial and Appeal Board (**PTAB**) of the U.S. Patent and Trademark Office.

As background, in January 2020 Liquidia submitted its initial NDA to the FDA for approval of Yutrepia™ (formerly known as LIQ861), a dry powder formulation of treprostinil for inhalation. The Yutrepia NDA was submitted under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug, and received tentative approval from the FDA in November 2021. If and when Liquidia launches Yutrepia, it would compete directly with Tyvaso, Tyvaso DPI, and our other treprostinil-based products.

Following the initial submission of the Yutrepia NDA, we filed a lawsuit in federal district court against Liquidia for infringement of three of our patents. As a result, the FDA is automatically precluded from granting final approval of Liquidia's NDA for up to 30 months (a period that expires in October 2022) or until final judgment is issued in the district court litigation, whichever occurs first. Liquidia contends that each asserted claim of these three patents is invalid and/or not infringed by Yutrepia. The trial was held during March 28-31, 2022, and we expect the court to issue a decision sometime between now and October of 2022.

Separately, Liquidia has been attempting to invalidate these patents by filing petitions for *inter partes* review (**IPR**) with the PTAB. Challengers in IPR proceedings have a lower burden of proof (preponderance of the evidence) relative to district court litigation (clear and convincing evidence) to successfully challenge the validity of patent claims.

- *U.S. Patent No. 9,593,066*: In October 2020, the PTAB declined to institute IPR proceedings relating to this patent because Liquidia failed to establish a reasonable likelihood of prevailing on any claim of this patent.
- *U.S. Patent No. 9,604,901*: In October 2021, the PTAB issued a final written decision on Liquidia's IPR relating to this patent. The PTAB upheld the patentability of two of the claims of this patent, one of which was being asserted against Liquidia in the district court litigation, and found that seven other claims of this patent were unpatentable. All claims of this patent remain valid until any IPR appeals are exhausted. In December 2021, we filed a stipulation in the district court litigation that the '901 patent is not infringed by Liquidia based on the court's claim construction ruling. That stipulation is subject to our right to appeal the court's claim construction at the appropriate time.
- *U.S. Patent No. 10,716,793*: In August 2021, the PTAB instituted IPR proceedings related to this patent. In July 2022, the PTAB issued a final written decision finding all claims of this patent to be unpatentable. We have the right to appeal this decision. We also have the right to request a rehearing, if we choose to do so, prior to any appeal. All claims of this patent remain valid until any IPR appeals are exhausted.

In order to prevail in our district court litigation against Liquidia, we need a judgment that at least one of the claims of at least one of these patents is not invalid and is infringed by Yutrepia. We must prove infringement by a preponderance of the evidence, and in order for Liquidia to prevail on its invalidity defense, it must prove invalidity by clear and convincing evidence. For further details, please see Note 13—*Litigation*, to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

Adcirca—Generic Competition

A U.S. patent for Adcirca for treatment of pulmonary hypertension expired in November 2017, and FDA-conferred regulatory exclusivity expired in May 2018, leading to the launch of a generic version of Adcirca by Mylan N.V. in August 2018, and by additional companies in February 2019. Generic competition for Adcirca has had a material adverse impact on Adcirca net product sales.

General

We intend to vigorously enforce our intellectual property rights related to our products. However, we may not prevail in defending our patent rights, and additional challenges from other ANDA filers or other challengers may surface with respect to our products. Our patents could be invalidated, found unenforceable, or found not to cover one or more generic forms of our products. If any ANDA filer or filer of a 505(b)(2) NDA for a branded treprostinil product were to receive approval to sell its treprostinil product and/or prevail in any patent litigation, our affected product(s) would become subject to increased competition. Patent expiration, patent litigation, and competition from generic or other branded treprostinil manufacturers could have a significant, adverse impact on our treprostinil-based product revenues — including the anticipated revenues from new products such as Tyvaso DPI — our profits, and our stock price. These potential effects are inherently difficult to predict. For additional discussion, refer to the risk factor entitled, *Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profit*s, contained in *Part II*, *Item 1A—Risk Factors* included in this Quarterly Report on Form 10-Q.

Operating Expenses

We devote substantial resources to our various clinical trials and other research and development efforts, which are conducted both internally and through third parties. From time to time, we also license or acquire additional technologies and compounds to be incorporated into our development pipeline. Our operating expenses include the costs described below.

Cost of Product Sales

Our cost of product sales primarily includes costs to manufacture our products, royalty and milestone payments under license agreements granting us rights to sell related products, direct and indirect distribution costs incurred in the sale of our products, and the costs of inventory reserves for current and projected obsolescence. These costs also include share-based compensation and salary-related expenses for direct manufacturing and indirect support personnel, quality review and release for commercial distribution, direct materials and supplies, depreciation, facilities-related expenses, and other overhead costs.

Research and Development

Our research and development expenses primarily include costs associated with the research and development of products and post-marketing research commitments. These costs also include share-based compensation and salary-related expenses for research and development functions, professional fees for preclinical and clinical studies, costs associated with clinical manufacturing, facilities-related expenses, regulatory costs, and costs associated with payments to third-party contract manufacturers before FDA approval of the relevant product. Expenses also include costs for third-party arrangements, including upfront fees and milestone payments required under license arrangements for therapies under development.

Selling, General, and Administrative

Our selling, general, and administrative expenses primarily include costs associated with the commercialization of approved products and general and administrative costs to support our operations. Selling expenses also include share-based compensation, salary-related expenses, product marketing and sales operations costs, and other costs incurred to support our sales efforts. General and administrative expenses also include our core corporate support functions such as human resources, finance, and legal, external costs to support our core business such as insurance premiums, legal fees, and other professional service fees.

Share-Based Compensation

Historically, we granted stock options under our Amended and Restated Equity Incentive Plan and awards under our Share Tracking Awards Plans (**STAP**). Issuance of awards under these plans was discontinued in 2015. Currently, we grant stock options and restricted stock units under the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (the **2015 Plan**), and restricted stock units under our 2019 Inducement Stock Incentive Plan (the **2019 Inducement Plan**). The grant date fair values of stock options and restricted stock units are recognized as share-based compensation expense ratably over their vesting periods.

The fair value of STAP awards and stock options is measured using inputs and assumptions under the Black-Scholes-Merton model. The fair value of restricted stock units is measured using our stock price on the date of grant. Although we no longer grant STAP awards, we had approximately 0.8 million STAP awards outstanding as of June 30, 2022. We account for STAP awards as liabilities because they are settled in cash. As such, we must re-measure the fair value of STAP awards at the end of each financial reporting period until the awards are no longer outstanding. Changes in our STAP liability resulting from such re-measurements are recorded as adjustments to share-based compensation expense and can create substantial volatility within our operating expenses from period to period. The following factors, among others, have a significant impact on the amount of

share-based compensation expense recognized in connection with STAP awards from period to period: (1) volatility in the price of our common stock (specifically, increases in the price of our common stock will generally result in an increase in our STAP liability and related compensation expense, while decreases in our stock price will generally result in a reduction in our STAP liability and related compensation expense); and (2) decreases in the number of outstanding awards.

Research and Development

We focus most of our research and development efforts on the following pipeline programs. We also engage in a variety of additional research and development efforts, including technologies designed to increase the supply of transplantable organs and tissues and improve outcomes for transplant recipients through regenerative medicine, 3-D organ bioprinting, xenotransplantation, and *ex-vivo* lung perfusion. Please note that our expectations regarding our research and development programs are subject to the risks described above under *Overview—Impact of COVID-19 on our Business*, and below in *Part II, Item 1A—Risk Factors—Risks Related to Our Products and Our Operations—We face risks and uncertainties related to the COVID-19 pandemic, which could significantly disrupt our operations and/or business for an unknown period of time.*

Select Pipeline Programs

Product	Mode of Delivery	Indication	Current Status STUDY NAME	Our Territory
Tyvaso (treprostinil)	Inhaled	PH-COPD	Phase 3 *PERFECT* study	Worldwide
RemoPro™ (subcutaneous prodrug)	Continuous subcutaneous	PAH	Phase 1	Worldwide
Tyvaso (treprostinil)	Inhaled	IPF	Phase 3 *TETON* studies	Worldwide
Ralinepag (IP receptor agonist)	Oral	PAH	Phase 3 *ADVANCE* studies	Worldwide, subject to out-licenses granted in certain Asian territories
Aurora-GT™ (gene therapy)	Intravenous	PAH	*SAPPHIRE* study (registration phase in Canada)	United States

Remunity Pump and RemoPro

In February 2021, we launched commercial sales of the Remunity Pump, which is a pre-filled, semi-disposable system for subcutaneous delivery of treprostinil, developed in collaboration with DEKA Research & Development Corp. (**DEKA**) under an exclusive development and license agreement. The Remunity Pump consists of a small, lightweight, durable pump and separate controller. The Remunity Pump uses disposable cartridges filled with Remodulin, which can be connected to the pump with less patient manipulation than is typically involved in filling other currently-available subcutaneous pumps. In November 2019, we entered into a supply agreement with an affiliate of DEKA to manufacture and supply the Remunity Pump to us. Under the terms of the agreement, we reimburse all of DEKA's and its affiliates' costs to manufacture the Remunity Pump. The Remunity Pump is being offered to patients primarily by contracted specialty pharmacies, which deliver Remunity Pump disposable cartridges pre-filled exclusively with Remodulin.

We are conducting a series of phase 1 studies to develop a new prodrug called RemoPro, which is intended to enable subcutaneous delivery of treprostinil analog therapy without the site pain currently associated with subcutaneous Remodulin. As a prodrug, RemoPro is designed to be inactive in the subcutaneous tissue, which should decrease or eliminate site pain, and to metabolize into treprostinil or a treprostinil analog once it is absorbed into the blood.

Finally, we are collaborating with two medical device manufacturers to develop alternative pump systems for Remodulin.

Tyvaso — *PERFECT* and *TETON* studies

We are enrolling a phase 3 registration study called *PERFECT*, which is a study of Tyvaso for the treatment of WHO Group 3 pulmonary hypertension associated with chronic obstructive pulmonary disease (**PH-COPD**). There are presently no FDA-approved therapies indicated for treatment of PH-COPD, which we estimate affects 100,000 patients in the United States. The *PERFECT* study protocol was written to allow for a seamless transition from an initial crossover design (where each patient is randomized to either placebo or the active study drug, and then "crosses over" into the opposite group after a 12-week period) to a parallel design (where each patient is assigned to either placebo or the active study drug, without the need for a second, 12-week crossover period), if missing data in the second crossover period threatens the interpretability of the study. Recently, we made the decision to trigger this transition and convert the *PERFECT* study into a single treatment period of 12 weeks. While this has resulted in an increase in the size of the study (from 136 patients to 314 patients), we believe this decision may increase site

and subject participation with a simpler, shorter, and more traditional study design. This change does not require a protocol amendment, and the clinical sites are still enrolling patients.

We are also enrolling a phase 3 study called *TETON 1*, which is a study of Tyvaso for the treatment of idiopathic pulmonary fibrosis (**IPF**). The primary endpoint of this study, which will be conducted entirely in the United States, is the change in absolute forced vital capacity (**FVC**) from baseline to week 52. The *TETON 1* study was prompted by data from the *INCREASE* study, which demonstrated improvements in certain key parameters of lung function in pulmonary hypertension patients with fibrotic lung disease (improved absolute FVC and reduced exacerbations of underlying lung disease). Specifically, in the *INCREASE* study, treatment with Tyvaso resulted in significant improvements in percent predicted FVC at weeks 8 and 16, with subjects having underlying etiologies of idiopathic interstitial pneumonias (week 8: 2.0%, p=0.0373 and week 16: 2.9%; p=0.0096) and IPF (week 8: 2.5%; p=0.0380 and week 16: 3.5%; p=0.0147) showing the greatest improvement. Consistent positive effects were also observed in patients with chronic hypersensitivity pneumonitis and environmental/occupational lung disease. In May 2022, data from the *INCREASE* open-label, long-term extension trial were presented at a medical conference, indicating that improvements in FVC were sustained for at least 64 weeks for IPF patients. For those patients who received placebo during the *INCREASE* study, marked improvements in FVC were observed following transition to active Tyvaso during the open-label extension study. These data points, combined with substantial preclinical evidence of antifibrotic activity of treprostinil, suggest that Tyvaso may offer a treatment option for patients with IPF. In December 2020, the FDA granted orphan designation for treprostinil to treat IPF. In March 2022, the European Medicines Agency also granted orphan designation for treprostinil to treat IPF. We are also in the process of commencing *TETON 2*, which is an additional phase 3 study of Tyvaso in IPF that is similar to *TETON 1*, but will be conducted outside the United States.

If the *PERFECT* and *TETON* studies are successful, we also plan to seek FDA approval to expand the Tyvaso DPI label to include PH-COPD and IPF, respectively.

Tyvaso DPI

On May 24, 2022, the FDA approved our dry power formulation of inhaled treprostinil called Tyvaso DPI for treatment of PAH and PH-ILD. We developed this product under an in-license from MannKind Corporation (**MannKind**), and launched this product commercially in the United States in June 2022. Tyvaso DPI incorporates the dry powder formulation technology and Dreamboat® inhalation device technology used in MannKind's Afrezza® (insulin human) Inhalation Powder product, which was approved by the FDA in 2014. We believe that this new inhaled treprostinil therapy provides substantial lifestyle benefits to PAH and PH-ILD patients, as compared with nebulized Tyvaso Inhalation Solution therapy, because it is: (1) less time consuming to administer and easier to maintain, as the device is provided in pre-filled, single use, disposable cassettes, eliminating the need for cleaning and filling; and (2) mobile and more convenient, as the compact design of the inhaler and drug cassettes used with Tyvaso DPI enables the device to easily fit into the patient's pocket and the device does not require electricity to function.

We completed two clinical studies of Tyvaso DPI. One was a study in healthy volunteers, comparing the pharmacokinetics of Tyvaso DPI to Tyvaso Inhalation Solution. We completed the study in October 2020 and announced in January 2021 that the study demonstrated comparable systemic treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution. In December 2020, we completed a clinical study called *BREEZE*, which evaluated the safety and pharmacokinetics of switching PAH patients from Tyvaso Inhalation Solution to Tyvaso DPI. The *BREEZE* study demonstrated the safety and tolerability of Tyvaso DPI in subjects with PAH transitioning from Tyvaso Inhalation Solution, and comparable systemic treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution.

In August 2021 we entered into a commercial supply agreement with MannKind (as amended, the **Supply Agreement**). Pursuant to the Supply Agreement, MannKind is responsible for manufacturing and supplying Tyvaso DPI to us on a cost-plus basis. Unless earlier terminated, the initial term of the Supply Agreement continues until December 31, 2031 and will thereafter be renewed automatically for additional, successive two-year terms unless we give 24 months' written notice of non-renewal, or MannKind gives 48 months' written notice of non-renewal, prior to the end of the initial term or any additional renewal term. In addition, each party has customary termination rights, including termination for the other party's material breach that is not cured within a specific timeframe or in the event of liquidation, bankruptcy or insolvency of the other party.

Ralinepag

Ralinepag is a next-generation, oral, selective, and potent prostacyclin receptor agonist being developed for treatment of PAH. We are enrolling two phase 3 studies of ralinepag: (1) *ADVANCE OUTCOMES*, which is an event-driven study of ralinepag in PAH patients with a primary endpoint of time to first clinical worsening event; and (2) *ADVANCE CAPACITY*, studying the effect of ralinepag on exercise capacity in PAH patients with a primary endpoint of change in peak oxygen uptake via cardiopulmonary exercise test. Both of these studies are global, multi-center, placebo-controlled trials of patients on approved oral background PAH therapies.

Aurora-GT

We are conducting a clinical study (called *SAPPHIRE*) of a gene therapy product called Aurora-GT, in which a PAH patient's own endothelial progenitor cells are isolated, transfected with the gene for human endothelial nitric oxide synthase, expanded *ex-vivo*, and then delivered back to the same patient. This product is intended to rebuild the blood vessels in the lungs that are

compromised by PAH. This study is being conducted in Canada, and is intended to be a registration-phase study for Canadian regulatory submission. This study is sponsored by Northern Therapeutics, Inc. (**Northern Therapeutics**), a Canadian entity in which we have a 49.7 percent voting stake and a 71.8 percent financial stake. We have the exclusive right to pursue this technology in the United States and will evaluate seeking FDA approval of Aurora-GT if *SAPPHIRE* is successful. Under our agreement with Northern Therapeutics, we have funded all of the expenses of the *SAPPHIRE* program, and will continue to do so through the end of 2022, after which time Northern Therapeutics will be solely responsible for all future costs of the *SAPPHIRE* program.

Organ Manufacturing

Each year, end-stage organ failure kills millions of people. A significant number of these patients could have benefited from an organ transplant. Unfortunately, the number of usable, donated organs available for transplantation has not grown significantly over the past half century while the need has soared. Our long-term goals are aimed at addressing this shortage. With advances in technology, we believe that creating an unlimited supply of tolerable manufactured organs is now principally an engineering challenge, and we are dedicated to finding engineering solutions. We are engaged in research and development of a variety of technologies designed to increase the supply of transplantable organs and tissues and to improve outcomes for transplant recipients through regenerative medicine, 3-D organ bioprinting, xenotransplantation, and *ex-vivo* lung perfusion.

In 2019, we entered into a collaboration agreement with the University of Alabama at Birmingham (**UAB**) to develop a pilot-scale, designated pathogen-free facility to house genetically-modified pigs, with a goal of commencing human clinical trials of xenotransplanted kidneys we call UKidneys™ from pigs to humans in the near term. In August 2020, UAB began to conduct operations at the facility with the first introduction of genetically modified pigs, and in March 2021, the facility received its recertification of compliance from the American Association for Accreditation of Laboratory Animal Care. In 2019, we also entered into agreements with NYU Langone Health (**NYU**) and University of Maryland Baltimore to conduct preclinical testing of our porcine xenografts, which have been generating data regarding our UKidneys, UThymoKidneys™, and UHearts™.

While we continue to develop and commercialize therapies for rare and life-threatening conditions, we view organ manufacturing as a complementary solution for a broad array of diseases, many of which (such as PAH) have proven incurable to date through more traditional pharmaceutical and biologic therapies. For this reason, in 2015 we created a wholly-owned PBC called Lung Biotechnology PBC, chartered with the express purpose of *"address[ing] the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply."* It is also why we included the development of *"technologies that expand the availability of transplantable organs"* as part of our express public benefit purpose when we converted United Therapeutics to a PBC in 2021.

Recently, we and our collaborators announced several key achievements in our organ manufacturing program:

- **First Successful Xenotransplantation of a Porcine Heart:** In January 2022, University of Maryland School of Medicine surgeons successfully transplanted an experimental, genetically-modified UHeart into a living human under an expanded access authorization by the FDA. The patient survived for approximately two months with the UHeart. In June 2022, data from this procedure were published in the *New England Journal of Medicine*.
- **Successful UKidney and UHeart Tests in Preclinical Human Models:** In September 2021, collaborators at NYU and UAB tested UThymoKidneys and UKidneys from our genetically modified pigs in brain-dead organ donors, providing preclinical evidence that genetically modified pig organs could transcend the most proximate immunological barriers to xenotransplantation. Results of the UAB experiment were published in the *American Journal of Transplantation* in January 2022, and results of the NYU experiments were published in the *New England Journal of Medicine* in May 2022.

  In June and July 2022, collaborators at NYU tested two UHearts from our genetically modified pigs in brain-dead organ donors. In each case, normal function was observed for our UHearts over a three-day study period, without signs of early rejection.
- ***Ex-Vivo* Lung Perfusion:** In January 2022, we announced that more than 200 patients had received lung transplants following use of our centralized *ex-vivo* lung perfusion service. This number has continued to grow steadily since that time. *Ex-vivo* lung perfusion technology increases the number of transplantable lungs by giving surgeons the ability to assess the function of marginal lungs to determine if the lungs are suitable for transplantation. This allows for the use of lungs that would have otherwise not been transplanted.
- **Drone Delivery of Organs:** In October 2021, we successfully completed the first-ever drone delivery of a lung for transplant at Toronto General Hospital, demonstrating the feasibility of our goal of delivering our manufactured organs with zero carbon footprint aircraft.

Future Prospects

We anticipate that overall revenue growth over the near-term will be driven primarily by: (1) growth in sales of Tyvaso as a result of the expansion of its label to include PH-ILD and the commercial launch of Tyvaso DPI; (2) continued growth in the number of patients prescribed with Orenitram following our expansion of the Orenitram label to reflect the results of the *FREEDOM-EV* study; and (3) modest price increases for some of our products; partially offset by further generic erosion of Adcirca sales. We believe that additional revenue growth in the medium- and longer-term will be driven by commercializing four key therapeutic platforms in our pipeline, which are comprised of the enabling technologies described below, among others:

Platform	**Enabling Technologies**
Tyvaso and Tyvaso DPI (inhaled treprostinil)	*PERFECT* study, *TETON* studies
Remodulin (parenteral treprostinil)	RemoPro, next-generation Remunity system, alternative pump systems
New Chemical Entities and New Biologics	Ralinepag
Organ Manufacturing and Transplantation	Xenotransplantation, three-dimensional organ bioprinting, regenerative medicine, *ex-vivo* lung perfusion

For further details regarding our research and development initiatives, refer to the section above entitled *Research and Development*.

Our ability to achieve our objectives, grow our business, and maintain profitability will depend on many factors, including among others: (1) the timing and outcome of preclinical research, clinical trials, and regulatory approval applications for products we develop; (2) the timing and degree of our success in commercially launching new products; (3) the demand for our products; (4) the price of our products and the reimbursement of our products by public and private health insurance organizations; (5) the competition we face within our industry, including competition from generic companies and new therapies; (6) our ability to effectively manage our business in an increasingly complex legal and regulatory environment; (7) our ability to defend against challenges to our patents; (8) the duration and severity of the COVID-19 pandemic; and (9) the risks identified in *Part II, Item 1A—Risk Factors*, included in this Quarterly Report on Form 10-Q.

We operate in a highly competitive market in which a small number of large pharmaceutical companies control a majority of available PAH therapies. These pharmaceutical companies are well established in the market and possess greater financial, technical, and marketing resources than we do. In addition, there are a number of investigational products in late-stage development that, if approved, may erode the market share of our existing commercial therapies and make market acceptance more difficult to achieve for any therapies we attempt to market in the future.

Results of Operations

Three and Six Months Ended June 30, 2022 and June 30, 2021

Revenues

The table below presents the components of total revenues (dollars in millions):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	Dollar Change	Percentage Change	2022	2021	Dollar Change	Percentage Change
Net product sales:								
Tyvaso	$ 201.0	$ 153.8	$ 47.2	31 %	$ 373.0	$ 276.8	$ 96.2	35 %
Remodulin	132.0	139.8	(7.8)	(6)%	263.7	270.0	(6.3)	(2)%
Orenitram	79.0	76.2	2.8	4 %	161.8	148.6	13.2	9 %
Unituxin	44.5	53.1	(8.6)	(16)%	100.1	97.0	3.1	3 %
Adcirca	10.4	23.6	(13.2)	(56)%	20.2	33.2	(13.0)	(39)%
Other	—	—	—	NM[1]	10.0	—	10.0	NM[1]
Total revenues	**$ 466.9**	**$ 446.5**	**$ 20.4**	**5 %**	**$ 928.8**	**$ 825.6**	**$ 103.2**	**13 %**

(1) Calculation is not meaningful.

Net product sales from our treprostinil-based products (Tyvaso, Remodulin, and Orenitram) grew by $42.2 million and $103.1 million for the three and six months ended June 30, 2022, respectively, as compared to the same periods in 2021.

Tyvaso net product sales for the three and six months ended June 30, 2022 increased as compared to the same periods in 2021, primarily due to an increase in quantities sold, reflecting an increased number of patients following the PH-ILD label expansion.

Remodulin net product sales for the six months ended June 30, 2022 decreased as compared to the same period in 2021, driven by a $10.5 million decrease in U.S. Remodulin net product sales, partially offset by a $4.2 million increase in international Remodulin net product sales. The decrease in U.S. Remodulin net product sales was primarily due to a decrease in quantities sold, partially offset by lower gross-to-net deductions. The increase in international Remodulin net product sales was primarily due to the timing of orders by our international distributors and does not precisely reflect trends in underlying patient demand.

Orenitram net product sales for the six months ended June 30, 2022 increased as compared to the same period in 2021, primarily due to a price increase and, to a lesser extent, lower gross-to-net deductions.

Unituxin net product sales for the three months ended June 30, 2022 decreased as compared to the same periods in 2021, due to a decrease in quantities sold, partially offset by a price increase. The decrease in quantities sold was primarily due to the timing of orders by our distributors and does not precisely reflect trends in underlying patient demand.

Adcirca net product sales for the three and six months ended June 30, 2022, decreased as compared to the same periods in 2021, primarily due to higher gross-to-net deductions and, to a lesser extent, a decline in quantities sold as a result of generic competition for Adcirca.

Gross-to-Net Deductions

We recognize revenues net of: (1) rebates and chargebacks; (2) prompt pay discounts; (3) allowance for sales returns; and (4) distributor fees. These are referred to as gross-to-net deductions and are primarily based on estimates reflecting historical experiences as well as contractual and statutory requirements. We currently estimate our allowance for sales returns using reports from our distributors and available industry data, including our estimate of inventory remaining in the distribution channel. The tables below include a reconciliation of the liability accounts associated with these deductions (in millions):

	Three Months Ended June 30, 2022				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, April 1, 2022	$ 65.5	$ 3.3	$ 6.1	$ 6.9	$ 81.8
Provisions attributed to sales in:					
Current period	47.7	10.7	—	8.3	66.7
Prior periods	(2.0)	—	—	1.1	(0.9)
Payments or credits attributed to sales in:					
Current period	(4.9)	(7.3)	—	(1.5)	(13.7)
Prior periods	(35.5)	(3.2)	(0.8)	(5.0)	(44.5)
Balance, June 30, 2022	**$ 70.8**	**$ 3.5**	**$ 5.3**	**$ 9.8**	**$ 89.4**

	Three Months Ended June 30, 2021				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, April 1, 2021	$ 56.3	$ 2.9	$ 12.3	$ 5.2	$ 76.7
Provisions attributed to sales in:					
Current period	50.5	10.2	—	5.1	65.8
Prior periods	1.4	—	(3.1)	1.6	(0.1)
Payments or credits attributed to sales in:					
Current period	(4.0)	(6.9)	—	(0.9)	(11.8)
Prior periods	(42.9)	(2.8)	(0.6)	(5.8)	(52.1)
Balance, June 30, 2021	**$ 61.3**	**$ 3.4**	**$ 8.6**	**$ 5.2**	**$ 78.5**

	Six Months Ended June 30, 2022				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2022	$ 67.8	$ 3.8	$ 6.3	$ 7.9	$ 85.8
Provisions attributed to sales in:					
Current period	93.3	20.6	—	16.6	130.5
Prior periods	(4.2)	(0.5)	—	0.5	(4.2)
Payments or credits attributed to sales in:					
Current period	(30.1)	(17.2)	—	(6.8)	(54.1)
Prior periods	(56.0)	(3.2)	(1.0)	(8.4)	(68.6)
Balance, June 30, 2022	**$ 70.8**	**$ 3.5**	**$ 5.3**	**$ 9.8**	**$ 89.4**

	Six Months Ended June 30, 2021				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2021	$ 60.7	$ 3.0	$ 12.5	$ 3.7	$ 79.9
Provisions attributed to sales in:					
Current period	92.9	19.0	—	14.4	126.3
Prior periods	0.2	—	(3.1)	0.2	(2.7)
Payments or credits attributed to sales in:					
Current period	(37.1)	(15.6)	—	(8.2)	(60.9)
Prior periods	(55.4)	(3.0)	(0.8)	(4.9)	(64.1)
Balance, June 30, 2021	**$ 61.3**	**$ 3.4**	**$ 8.6**	**$ 5.2**	**$ 78.5**

Cost of Product Sales

The table below summarizes cost of product sales by major category (dollars in millions):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	Dollar Change	Percentage Change	2022	2021	Dollar Change	Percentage Change
Category:								
Cost of product sales	$ 27.1	$ 35.8	$ (8.7)	(24)%	$ 53.7	$ 57.1	$ (3.4)	(6)%
Share-based compensation expense[1]	2.6	1.4	1.2	86 %	1.9	3.1	(1.2)	(39)%
Total cost of product sales	**$ 29.7**	**$ 37.2**	**$ (7.5)**	**(20)%**	**$ 55.6**	**$ 60.2**	**$ (4.6)**	**(8)%**

(1) Refer to *Share-Based Compensation* section below for discussion.

Cost of product sales, excluding share-based compensation. Cost of product sales for the three and six months ended June 30, 2022 decreased as compared to the same periods in 2021, primarily due to a decrease in royalty expense for Adcirca resulting from a decrease in Adcirca net product sales.

Research and Development

The table below summarizes research and development expense by major category (dollars in millions):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	Dollar Change	Percentage Change	2022	2021	Dollar Change	Percentage Change
Category:								
Research and development projects	$ 79.5	$ 69.5	$ 10.0	14 %	$ 152.1	$ 366.7	$ (214.6)	(59)%
Share-based compensation expense[1]	14.4	4.8	9.6	200 %	10.8	11.3	(0.5)	(4)%
Total research and development expense	**$ 93.9**	**$ 74.3**	**$ 19.6**	**26 %**	**$ 162.9**	**$ 378.0**	**$ (215.1)**	**(57)%**

(1) Refer to *Share-Based Compensation* section below for discussion.

Research and development expense, excluding share-based compensation. Research and development expense for the three months ended June 30, 2022 increased as compared to the same period in 2021, primarily due to increased spending on preclinical work on technologies designed to increase the supply of transplantable organs.

Research and development expense for the six months ended June 30, 2022 decreased as compared to the same period in 2021, due to: (1) a $107.3 million IPR&D impairment charge related to our March 2021 decision to discontinue the U.S. development of Trevyent; (2) a $105.0 million purchase of a pediatric disease priority review voucher in January 2021, which we redeemed upon submission of our NDA for Tyvaso DPI; and (3) an $11.6 million impairment charge related to repurposing one of our facilities during the first quarter of 2021. These decreases in expense were partially offset by increased spending on preclinical work on technologies designed to increase the supply of transplantable organs.

Selling, General, and Administrative

The table below summarizes selling, general, and administrative expense by major category (dollars in millions):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	Dollar Change	Percentage Change	2022	2021	Dollar Change	Percentage Change
Category:								
General and administrative	$ 76.9	$ 72.8	$ 4.1	6 %	$ 158.2	$ 144.4	$ 13.8	10 %
Sales and marketing	16.1	17.1	(1.0)	(6)%	30.6	30.8	(0.2)	(1)%
Share-based compensation expense[1]	48.5	22.9	25.6	112 %	31.7	54.8	(23.1)	(42)%
Total selling, general, and administrative expense	**$ 141.5**	**$ 112.8**	**$ 28.7**	**25 %**	**$ 220.5**	**$ 230.0**	**$ (9.5)**	**(4)%**

(1) Refer to *Share-Based Compensation* below for discussion.

General and administrative, excluding share-based compensation. The increase in general and administrative expense for the six months ended June 30, 2022, as compared to the same period in 2021, was primarily due to: (1) an increase in legal expenses related to litigation matters; and (2) an increase in branded prescription drug fee expense associated with sales of Tyvaso.

Share-Based Compensation

The table below summarizes share-based compensation expense by major category (dollars in millions):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	Dollar Change	Percentage Change	2022	2021	Dollar Change	Percentage Change
Category:								
Stock options	$ 5.6	$ 5.7	$ (0.1)	(2)%	$ 11.1	$ 14.0	$ (2.9)	(21)%
Restricted stock units	7.4	6.5	0.9	14 %	13.7	12.2	1.5	12 %
STAP awards	52.1	16.4	35.7	218 %	18.7	42.1	(23.4)	(56)%
Employee stock purchase plan	0.4	0.5	(0.1)	(20)%	0.9	0.9	—	— %
Total share-based compensation expense	**$ 65.5**	**$ 29.1**	**$ 36.4**	**125 %**	**$ 44.4**	**$ 69.2**	**$ (24.8)**	**(36)%**

The table below summarizes share-based compensation expense by line item in our consolidated statements of operations (dollars in millions):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	Dollar Change	Percentage Change	2022	2021	Dollar Change	Percentage Change
Cost of product sales	$ 2.6	$ 1.4	$ 1.2	86 %	$ 1.9	$ 3.1	$ (1.2)	(39)%
Research and development	14.4	4.8	9.6	200 %	10.8	11.3	(0.5)	(4)%
Selling, general, and administrative	48.5	22.9	25.6	112 %	31.7	54.8	(23.1)	(42)%
Total share-based compensation expense	**$ 65.5**	**$ 29.1**	**$ 36.4**	**125 %**	**$ 44.4**	**$ 69.2**	**$ (24.8)**	**(36)%**

The increase in share-based compensation expense for the three months ended June 30, 2022, as compared to the same period in 2021, was primarily due to an increase in STAP expense driven by a 31 percent increase in our stock price for the three months ended June 30, 2022, as compared to a seven percent increase in our stock price for the same period in 2021. The decrease in share-based compensation expense for the six months ended June 30, 2022, as compared to the same period in 2021, was primarily due to: (1) a decrease in STAP expense driven by a nine percent increase in our stock price for the six months ended June 30, 2022, as compared to an 18 percent increase in our stock price for the same period in 2021; and (2) a decrease in stock option expense due to fewer awards outstanding in 2022. For more information, refer to Note 9—*Share-Based Compensation* to our consolidated financial statements.

Other (Expense) Income, Net

The change in *other (expense) income, net* for the three months ended June 30, 2022, as compared to the same period in 2021, was primarily due to unrealized losses on equity securities. The change in *other (expense) income, net* for the six months ended June 30, 2022, as compared to the same period in 2021, was primarily due to net unrealized and realized gains and losses on equity securities. During the first quarter of 2021, we sold an investment that we held in a publicly-traded company. We received $108.9 million in cash from the sale of the investment and realized a gain of $91.9 million. Refer to Note 3—*Investments* to our consolidated financial statements.

Income Tax Expense

Income tax expense for the six months ended June 30, 2022 and 2021 was $103.4 million and $48.1 million, respectively. Our effective income tax rate (**ETR**) for the six months ended June 30, 2022 and 2021 was 23 percent and 19 percent, respectively. Our ETR for the six months ended June 30, 2022 increased compared to our ETR for the six months ended June 30, 2021 primarily due to an increase in the valuation allowance in the current period compared to a decrease in the prior period.

Financial Condition, Liquidity, and Capital Resources

We have funded our operations principally through sales of our commercial products and, from time-to-time, third-party financing arrangements. We believe that our current sources of liquidity are sufficient to fund ongoing operations and future business plans as we expect aggregate growth in revenues from our commercial products. Furthermore, our customer base remains stable and we believe that it presents minimal credit risk. However, any projections of future cash flows are inherently subject to uncertainty and we may seek other forms of financing. In March 2022, we entered into a credit agreement (the **2022 Credit Agreement**), which provides for unsecured revolving credit facilities of up to $2.0 billion. Our aggregate outstanding balance under the 2022 Credit Agreement, which matures in 2027, was $800.0 million and classified as a non-current liability in our consolidated balance sheet as of June 30, 2022. See *Unsecured Revolving Credit Facilities* below for further details.

Cash and Cash Equivalents and Marketable Investments

Cash and cash equivalents and marketable investments comprise the following (dollars in millions):

	June 30, 2022	December 31, 2021	Dollar Change	Percentage Change
Cash and cash equivalents	$ 795.2	$ 894.8	$ (99.6)	(11)%
Marketable investments—current	1,460.0	1,035.9	424.1	41 %
Marketable investments—non-current	1,641.9	1,649.9	(8.0)	— %
Total cash and cash equivalents and marketable investments	**$ 3,897.1**	**$ 3,580.6**	**$ 316.5**	**9 %**

Cash Flows

Cash flows comprise the following (dollars in millions):

	Six Months Ended June 30,		Dollar Change	Percentage Change
	2022	2021		
Net cash provided by operating activities	$ 415.7	$ 238.0	$ 177.7	75 %
Net cash used in investing activities	$ (528.2)	$ (55.2)	$ (473.0)	(857)%
Net cash provided by financing activities	$ 12.9	$ 20.7	$ (7.8)	(38)%

Operating Activities

Our operating assets and liabilities consist primarily of accounts receivable, inventories, accounts payable, accrued expenses, liabilities for our STAP awards, and tax-related payables and receivables.

The increase of $177.7 million in net cash provided by operating activities for the six months ended June 30, 2022, as compared to the six months ended June 30, 2021, was primarily due to: (1) a $105.0 million purchase of a pediatric disease priority review voucher during the six months ended June 30, 2021; and (2) a $16.5 million decrease in cash paid to settle STAP awards. The remainder of the increase in cash provided by operating activities was due to other changes in assets and liabilities.

Investing Activities

The increase of $473.0 million in net cash used in investing activities for the six months ended June 30, 2022, as compared to the six months ended June 30, 2021, was primarily due to a $477.2 million increase in cash used for total purchases, sales, and maturities of marketable investments.

Financing Activities

The decrease of $7.8 million in net cash provided by financing activities for the six months ended June 30, 2022, as compared to the six months ended June 30, 2021, was primarily due to a $7.5 million increase in payments of debt issuance costs related to the 2022 Credit Agreement.

Unsecured Revolving Credit Facilities

In March 2022, we entered into the 2022 Credit Agreement, which provides for unsecured revolving credit facilities of up to $2.0 billion. On March 31, 2022, we borrowed $800.0 million under the facilities and used the funds to repay outstanding indebtedness under the then-existing credit agreement (the **2018 Credit Agreement**). This balance remained outstanding as of June 30, 2022. Refer to Note 8—*Debt—2022 Credit Agreement* to our consolidated financial statements.

Summary of Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with U.S. generally accepted accounting principles requires our management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. We continually evaluate our estimates and judgments to determine whether they are reasonable, relevant, and appropriate. These assumptions are frequently developed from historical data or experience, currently available information, and anticipated developments. By their nature, our estimates are subject to an inherent degree of uncertainty; consequently, actual results may differ. We discuss critical accounting policies and estimates that involve a higher degree of judgment and complexity in *Part II, Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations* in our 2021 Annual Report. There have been no material changes to our critical accounting policies and estimates as disclosed in our 2021 Annual Report.

Recently Issued Accounting Standards

See Note 2—*Basis of Presentation*, to our consolidated financial statements for information on our adoption during the current period and anticipated adoption of recently issued accounting standards.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk has not materially changed since December 31, 2021.

Item 4. Controls and Procedures

Based on their evaluation, as of June 30, 2022, our Chairperson and Chief Executive Officer and our Chief Financial Officer and Treasurer have concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, summarized, processed, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chairperson and Chief Executive Officer and our Chief Financial Officer and Treasurer, as appropriate to allow timely decisions regarding required disclosure. There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, such internal control over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

Please refer to Note 13—*Litigation* to our consolidated financial statements contained elsewhere in this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

Item 1A. Risk Factors

Risks Related to Our Products and Our Operations

We rely heavily on sales of Tyvaso, Remodulin, and Orenitram to generate revenues and support our operations.

Sales of Tyvaso, Remodulin, and Orenitram comprise the vast majority of our revenues. Substantially decreased sales of any of these products could have a material adverse impact on our operations. A wide variety of events, such as withdrawal of regulatory approvals or substantial changes in prescribing practices or dosing patterns, many of which are described in other risk factors below, could cause sales of these products to materially decline, or to grow more slowly than expected. The current and expected availability of generic versions of our products has decreased and may continue to decrease our revenues. The approval of new therapies may negatively impact sales of our current and potential new products. Sales may decrease if any third party that manufactures, markets, distributes, or sells our commercial products cannot do so satisfactorily, or we cannot manage our internal manufacturing processes. Finally, if demand for Tyvaso DPI does not meet our expectations, the revenue opportunity for our treprostinil products could be significantly lower than we expect.

If our products fail in clinical trials, we will be unable to sell those products.

To obtain approvals from the FDA and international regulatory agencies to sell new products, or to expand the product labeling for our existing products, we must conduct clinical trials demonstrating that our products are safe and effective. Regulators have substantial discretion over the approval process. Regulators may require us to amend ongoing trials or perform additional trials, which have in the past and could in the future result in significant delays and additional costs and may be unsuccessful. Delays and costs associated with regulatory requirements to change or add trials have sometimes caused us to discontinue efforts to develop a particular product, and may do so again in the future. If our clinical trials are not successful, or we fail to address identified deficiencies adequately, we will not obtain required approvals to market the new product or new indication. We cannot predict with certainty how long it will take, or how much it will cost, to complete necessary clinical trials or obtain regulatory approvals of our current or future products. The time and cost needed to complete clinical trials and obtain regulatory approvals varies by product, indication, and country. In addition, failure to obtain, or delays in obtaining, regulatory approval has in the past and could in the future require us to recognize impairment charges.

Our clinical trials have in the past and may in the future be discontinued, delayed, canceled, or disqualified for various reasons, including: (1) the COVID-19 pandemic, which initially caused us to suspend enrollment of most of our clinical studies, and may do so again; (2) the drug is ineffective, or physicians and/or patients believe that the drug is ineffective, or that other therapies are more effective or convenient; (3) patients do not enroll in or complete clinical trials at the rate we expect; (4) we, or clinical trial sites or other third parties do not adhere to trial protocols and required quality controls under good clinical practices (**GCP**) regulations and similar regulations outside the United States; (5) patients experience severe side effects during treatment or die during our trials because of adverse events; and (6) the results of clinical trials conducted in a particular country are not acceptable to regulators in other countries.

We may not compete successfully with established or newly developed drugs or products.

Competition could negatively impact our operating results. We compete with well-established drug companies for market share, as well as, among other things, funding, licenses, expertise, personnel, clinical trial patients and investigators, consultants, and third-party collaborators. Many of these competitors have substantially greater financial, marketing, manufacturing, sales, distribution, and technical resources, and a larger number of approved products, than we do. Many of these competitors also possess greater experience in areas critical to success such as research and development, clinical trials, sales and marketing, and regulatory matters.

Numerous treatments currently compete with our commercial therapies. For example, for treatment of PAH, we compete with over fifteen branded and generic drugs. Sales of a generic version of Adcirca launched in August 2018 have had a material adverse impact on our sales of Adcirca. The availability of generic versions of Remodulin in the United States could materially impact our revenues, and generic competition has materially impacted our Remodulin revenues outside the United States. Our competitors are also developing new products that may compete with ours. For example, Liquidia is developing Yutrepia, which if successful would compete directly with Tyvaso, Tyvaso DPI, and our other treprostinil-based products.

Patients and doctors may discontinue use of our products if they perceive competing products as safer, more effective, less invasive, more convenient, and/or less expensive than ours. Doctors may reduce the prescribed doses of our products if they prescribe them in combination with competing products. In addition, many competing therapies are less invasive or more convenient than our products, and use of these competing therapies often delays or prevents initiation of our therapies.

The successful commercialization of our products depends on the availability of coverage and adequacy of reimbursement from third-party payers, including governmental authorities and private health insurers. Pharmaceutical pricing and reimbursement pressures may negatively impact our sales.

The commercial success of our products depends, in significant part, on coverage by governmental payers such as Medicare and Medicaid, and private insurance companies. A reduction in the availability or extent of reimbursement from domestic or foreign government health care programs could have a material adverse effect on our business and results of our operations. Government payers and/or third-party payers are increasingly attempting to limit the price of medicinal products and frequently challenge the pricing of new or expensive drugs. In many markets outside the United States, governments control the prices of prescription pharmaceuticals through the implementation of reference pricing, price cuts, rebates, revenue-related taxes, and profit control. Financial pressures may cause United States government payers and/or private health insurers to implement policies that would reduce reimbursement rates for our products, limit future price increases, cap reimbursement rates for pharmaceuticals to rates paid internationally, require the automatic substitution of generic products, demand more rigorous requirements for initial coverage for new products, implement step therapy policies that require patients to try other medicines, including generic products, before using our products, or take other similar steps that could make it more difficult for patients to access our products.

Our prostacyclin analogue products (Tyvaso, Tyvaso DPI, Remodulin, and Orenitram) and our oncology product (Unituxin) are expensive therapies. Specialty pharmacy distributors may not be able to obtain adequate reimbursement for our products from commercial and government payers to motivate them to support our products. Third-party payers may reduce the amount of reimbursement for our products based on changes in pricing of other therapies for the same disease or the development of new payment methodologies to cover and reimburse treatment costs, such as the use of cost-effectiveness research or value-based payment contracts. Third-party payers often encourage the use of less-expensive generic alternative therapies, which has materially impacted our Adcirca revenues and which may materially impact our Remodulin revenues. If commercial and/or government payers do not cover our products or limit payment rates, patients and physicians could choose covered competing products and may have lower out-of-pocket costs.

Our manufacturing strategy exposes us to significant risks.

We must be able to manufacture sufficient quantities of our commercial products to satisfy demand. We manufacture Remodulin, Orenitram, Tyvaso, and Unituxin, including the active ingredient in each of these products, at our own facilities and rely on third parties for additional manufacturing capacity for Remodulin and Tyvaso. We rely entirely on MannKind to manufacture Tyvaso DPI, Minnetronix Inc. to manufacture the Tyvaso Inhalation System, and DEKA to manufacture Remunity Pumps, and we rely on a variety of other third-party sole manufacturers for certain elements of our commercial and development-stage products, as detailed under the risk factor below entitled, *We rely in part on third parties to perform activities that are critical to our business.* If any of our internal or third-party manufacturing and supply arrangements are interrupted for compliance issues, issues related to the COVID-19 pandemic, or other reasons, we may not have sufficient inventory to meet future demand. Changes in suppliers and/or service providers could interrupt the manufacturing of our commercial products and impede the progress of our commercial launch plans and clinical trials.

Our internal manufacturing process subjects us to risks as we engage in increasingly complex manufacturing processes. We manufacture our entire supply of Orenitram and Unituxin without an FDA-approved back-up manufacturing site, and do not plan to engage a third party to manufacture these materials. Our long-term organ manufacturing programs will involve exceptionally complicated manufacturing processes, many of which have never been attempted on a clinical or commercial scale. It will take substantial time and resources to develop and implement such manufacturing processes, and we may never be able to do so successfully. Additional risks of our manufacturing strategy include the following:

- We, our third-party manufacturers, and other third parties involved in the manufacturing process, such as third parties that operate testing and storage facilities, are subject to the FDA's current good manufacturing practices regulations, current good tissue practices, and similar international regulatory standards, and other quality standards related to device manufacturing. Our ability to exercise control over regulatory compliance by our third-party manufacturers is limited.
- We may experience difficulty designing and implementing processes and procedures to ensure compliance with applicable regulations as we develop manufacturing operations for new products.
- Natural and man-made disasters (such as fires, contamination, power loss, hurricanes, earthquakes, flooding, terrorist attacks, and acts of war), disease outbreaks, and pandemics such as COVID-19 impacting our internal and third-party manufacturing sites could cause a supply disruption.
- Even if we, our third-party manufacturers, and other third parties involved in the manufacturing process comply with applicable drug and device manufacturing regulations, the sterility and quality of our products could be substandard and such products could not be sold or used or could be subject to recalls.
- The FDA and its international counterparts would require new testing and compliance inspections of new manufacturers of our products, or new manufacturing facilities we operate.

- The FDA and other regulatory agencies may not be able to timely inspect our facilities, or those of our third-party manufacturers, due to COVID-19-related delays or other reasons, which could result in delays in obtaining necessary regulatory approvals for our products.
- We may be unable to contract with needed manufacturers on satisfactory terms or at all.
- The supply of materials and components necessary to manufacture and package our products may become scarce or unavailable, which could delay the manufacturing and subsequent sale of such products. Products manufactured with substituted materials or components must be approved by the FDA and applicable international regulatory agencies before they could be sold. For example, supply disruptions caused by COVID-19 impacted DEKA's ability to secure certain components and raw materials necessary to manufacture sufficient quantities of Remunity Pumps and accessories, delaying our ability to commence commercial sales, and ongoing global semiconductor supply disruptions could impact our third-party manufacturers' ability to secure semiconductor chips necessary to manufacture sufficient quantities of devices required to deliver Tyvaso and Remodulin, which would have a material impact on our operations.
- Our business partners who manufacture the devices to deliver our products are subject to the FDA's medical device requirements. Any non-compliance, recall, or enforcement action issued against them could adversely impact our sales and operations.
- The infrastructure of our internal manufacturing facilities, along with certain facilities of our third-party manufacturers, is aging. These facilities have highly sophisticated and complex utility systems. If any of these systems require long-term repair or replacement, the impacted facility may not be able to manufacture product for a substantial period of time.
- We, along with our third-party manufacturers, rely upon local municipalities to supply our facilities with clean water, which is processed into high purity water and used as a key ingredient for three of our commercial drug products. If local municipalities are unable to supply water that meets relevant quality standards, we and our third-party manufacturers may be unable to manufacture product until such a situation is remediated.
- Our supply chain for raw materials and consumables extends worldwide and is complex. Suppliers based in China play a substantial role in our supply chain. Political unrest or trade disputes involving China or other countries in our supply chain could impact our ability and the ability of our third-party manufacturers to source raw materials and consumables.
- We are closely monitoring the military conflict in Ukraine. Although we do not directly source any raw materials or consumables from Ukraine, Russia, or Belarus, our European-based suppliers and service providers could be impacted by an extended conflict or an escalation into neighboring countries.

Any of these factors could disrupt sales of our commercial products, delay clinical trials or commercialization of new products, result in product liability claims and product recalls, and entail higher costs. Interruptions in our manufacturing process could be significant given the length of time and complexity involved in obtaining necessary regulatory approvals for alternative arrangements, through either third parties or internal manufacturing processes.

We face risks and uncertainties related to the COVID-19 pandemic, which could significantly disrupt our operations and/or business for an unknown period of time.

Our business, operations, financial results, liquidity, and stock price could be adversely impacted by the effects of the global COVID-19 pandemic. The extent of such impact, including the duration and magnitude of such effects, will depend on numerous factors that we cannot accurately predict or assess, including, among others: the duration and scope of the pandemic, including the emergence of new strains, such as the "Delta", "Omicron", and future variants; its impact on global and regional healthcare infrastructure, and the ability of patients to obtain medical care; the negative impact on global and regional economies and economic activity; actions governments, businesses, and individuals take in response to the pandemic; the roll-out and long-term safety and efficacy of vaccines; and how quickly economies and medical systems recover after the pandemic subsides. Our business could be materially adversely affected as a result of the COVID-19 pandemic due to social distancing/self-isolation, the burden the pandemic has placed on healthcare infrastructure, workplace and physician office closures, travel disruptions, quarantines, and other factors, which could cause, among other things:

- ***Interruption of our development pipeline.*** Approvals of new products we are developing, potential label expansions for existing products, and the launch of newly-approved products may be delayed or hindered, which would harm our revenue growth prospects. The pandemic has caused, and may continue to cause, delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff. Any prolongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our new products and label expansions.
- ***A decrease in revenues from our existing products.*** COVID-19 made it difficult or impossible for many patients to visit their physicians' offices to determine whether our medicines may be appropriate, and also prevented our field-based teams from meeting in-person with physicians. As a result, in April 2020 we experienced a temporary decline in the number of new patients starting our treprostinil-based medicines. While new patient starts returned to pre-pandemic levels, a decline could recur as the COVID-19 pandemic continues or if the pandemic causes access to medical care to become further restricted, which could cause a negative impact on our revenues. In addition, disruption of our supply chain caused by COVID-19 could negatively impact our revenues.
- ***Disruption of our operations.*** COVID-19 could disrupt many aspects of our operations, which could harm our business and prospects. We and third parties with which we engage also may experience operational challenges caused by sickness of

employees or their families, the desire of employees to avoid contact with large groups of people, or employees working from home. Mass vaccine production and distribution efforts (such as Operation Warp Speed), as well as backlogs at major ports of entry, impacted availability and lead times for certain materials used in the manufacture of our products. If we, or our third-party suppliers and contract manufacturers, are unable to source materials, it may prevent us from manufacturing our products for an indefinite period until such materials become available.

COVID-19, and the volatile regional and global economic conditions stemming from the pandemic, could also precipitate or aggravate the other risk factors discussed in this Quarterly Report on Form 10-Q, which could materially adversely affect our business, financial condition, results of operations, liquidity, and stock price. Further, the COVID-19 pandemic, or any future outbreak of disease, may also affect our operating and financial results in a manner that is not presently known to us or that we currently do not consider to present significant risks. The possible extent of the impact of the COVID-19 pandemic is inherently difficult to predict and will ultimately depend on a number of factors outside our control, including the ultimate duration and severity of the pandemic and the resulting economic impact.

We rely in part on third parties to perform activities that are critical to our business.

Third parties assist us in activities critical to our operations, such as: (1) manufacturing our clinical and commercial products; (2) conducting clinical trials, preclinical studies, and other research and development activities; (3) obtaining regulatory approvals; (4) conducting pharmacovigilance-related and product complaint activities, including drug safety, reporting adverse events, and product complaints; (5) obtaining medical device clearances and approvals for the devices used to deliver our drugs; and (6) marketing and distributing our products. Any disruption in the ability of third parties to continue to perform these critical activities, including as a result of the COVID-19 pandemic, could materially adversely impact our business and results of operations. Any change in service providers could interrupt the manufacture and distribution of our products and services, and impede the progress of our clinical trials, commercial launch plans, and related revenues.

We rely on various distributors to market, distribute, and sell our commercial products. If they are unsuccessful in, or reduce or discontinue, their sales efforts, our revenues may decline materially. Outside the United States, we rely substantially on our international distributors to obtain and maintain regulatory approvals for our products and to market and sell our products in compliance with applicable laws and regulations. In the United States, we derive all of our treprostinil revenues from sales to two distributors, Accredo and CVS Specialty. If either of these two distributors places significantly larger or smaller orders in a given time period, our revenues can be materially impacted in a way that does not reflect patient demand.

We rely entirely on third parties to supply pumps and other supplies necessary to deliver Remodulin. There are a limited number of pumps available in the market, and the discontinuation of any particular pump could have a material, adverse impact on our Remodulin revenues if a viable supply of an alternate pump is not available. Smiths Medical discontinued manufacturing the CADD MS-3 system used to deliver subcutaneous Remodulin, and has announced plans to discontinue the CADD Legacy system used to deliver intravenous Remodulin. Historically, these are the pumps primarily used to deliver Remodulin to patients in the United States. We recently launched the Remunity Pump to deliver subcutaneous Remodulin, and Smiths Medical plans to make an alternative pump, the CADD Solis, available for intravenous Remodulin. We are also engaged in further efforts to develop alternative pumps to deliver Remodulin. However, if these alternative systems are not seen as adequate substitutes, or are not developed on a timely basis, our sales of Remodulin could be materially, adversely impacted.

Lilly manufactures and supplies Adcirca for us. We use Lilly's pharmaceutical wholesaler network to distribute Adcirca. If Lilly is unable to manufacture or supply Adcirca or its distribution network is disrupted, it could delay, disrupt, or prevent us from selling Adcirca. We rely entirely on Minnetronix Inc. as the sole manufacturer of the Tyvaso Inhalation System. As Tyvaso is a drug-device combination, we cannot sell Tyvaso without the Tyvaso Inhalation System.

We rely heavily on MannKind and other third parties to manufacture, test, and store Tyvaso DPI, and to meet all FDA requirements related to the manufacture of Tyvaso DPI. This includes maintaining an FDA-compliant facility and addressing any FDA concerns regarding the manufacturing process. If MannKind is unable to manufacture Tyvaso DPI for us for any reason, our commercial sales of Tyvaso DPI could be materially and adversely impacted.

We rely exclusively on DEKA and its affiliates for the manufacture of the Remunity Pump for Remodulin, and on Minnetronix, Inc. to manufacture the Tyvaso Inhalation System used to deliver nebulized Tyvaso. Finally, we also rely on various sole-source suppliers for manufacturing activities related to ralinepag, RemoPro, and other pumps we are developing for Remodulin. For a further discussion of risks created by the use of third-party contract manufacturers, see the risk factor above entitled, *Our manufacturing strategy exposes us to significant risks*.

We rely heavily on third-party contract research organizations, contract laboratories, clinical investigative sites, and other third parties to conduct our clinical trials, preclinical studies and other research and development activities. In addition, the success of certain products we are developing will depend on clinical trials sponsored by third parties. Third-party failure to conduct or assist us in conducting clinical trials in accordance with study protocols, quality controls, GCP, or other applicable requirements or to submit associated regulatory filings, could limit or prevent our ability to rely on results of those trials in seeking regulatory approvals.

Reports of actual or perceived side effects and adverse events associated with our products could cause our sales to decrease.

Reports of side effects and adverse events associated with our products could affect a physician's decision to prescribe or a patient's willingness to use our products, which may have a significant adverse impact on sales of our products. An example of a

known risk associated with the delivery system used for intravenous Remodulin is sepsis, which is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. In addition, Unituxin is associated with severe side effects, and its label contains a boxed warning related to potential infusion reactions and neurotoxicity. We are required to report certain adverse events to the FDA. Development of new products, and new formulations and indications for existing products, could result in new side effects and adverse events which may be serious in nature.

Negative attention from special interest groups may impair our business.

Our early-stage research and development involves animal testing required by regulatory authorities, which we conduct both directly and through contracts with third parties. Our xenotransplantation and regenerative medicine programs rely heavily on the use of animals to manufacture and test our products. Certain special interest groups categorically object to the use of animals for research purposes. Any negative attention, threats or acts of vandalism directed against our animal research activities could impede the operation of our business.

We may not maintain adequate insurance coverage to protect us against significant product liability claims.

The testing, manufacturing, marketing, and sale of drugs and diagnostics involve product liability risks. We may not be able to maintain our current product liability insurance at an acceptable cost, if at all. In addition, our insurance coverage may not be adequate for all potential claims. If losses significantly exceed our liability insurance coverage, we may experience financial hardship or potentially be forced out of business. Clinical testing and eventual marketing and sale of new products, reformulated versions of existing products, or use of existing products in new indications could expose us to new product liability risks that are not covered by our existing policies.

If we fail to attract and retain key management and qualified scientific and technical personnel, we may not be able to achieve our business objectives.

Members of our management team, including our founder, Chairperson and Chief Executive Officer, Dr. Martine Rothblatt, play a critical role in defining our business strategy and maintaining our corporate culture. The loss of the services and leadership of Dr. Rothblatt or any other members of our senior management team could have an adverse effect on our business. We do not maintain key person life insurance on our senior management team members. Failure to identify, hire, and retain suitable successors for members of our senior management team and to transfer knowledge effectively could impede the achievement of our business objectives. Our future success also depends on our ability to attract and retain qualified scientific and technical personnel. Competition for such personnel in our industries is intense. If we fail to attract and retain such employees, whom we call "Unitherians," we may not be successful in developing and commercializing new therapies.

Risks Related to Legal Compliance

We must comply with extensive laws and regulations in the United States and other countries. Failure to obtain approvals on a timely basis or to comply with these requirements could delay, disrupt, or prevent commercialization of our products.

The products we develop must be approved for marketing and sale by regulatory agencies. Our research and development efforts must comply with extensive regulations, including those promulgated by the FDA and the U.S. Department of Agriculture. The process of obtaining and maintaining regulatory approvals for new drugs, biologics, and medical devices is lengthy, expensive, and uncertain. The regulatory approval process is particularly uncertain for our transplantation programs, which include the development of xenotransplantation, regenerative medicine, 3-D organ bioprinting, and cell-based products. Once approved, the manufacture, distribution, advertising, and marketing of our products are subject to extensive regulation, including product labeling, strict pharmacovigilance and adverse event and medical device reporting, complaint processing, storage, distribution, and record-keeping requirements. Our product candidates have in the past and may in the future fail to receive regulatory approval. If granted, product approvals can be conditioned on the completion of post-marketing clinical studies, accompanied by significant restrictions on the use or marketing of a given product and withdrawn for failure to comply with regulatory requirements, such as post-marketing requirements and post-marketing commitments, or upon the occurrence of adverse events subsequent to commercial introduction. Our ability to obtain FDA approval for our products has been, and in the future may be, materially impacted by the outcome and quality of our clinical trials and other data submitted to regulators, as well as the quality of our manufacturing operations and those of our third-party contract manufacturers and contract laboratories. In addition, third parties may submit citizen petitions to the FDA seeking to delay approval of, or impose additional approval conditions for, our products. If successful, citizen petitions can significantly delay, or even prevent, the approval of our products. For example, a third party 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. This led to a delay in the FDA's approval of our NDA for Tyvaso DPI.

Regulatory approval for our currently marketed products is limited by the FDA and other regulators to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval of our products is limited to specific diseases and indications for which our products have been deemed safe and effective by the FDA. FDA approval is also required for new formulations and new indications for an approved product. While physicians may prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities (called "off-label" uses), our ability to promote our products is limited to those indications that are specifically approved by the FDA. Failure to follow FDA rules and guidelines related to promotion and advertising can result

in the FDA's refusal to approve a product, suspension or withdrawal of an approved product from the market, product recalls, enforcement action, civil lawsuits, or criminal prosecution.

We must comply with various laws in jurisdictions around the world that restrict certain marketing practices.

Our business activities may be subject to challenge under laws in jurisdictions around the world restricting particular marketing practices, such as:

- Anti-kickback and false claim statutes, the Foreign Corrupt Practices Act, and the United Kingdom Bribery Act. In the United States, the Federal Anti-Kickback Statute prohibits, among other activities, knowingly and willfully offering, paying, soliciting, or receiving remuneration (i.e., anything of value) to induce, or in return for, the purchase, lease, order or arranging the purchase, lease or order of any health care product or service reimbursable under any federally financed healthcare program like Medicare or Medicaid. This statute is interpreted broadly to apply to arrangements between pharmaceutical manufacturers and prescribers, purchasers, specialty pharmacies, formulary managers, patients, and others. Our practices may not always qualify for safe harbor protection under this statute.
- The Federal False Claims Act, which prohibits any person from knowingly presenting or causing to be presented a false or fraudulent claim for payment of government funds, or making or causing a false statement material to a false or fraudulent claim. Pharmaceutical and health care companies have faced liability under this law for causing false claims to be submitted because they marketed a product for unapproved and non-reimbursable uses.
- Analogous state laws and regulations, including anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid or, in several states, regardless of the payer, including private payers.

Compliance with these and similar laws on a state-by-state basis is difficult, time consuming, and requires substantial resources. Any investigation, inquiry, or other legal proceeding under these laws related to our operations, even if we successfully defend against it, or any penalties imposed upon us for failure to comply, could have a material adverse effect on our business and financial condition or reputation. Sanctions under these federal and state laws may include treble civil monetary penalties, payment of damages, fines, exclusion of our products from reimbursement under federal health care programs, imprisonment, and the curtailment or restructuring of our operations.

Government healthcare reform and other reforms could adversely affect our revenue, costs, and results of operations.

Our industry is highly regulated and changes in law or government health care programs may adversely impact our business, operations, or financial results. We cannot predict how future federal or state legislative or administrative changes related to healthcare reform will affect our business.

Political, economic, and regulatory influences may lead to fundamental changes in the U.S. healthcare industry, particularly given the current atmosphere of mounting criticism of prescription drug costs in the U.S. We expect there will continue to be legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to commercialize and to sell our products profitably. For example, we anticipate that the Biden Administration, U.S. Congress, state legislatures, and regulators may adopt or accelerate adoption of new healthcare policies and reforms intended to curb healthcare costs, such as federal and state controls on government-funded reimbursement for drugs (including in Medicare and Medicaid), new or enhanced requirements to pay prescription drug rebates and penalties to government healthcare programs, and additional pharmaceutical cost transparency measures that aim to require drug companies to justify their prices through required disclosures.

At the federal level, there have been and continue to be a number of healthcare-related legislative and regulatory initiatives and reforms that significantly affect the pharmaceutical industry. For example, the Patient Protection and Affordable Care Act of 2010 (**PPACA**) substantially changed the way healthcare is financed by both governmental and commercial payers, and has significantly impacted the U.S. pharmaceutical industry. The PPACA is a broad measure intended to expand healthcare coverage within the United States, primarily through the imposition of health coverage-related mandates on employers and individuals and expansion of the Medicaid program. The PPACA and certain of its provisions have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation or implementation. It is unclear how the PPACA and its implementation, as well as efforts to repeal, replace, or otherwise modify, or invalidate, the PPACA, or portions thereof, will affect our business.

Additionally, there has been increasing legislative, regulatory, and enforcement interest in the United States regarding drug pricing practices. Among other things, there have been several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things: bring more transparency to drug pricing; reduce the cost of prescription drugs under government payer programs; review the relationship between pricing and manufacturer patient programs; and reform government program reimbursement methodologies for drugs. For example, on November 20, 2020, the U.S. Centers for Medicare & Medicaid Services (**CMS**) issued the Most Favored Nation demonstration project discussed above, and there is also proposed legislation pending that would establish an international reference price-based Medicare Part B drug and biological payment methodology.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement limitations, marketing cost disclosure, and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to

determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

We anticipate that the PPACA and other healthcare reform measures that may be adopted in the future may result in additional downward pressure on coverage and the payment that we receive for any approved product, and adversely impact our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payment from commercial 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. Further state and federal healthcare reform measures adopted in the future could limit the amounts that state and federal governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. In October 2020, HHS and the FDA issued a final rule and guidance concerning two new pathways for importing lower-cost drugs into the United States. The final rule allows certain prescription drugs to be imported from Canada, and the guidance describes procedures for drug manufacturers to facilitate the importation of FDA-approved drugs and biologics manufactured abroad and originally intended for sale in a foreign country into the United States. Additionally, in November 2020, the HHS adopted a rule that will eliminate the safe harbor shielding Medicare Part D rebates to pharmacy benefit managers from the federal Anti-Kickback Statute. In response to a legal challenge brought by a trade association representing PBMs, the Biden Administration agreed to delay the effective date of the rule until January 1, 2023. It is difficult to predict the impact, if any, of any such legislation or executive actions on the use of and reimbursement for our products in the United States, including the potential for the importation of generic versions of our products.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines, which could adversely impact our business, financial condition, results of operations, and prospects.

We participate in, and have certain price reporting obligations to, the Medicaid Drug Rebate program and other governmental programs that require us to pay rebates or offer discounts on our products. Certain programs, such as the 340B program and the U.S. Department of Veteran Affairs (**VA**) Federal Supply Schedule (**FSS**) pricing program, impose limits on the price we are permitted to charge certain entities for our products or for any future products for which we receive regulatory approval. Statutory and regulatory changes regarding these programs and their requirements could negatively affect the coverage and reimbursement by these programs of our products or any future products for which we receive regulatory approval and could negatively impact our results of operations. Our failure to comply with these price reporting, rebate payment, or pricing requirements could adversely impact our financial results. Applicable laws and regulations, including the PPACA, and regulations promulgated thereunder, could affect our obligations in ways we cannot anticipate.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. If we must restate or recalculate information provided under these programs, our costs of compliance could increase. Additionally, we could be held liable for errors associated with our submission of pricing data, including retroactive rebates and program refunds. We may incur significant civil monetary penalties if we are found to have knowingly submitted false average manufacturer price or best price information to the government, to have made a misrepresentation in our reporting of average sales price figures, to have knowingly provided false information in connection with a non-federal average manufacturing price filing, or to have charged 340B covered entities more than the statutorily mandated ceiling price. Certain failures to timely submit required data also could result in a civil monetary penalty for each day the information is late. We could also become subject to allegations under the False Claims Act and other laws and regulations. In addition, misreporting and failure to timely report data to CMS also can be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid Drug Rebate program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

CMS, the VA, and the Office of Inspector General of the Department of Health and Human Services (**OIG**) have pursued manufacturers that were alleged to have failed to report data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot guarantee that our submissions will not be found by CMS, the VA, or other governmental agencies to be incomplete or incorrect.

We may be subject to enforcement action or penalties based on our current policy regarding the distribution of 340B program drugs at 340B ceiling prices through third-party pharmacies that contract with covered entities participating in the 340B program, known as "340B contract pharmacies". Increasing use of 340B contract pharmacies, coupled with a lack of oversight and transparency, has resulted in increased risks of 340B statutory violations related to the diversion of 340B-purchased drugs to individuals who are not patients of the 340B covered entity, and to prohibited "duplicate discounts" when 340B-purchased drugs are also billed to Medicaid. These program integrity risks have been exacerbated by the exponential growth in the use of 340B contract pharmacies over the past decade. We adopted a new 340B contract pharmacy policy to address these risks by limiting shipments to 340B contract pharmacies that meet certain criteria. Our new contract pharmacy policy is intended to preserve patient access, while addressing compliance and integrity concerns resulting from the proliferation of contract pharmacies — problems that overshadow and threaten to undermine this vital safety net program. Nonetheless, certain 340B covered entities and the HHS, in a non-binding (and now-retracted) Advisory Opinion, stated that, in their view, manufacturers in the 340B program are obligated to sell 340B drugs at the 340B ceiling prices to all contract pharmacies acting as agents of a covered entity.

We and certain other manufacturers initiated litigation challenging the Advisory Opinion and HRSA's position on contract pharmacies generally. HRSA subsequently withdrew the Advisory Opinion, but issued letters to manufacturers, including us, threatening enforcement action if the manufacturers do not abandon their 340B contract pharmacy policies. We filed suit against HHS and HRSA on June 23, 2021 in the U.S. District Court for the District of Columbia. On September 22, 2021, HRSA sent to us, along with the other manufacturers challenging HRSA's 340B interpretation, letters stating that HRSA is referring "this issue to the HHS Office of the Inspector General" for potential enforcement action. We have not had any communication from OIG regarding our 340B contract pharmacy policy. On November 5, 2021, the court granted our motion for summary judgment, ruling that the letters threatening enforcement action "contain legal reasoning that rests upon an erroneous reading of Section 340B." HRSA filed a notice of appeal on December 28, 2021, and the appeal is pending. The court has set a briefing schedule concluding on July 27, 2022, but has not set a date for oral argument. If HRSA prevails on appeal or develops a new theory of liability, we may face enforcement action or penalties as well as adverse publicity. We expect the compliance of policies like ours will continue to be litigated.

If we and other manufacturers are unable to curb the proliferation of abuses caused by 340B contract pharmacies, we could see an increased prevalence of sales at reduced 340B ceiling prices, which could have a material adverse impact on our revenues.

Patient assistance programs for pharmaceutical products have come under increasing scrutiny by governments, legislative bodies, and enforcement agencies. These activities may result in actions that effectively reduce prices or demand for our products, harm our business or reputation, or subject us to fines or penalties.

Company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and manufacturers' donations to third-party charities that provide such assistance, are subject to heightened scrutiny. The Department of Justice (**DOJ**) has taken enforcement action against pharmaceutical companies alleging violations of the Federal False Claims Act and other laws in connection with patient assistance programs. In December 2017, we entered into a civil Settlement Agreement with the U.S. Government to resolve a DOJ investigation of our support of non-profit patient assistance programs and paid $210.0 million, plus interest, to the U.S. Government upon settlement. We also entered into a Corporate Integrity Agreement (the **CIA**) with the OIG, which requires us to maintain our corporate compliance program and to undertake a set of defined corporate integrity obligations for five years.

We may be required to incur significant future costs to comply with the CIA. If we fail to comply with applicable regulatory requirements or the CIA, or if our vendors or donation recipients fail to comply with applicable requirements or guidance, we could be subject to penalties including fines, suspension of regulatory approvals that cause us to suspend production, distribution or marketing activities, product recalls, seizure of our products, criminal prosecution, exclusion from participation in government healthcare programs, including Medicare and Medicaid, and burdensome remediation measures. Any of these penalties could adversely affect our operating results, the value of our company and our reputation. Patients and physicians may avoid using our products even after we have resolved the issues that led to adverse regulatory action.

Members of Congress have called upon the OIG to issue revised guidance about patient assistance programs. Actions taken by the OIG, the DOJ or other agencies as a result of this industry-wide inquiry could reduce demand for our products and/or coverage of our products by federal and state health care. If any or all of these events occur, our business, prospects, and stock price could be materially and adversely affected.

Payers and pharmacy benefit managers (**PBMs**) have developed mechanisms to limit the benefits of co-pay assistance for commercially insured programs through co-pay accumulator programs. These programs do not allow a patient using co-pay assistance to count the manufacturer's co-payment contribution toward their annual out-of-pocket payment maximum. Therefore, patients using co-pay assistance are penalized financially for using these programs. Some states have passed legislation to limit the use of co-pay accumulator programs, while some other states have indicated that these programs should be allowed to limit cost of care and encourage patients to use lower cost generics. In addition, some states have imposed restrictions on manufacturer co-pay programs when therapeutic equivalents are available. Growing use of such programs, or new laws limiting manufacturer ability to provide co-pay assistance, could affect patient access to our products and limit product utilization, which may, in turn, adversely affect our business, prospects, and stock price.

Improper handling of hazardous materials used in our activities could expose us to significant remediation liabilities.

Our research and development and manufacturing activities involve the controlled use of chemicals and hazardous substances. We are expanding these activities in both scale and location. Patients may dispose of our products using means we do not control. Such activities subject us to numerous federal, state, and local environmental and safety laws and regulations that govern the management, storage, and disposal of hazardous materials. Compliance with current and future environmental laws and regulations can require significant costs. The risk of accidental contamination or injury from these materials cannot be completely eliminated. Once chemical and hazardous materials leave our facilities, we cannot control the manner in which such hazardous waste is disposed of by our contractors. We could be liable for substantial civil damages or costs associated with the cleanup of the release of hazardous materials and such liability could have a material adverse effect on our business.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate information about our products and the diseases that our therapies are designed to treat. Social media practices in our industry continue to evolve and regulations related to such use are not always clear. This evolution creates uncertainty and risk of noncompliance. For example, patients and others may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend against political and market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate comments about us on any social networking website. If any of these events occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions, or incur other harm to our business.

Risks Related to Our Intellectual Property and Data Privacy

If any of the agreements under which we license or acquired intellectual property rights are breached or terminated, we could lose our rights to continue to develop, manufacture, and sell the products covered by such agreements.

Our business depends upon our continuing ability to exploit our intellectual property rights acquired from third parties under product license and purchase agreements covering drugs or other products or technology. We may be required to license additional intellectual property owned by third parties to continue to develop and commercialize our products. This dependence on intellectual property developed by others involves the following risks:

- We may be unable to obtain rights to intellectual property that we need for our business at a reasonable cost or at all;
- If any of our product licenses or purchase agreements are terminated, we may lose our rights to develop, make, and sell the products to which such licenses or agreements relate;
- Our rights to develop and market products to which the intellectual property relates are frequently limited to specific territories and fields of use (such as treatment of particular diseases); and
- If a licensor of intellectual property fails to maintain the intellectual property licensed, we may lose any ability to prevent others from developing or marketing similar products covered by such intellectual property. In addition, we may be forced to incur substantial costs to maintain the intellectual property ourselves or take legal action seeking to force the licensor to do so.

Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profits.

The period under which our commercial and developmental therapies are protected by our patent rights is limited. Three of our U.S. patents covering our current methods of synthesizing and producing treprostinil, the active ingredient in Tyvaso, Tyvaso DPI, Remodulin, and Orenitram, expired in October 2017, and three more will expire in 2028. Our patents related to our individual treprostinil-based products expire at various times between 2024 and 2031. We entered into settlement agreements with a number of generic drug companies permitting certain companies to launch generic versions of Remodulin in the United States and other companies to launch generic versions of Orenitram and Tyvaso in the United States. A U.S. patent for Adcirca for treatment of pulmonary hypertension expired in November 2017, and FDA-conferred regulatory exclusivity expired in May 2018, leading to the launch of a generic version of Adcirca in August 2018. We have no issued patents or pending patent applications covering Unituxin. For further details, please see *Part I, Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations—Generic Competition and Challenges to our Intellectual Property Rights.*

We cannot be sure that our existing or any new patents will effectively deter or delay competitors' efforts to bring new products to market, or that additional patent applications will result in new patents. When our patents expire, competitors may develop generic versions of our products and market them at a lower price to compete with our products. Competitors may also seek to design around our patents or exclude patented methods of treatment, such as patent-protected indications, from the label for generic versions of our products in an effort to develop competing products that do not infringe our patents. In addition, patent laws of foreign jurisdictions may not protect our patent rights to the same extent as the patent laws of the United States.

Third parties have challenged, and may in the future challenge, the validity of our patents, through patent litigation and/or initiating proceedings, including re-examinations, IPRs, post-grant reviews, and interference proceedings, before the USPTO or other applicable patent filing offices, or other means. For example, Liquidia is challenging various patents related to Tyvaso and our other treprostinil-related patents.

Patent litigation can be time consuming, distracting, and costly, and the outcome may be difficult to predict and unfavorable to us. If we are unsuccessful in the defense of our patents, our business could be negatively impacted. Even if our patents are determined to be valid or enforceable, a competitor could circumvent our patents by effectively designing around the claims of our patents. Accordingly, our patents may not provide us with any competitive advantage.

We also rely on trade secrets to protect our proprietary know-how and other technological advances that we do not publicly disclose. Our confidentiality agreements with our Unitherians and others to whom we disclose trade secrets and confidential information may not necessarily prevent our trade secrets from being used or disclosed without our authorization. These

agreements may be difficult, time-consuming, and expensive to enforce or may not provide an adequate remedy in the event of unauthorized disclosure. If our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us, and our business and competitive position could be harmed.

Third parties may allege that our products or services infringe their patents and other intellectual property rights, which could result in the payment of royalties that negatively affect our profits, subject us to costly and time-consuming litigation, or cause us to lose the ability to sell the related products.

To the extent third-party patents to which we currently do not hold licenses are necessary for us to manufacture, use, or sell our products, we would need to obtain necessary licenses to prevent infringement. For products or services that utilize intellectual property of strategic collaborators or other suppliers, such suppliers may have an obligation to secure the needed license to these patents at their cost; if not, we would be responsible for the cost of these licenses. Royalty payments and other fees under these licenses would erode our profits from the sale of related products and services. Moreover, we may be unable to obtain these licenses on acceptable terms or at all. If we fail to obtain a required license or are unable to alter the design of the product to avoid infringing a third-party patent, we would be unable to continue to manufacture or sell related products.

If a third party commences legal action against us for infringement, we may incur significant costs to defend the action and our management's attention could be diverted from our day-to-day business operations, whether or not the action has merit. An adverse judgment or settlement resulting from the action could require us to pay substantial amounts in damages for infringement or to obtain a license to continue to use the intellectual property that is the subject of the infringement claim, or could result in injunctive relief limiting our ability to develop, manufacture, or sell our products.

Information technology security breaches and other disruptions could compromise our information and expose us to legal responsibility which would cause our business and reputation to suffer.

We are increasingly dependent on information technology systems and infrastructure, much of which is outsourced to third parties including in "cloud" based platforms. We collect, store, and use sensitive or confidential data, including intellectual property, our proprietary business information and that of our suppliers, customers, and business partners, and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. We are subject to laws and regulations in the United States and abroad, such as the Health Insurance Portability and Accountability Act of 1996 and European Union regulations related to data privacy, which require us to protect the privacy and security of certain types of information. Our information technology and infrastructure may be vulnerable to attacks by hackers, breached due to employee error, malfeasance, or other disruptions, or subject to system failures. Because the techniques used to obtain unauthorized access, disable, or degrade service, or sabotage systems change frequently and may be difficult to detect for long periods of time, we may be unable to anticipate these techniques or implement adequate preventive measures. Any breaches or failures could compromise sensitive and confidential information stored on our networks or those of third parties and expose such information to public disclosure, loss, or theft. Any actual or alleged unauthorized access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disruption of our operations, and damage to our reputation, any of which could adversely affect our business, financial condition, or results of operations. Costs we may incur as a result of any of the foregoing, could adversely affect our business, financial condition, or results of operations. Given the increasing use of conferencing technologies to conduct business virtually in light of the COVID-19 pandemic, these cybersecurity risks are becoming more prevalent.

Risks Related to Our Financing Capacity, Indebtedness, and Investments

If we need additional financing and cannot obtain it, our product development and sales efforts may be limited.

We may be required to seek additional sources of financing to meet unplanned or planned expenditures. Unplanned expenditures could be significant and may result from necessary modifications to product development plans or product offerings in response to difficulties encountered with clinical trials. We may also face unexpected costs in preparing products for commercial sale, or in maintaining sales levels of our currently marketed therapeutic products. Our 2022 Credit Agreement contains affirmative and negative covenants that, among other things, limit our ability to incur additional indebtedness. If we are unable to obtain additional funding on commercially reasonable terms or at all, we may be compelled to delay clinical studies, curtail operations, or obtain funds through collaborative arrangements that may require us to relinquish rights to certain products or potential markets.

We may not be able to generate sufficient cash to service or repay our indebtedness, which may have a material adverse effect on our financial position, results of operations, and cash flows.

We may borrow up to $2.0 billion under our 2022 Credit Agreement, which matures in March 2027. Currently, our outstanding principal balance is $800.0 million. Our ability to repay or refinance our debt obligations under our 2022 Credit Agreement and any future debt that we may incur will depend on our financial condition and operating performance, which are subject to a number of factors beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal and interest on our indebtedness. Our inability to generate sufficient cash flows to satisfy our debt

obligations would materially and adversely affect our financial position and results of operations. If we cannot repay or refinance our debt as it becomes due, we may be forced to take disadvantageous actions, including reducing or delaying investments and capital expenditures, disposing of material assets or operations, seeking additional debt or equity capital, or restructuring or refinancing our indebtedness. We may not be able to effect any such alternative measures on commercially reasonable terms or at all and, even if successful, such actions may not enable us to meet any such debt service obligations. In addition, our ability to withstand competitive pressures and to react to changes in our industry could be impaired.

Our portfolio of investments is subject to market, interest, operational, and credit risk that may reduce its value.

We maintain a portfolio of investments that includes: (1) corporate debt securities; (2) strategic investments in publicly-traded equity securities; and (3) strategic debt and equity investments in privately-held companies. These investments are subject to general economic conditions, volatility in the financial marketplace, market- and industry-wide dynamics, changes in interest rates, industry- and company-specific developments impacting the business, prospects, and credit ratings of the issuer of the securities, and other factors, each of which has affected, and may in the future affect, the income that we receive from our investments, the net realizable value of our investments, and our ability to sell them. These factors have caused, and could in the future cause, us to: (a) experience a decline in our investment income; (b) record impairment charges to reduce the carrying value of our investment portfolio; or (c) sell investments for less than our acquisition cost; each of which in turn could negatively impact our liquidity and our earnings. Our efforts to mitigate these risks through diversification of our investments and monitoring of our portfolio's overall risk profile may not be successful and the value of our investments may decline. The privately-held companies we have invested in may be particularly susceptible to the factors described above as these companies are typically in the early stages of developing technologies or products that may never materialize, which could result in a loss of all or a substantial part of our investment in these companies.

Risks Related to Our Common Stock

The price of our common stock can be highly volatile and may decline.

The price of common stock can be highly volatile within the pharmaceutical and biotechnology sector. Consequently, significant price and volume fluctuations in the market may not relate to operating performance. The price of our common stock could decline sharply due to general market conditions as well as the following factors, among others:

- Developments related to the COVID-19 pandemic and the associated economic impact, and their effects on our business, financial condition, or results of operations;
- Quarterly and annual financial results and any failure to meet our expectations or those of securities analysts;
- Timing of enrollment and results of our clinical trials;
- Announcements regarding generic or other challenges to the intellectual property related to our products, the launch of generic versions of our products or other competitive products, and the impact of competition from generic and other products on our revenues;
- Announcements regarding litigation matters, including our ongoing patent litigation with Liquidia related to its NDA for Yutrepia, among others;
- Announcements regarding our efforts to obtain FDA approval of, and to launch, new products;
- Physician, patient, investor, or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;
- Changes in, or new laws and regulations affecting reimbursement of, our therapeutic products by government payers, changes in reimbursement policies of private insurance companies, and negative publicity surrounding the cost of high-priced therapies;
- Announcements of technological innovations or new products or announcements regarding our existing products, including in particular the development of new, competing therapies;
- Substantial sales of our common stock by us or our existing shareholders, or concerns that such sales may occur;
- Future issuances of common stock by us or other activity which could be viewed as being dilutive to our shareholders;
- Rumors or incorrect statements by investors and/or analysts concerning our company, our products, or our operations;
- Failures or delays in our efforts to obtain or maintain domestic or international regulatory approvals;
- Discovery of previously unknown problems with our marketed products, or problems with our manufacturing, regulatory, compliance, promotional, marketing or sales activities that result in regulatory penalties or restrictions on our products, up to the withdrawal of our products from the market; and
- Accumulation of significant short positions in our common stock by hedge funds or other investors or the significant accumulation of our common stock by hedge funds or other institutional investors with investment strategies that may lead to short-term holdings.

Provisions of Delaware law, our charter, bylaws and employment and license agreements, among other things, could prevent or delay a change of control or change in management that may be beneficial to our public shareholders.

Certain provisions of Delaware law, our restated certificate of incorporation, and our ninth amended and restated bylaws may prevent, delay, or discourage a merger, tender offer, or proxy contest; the assumption of control by a holder of a large block of our securities; and/or the replacement or removal of current management by our shareholders. For example, our restated certificate of incorporation previously divided our Board of Directors into three classes. The recent declassification of our Board will be phased in and all directors will not be elected annually until our 2023 annual meeting of shareholders. This provision may make it more difficult for shareholders to replace the majority of directors until such time. It may also deter the accumulation of large blocks of our common stock by limiting the voting power of such blocks. In addition, as a result of our recent conversion to a PBC, our Board is required to consider and balance the financial interests of shareholders, the interests of stakeholders materially affected by our conduct, and the pursuit of our specific public benefit purpose when evaluating takeover offers. This requirement of Delaware PBC law may make our company a less attractive takeover target than a traditional for-profit corporation.

Non-competition and all other restrictive covenants in most of our employment agreements will terminate upon a change of control that is not approved by our Board. Similarly, a change of control, under certain circumstances, could accelerate the vesting of outstanding stock options, and restricted stock units. Any increase in our stock price resulting from the announcement of a change of control, and our broad-based change of control severance program, under which Unitherians may be entitled to severance benefits if they are terminated without cause (or they terminate their employment for good reason) following a change of control, could make an acquisition of our company significantly more expensive to the purchaser.

We enter into certain license agreements that generally prohibit our counterparties or their affiliates from taking necessary steps to acquire or merge with us, directly or indirectly throughout the term of the agreements, plus a specified period thereafter. We are also party to certain license agreements that restrict our ability to assign or transfer the rights licensed to us to third parties, including parties with whom we wish to merge, or those attempting to acquire us. These agreements often require that we obtain prior consent of the counterparties if we contemplate a change of control. If these counterparties withhold consent, related agreements could be terminated and we would lose related license rights. For example, Lilly and MannKind have the right to terminate our license agreements related to Adcirca and Tyvaso DPI, respectively, in the event of certain change of control transactions. These restrictive change of control provisions could impede or prevent mergers or other transactions that could benefit our shareholders.

Our shareholders must rely on stock appreciation for any return on their investment in us.

We have never paid, and do not intend to pay, cash dividends. Our 2022 Credit Agreement may restrict us from doing so. As a result, the return on an investment in our common stock depends entirely upon the future appreciation, if any, in the price of our common stock.

Our exclusive forum bylaw may limit our shareholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers, or other Unitherians.

Our bylaws provide that, to the fullest extent permitted by law, unless we agree in writing to an alternative forum, (a) the Delaware Court of Chancery (or, if such court does not have, or declines to accept, jurisdiction, another state court or a federal court located in Delaware) will be the exclusive forum for any complaint asserting any internal corporate claims, including claims in the right of the corporation based upon a violation of a duty by a current or former director, officer, Unitherian, or stockholder in such capacity, or as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery, and (b) the federal district courts will be the exclusive forum for any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. The choice of forum provision may limit our shareholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers, or other Unitherians, and may discourage such lawsuits. There is uncertainty as to whether a court would enforce this provision. If a court ruled the choice of forum provision was inapplicable or unenforceable in an action, we may incur additional costs to resolve such action in other jurisdictions. Our choice of forum provision is intended to apply to the fullest extent permitted by law to the above-specified types of actions and proceedings, including any derivative actions asserting claims under state law or the federal securities laws. Our shareholders will not be deemed, by operation of the choice of forum provision, to have waived our obligation to comply with all applicable federal securities laws and the rules and regulations thereunder.

In September 2021, we converted to a Delaware PBC. Conversion may not result in the benefits that we anticipate, requires our directors to balance the interest of shareholders with other interests, and may subject us to additional litigation and other risks.

On September 30, 2021, our shareholders approved an amendment to our restated certificate of incorporation to become a PBC, and we completed the conversion to a PBC that same day. While our Board believes that our conversion to a PBC is in the best interest of shareholders, our status as a PBC may not result in the benefits that we anticipate. For example, we may not be able to achieve our public benefit purpose or realize the expected positive impact from being a PBC.

One of the primary distinctions between a PBC and a traditional Delaware for-profit corporation is that, in making decisions, the directors of a PBC have an obligation to balance the financial interests of shareholders, the interests of stakeholders materially affected by the PBC's conduct, and the pursuit of the corporation's specific public benefit purpose. The application of this balancing obligation may allow our directors to make decisions that they could not have made pursuant to the fiduciary duties applicable prior to PBC conversion. There is no guarantee that our Board will resolve conflicts among the financial interests of

our shareholders, our specific public benefit purpose, or stakeholders materially affected by our conduct, in favor of our shareholders' financial interests. For instance, in a sale of control transaction, our Board would be required to consider and balance the factors listed above and might choose to accept an offer that does not maximize short-term shareholder value due to its consideration of other factors. This requirement of Delaware PBC law may make our company a less attractive takeover target than a traditional for-profit corporation.

A Delaware PBC must also provide its shareholders with a statement, at least every other year, as to the PBC's assessment of the success of its efforts to promote its public benefit purpose and the best interests of those materially affected by the PBC's conduct. If the public perceives that we are not successful in promoting our public benefit purpose, or that our pursuit of our public benefit purpose is having a negative effect on the financial interests of our shareholders, that perception could negatively affect our reputation, which could adversely affect our business, results of operations and stock price. In addition, Delaware's PBC statute may be amended to require more explicit or burdensome reporting requirements that could increase the time and expense required to comply.

As a Delaware PBC, we may be subject to increased litigation risk.

Shareholders of a Delaware PBC (if they, individually or collectively, own the lesser of (1) two percent of the PBC's outstanding shares; or (2) shares with a market value of $2 million or more on the date the lawsuit is instituted) can file a derivative lawsuit claiming the directors failed to balance shareholder and public benefit interests. Traditional Delaware for-profit corporations are not subject to this potential liability. As a PBC, we may be subject to increased derivative litigation, which may be costly and require management's attention, which may adversely affect our financial condition and results of operations. In addition, there is currently limited case law involving PBCs (including case law interpreting and applying the balancing obligation of PBC directors), which may expose us to additional litigation risk generally until additional case law develops or additional legislative action is taken.

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

During the six months ended June 30, 2022 we did not (a) repurchase any of our outstanding equity securities; or (b) sell any of our equity securities in transactions that were not registered under the Securities Act of 1933, as amended.

Item 6. Exhibits

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed October 1, 2021.
3.2	Ninth Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed February 5, 2021.
4.1	Reference is made to Exhibits 3.1 and 3.2.
10.1*+	License and Collaboration Agreement, dated as of September 3, 2018, by and between the Registrant and MannKind Corporation.
10.2	United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 28, 2022.
10.3*+	Second Amendment to Specialty Pharmacy Network Agreement, dated June 13, 2022, between the Registrant and Accredo Health Group, Inc.
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 3, 2022, formatted in Inline Extensible Business Reporting Language (iXBRL): (1) our Consolidated Balance Sheets as of June 30, 2022 and December 31, 2021; (2) our Consolidated Statements of Operations for the three- and six-month periods ended June 30, 2022 and 2021; (3) our Consolidated Statements of Comprehensive Income for the three- and six-month periods ended June 30, 2022 and 2021; (4) our Consolidated Statements of Stockholders' Equity for the three- and six-month periods ended June 30, 2022 and 2021; (5) our Consolidated Statements of Cash Flows for the six-month periods ended June 30, 2022 and 2021; and (6) the Notes to our Consolidated Financial Statements.
104*	Cover Page Interactive Data File (embedded within the iXBRL document)

* Filed herewith.

\+ Certain identified information has been omitted from this exhibit because it is both (1) not material; and (2) would be competitively harmful if publicly disclosed.

Note: Except as otherwise noted above, all exhibits incorporated by reference to the Registrant's previously filed reports with the Securities and Exchange Commission are filed under File No. 000-26301.

Signatures

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

UNITED THERAPEUTICS CORPORATION

August 3, 2022

By: /s/ MARTINE ROTHBLATT
Martine Rothblatt, Ph.D.
Title: *Chairperson and Chief Executive Officer*
(Principal Executive Officer)

By: /s/ JAMES C. EDGEMOND
James C. Edgemond
Title: *Chief Financial Officer and Treasurer*
(Principal Financial and Accounting Officer)

Certain information (marked as [***]) has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Exhibit 10.1
EXECUTION COPY – CONFIDENTIAL

LICENSE AND COLLABORATION AGREEMENT

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

RECITALS

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

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

Whereas, United Therapeutics desires to obtain from MannKind, and MannKind desires to grant to United Therapeutics, certain exclusive rights and licenses to develop Product in the Territory in collaboration with MannKind and to commercialize Product in the Territory subject to the terms and conditions of this Agreement.

AGREEMENT

Now, Therefore, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, MannKind and United Therapeutics hereby agree as follows:

ARTICLE 1

DEFINITIONS

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

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

1.2 "***Affiliate***" of a Person shall mean any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Person, as the case may be, but for only so long as such control exists. As used in this Section 1.2, "control" shall mean direct or indirect beneficial ownership of at least 50% (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such Person.

1.3 "***Antitrust Laws***" shall mean the Clayton Act, as amended, the HSR Act, and all other applicable laws and regulations issued by a Governmental Authority, whether domestic or

foreign, that are designed or intended to prohibit, restrict or regulate actions having the purpose or effect of monopolization or restraint of trade or lessening of competition.

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

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

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

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

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

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

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

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

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

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

1.14 "***Change of Control***" means, with respect to a Party: (a) completion of a merger, reorganization, amalgamation, arrangement, share exchange, consolidation, tender or exchange offer, private purchase, business combination, recapitalization or other transaction involving the Party as a result of which either (1) the stockholders of the Party immediately preceding such transaction hold less than 50% of the outstanding shares, or less than 50% of the outstanding voting power, respectively, of the ultimate company or entity resulting from such transaction immediately after consummation thereof (including a company or entity which as a result of such transaction owns the then-outstanding securities of the Party or all or substantially all of the Party's assets, including Party's assets related to Product, either directly or through one or more subsidiaries), or (2) any single Third Party person or group (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect, referred to as a "***Group***") holds 50% or more of the outstanding shares or voting power of the ultimate company or entity resulting from such transaction immediately after the consummation thereof (including a company or entity which as a result of such transaction owns the then outstanding securities of the Party or all or substantially all of the Party's assets either directly or through one or more subsidiaries); or (b) the direct or indirect acquisition (including by means of a tender offer or an

exchange offer) by any Third Party person or Group of beneficial ownership (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect), or the right to acquire beneficial ownership, or formation of any Third Party Group which beneficially owns or has the right to acquire beneficial ownership, of 50% or more of either the outstanding voting power or the then-outstanding shares of the Party, in each case on a fully diluted basis.

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

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

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

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

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

1.20 [***].

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.45 "***Government Health Care Program***" shall mean the Medicare program (Title XVIII of the Social Security Act), the Medicaid program (Title XIX of the Social Security Act), the Department of Veterans Affairs FSS Program, TRICARE, and the Public Health Service 340B Program, and any similar federal, state, and local governmental health care plans and programs.

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

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

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

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

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

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

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

1.53 "***Information***" shall mean all technical, scientific, marketing, financial, commercial and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, discoveries, inventions, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, prototypes, specifications, data, results, customer lists, marketing materials, and other material, including: drug discovery and development technology; biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; assays and biological methodology; manufacturing and quality control procedures and data, including test procedures; and synthesis, purification and isolation techniques, in each case (whether or not confidential, proprietary, patented or patentable, of commercial advantage or not) in written, electronic or any other form now known or hereafter developed.

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

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

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

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

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

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

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

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

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

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

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

1.65 "***MannKind Know-How***" shall mean all Information not included in the MannKind Patents that is Controlled by MannKind or any of its Affiliates (subject to Section 15.9) as of the Effective Date or during the Term that is necessary or reasonably useful for the development, manufacture, use, import, offer for sale or sale of Product in the Field, including all such Information related to the design and utility of the Device and to the creation of a Formulation, and any replication or any part of such Information.

1.66 "***MannKind Patents***" shall mean all Patents Controlled by MannKind or any of its Affiliates (subject to Section 15.9) as of the Effective Date or during the Term that claim or disclose Product or its components, or are necessary or reasonably useful for the development, manufacture, use, import, offer for sale, or sale of Product in the Field in the Territory, including all such Patents claiming or covering the design or utility of a Device or a Formulation, but excluding any Joint Patents.

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

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

1.69 "***Marketing Approval***" shall mean all clearances, approvals, licenses, registrations or authorizations of Regulatory Authorities in a country necessary for the manufacture, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of a pharmaceutical product and/or medical device in such country. For countries where governmental approval is required for pricing or reimbursement for a pharmaceutical product to be reimbursed by national health insurance (or its local equivalent), "Marketing Approval" shall not be deemed to occur until such pricing or reimbursement approval is obtained.

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

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

(a) trade, quantity and cash discounts;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.80 "***Product***" shall mean a product in a form suitable for human applications consisting of (a) a Formulation that contains API for use in an inhalation device or a Device, (b) a Device, but only to the extent that it is sold (or intended to be sold) for use with such a Formulation described in clause (a), (c) both a Device and such a Formulation described in clause (a) for use together, or (d) an Accessory Apparatus for use with the Product configuration described in (c), in each case, including all improvements incorporated therein. For clarification, Product shall not include a Device to the extent that it is sold (or intended to be sold) for administration of a Formulation that contains an active pharmaceutical ingredient other than API unless such active pharmaceutical ingredient is an Optioned Agent that has been added to this Agreement pursuant to Section 2.6.

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

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

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

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

1.85 "***Regulatory Authority***" shall mean any Governmental Authority whose review or approval is necessary for the development, design, manufacture, packaging, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of Product. Where governmental approval is required for pricing or reimbursement for Product to be reimbursed by national health insurance (or its local equivalent), "Regulatory Authority" shall also include any Governmental Authority whose review or approval of pricing or reimbursement is required.

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

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

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

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

1.90 "***Segregate***" shall mean with respect to a product or program, to use Commercially Reasonable Efforts to segregate the development and commercialization activities

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

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

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

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

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

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

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

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

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

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

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

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

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

ARTICLE 2

GRANT OF LICENSE

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

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

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

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

the licenses expressly granted to MannKind in this Agreement or any other written agreement between the Parties.

2.5 Exclusivity.

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

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

2.6 Option to Add Additional Products.

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

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

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

ARTICLE 3

GOVERNANCE

3.1 Executive Steering Committee.

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

(b) Membership. The ESC shall be composed of six members, three of whom shall be nominated by MannKind and three of whom shall be nominated by United Therapeutics, which members shall be employees of the applicable Party with the requisite experience and seniority to make decisions on behalf of the Parties with respect to issues within the jurisdiction of the ESC. MannKind and United Therapeutics shall designate their respective initial members of the ESC within 30 days after the Effective Date. Each Party may change its ESC members at any time by written notice to the other Party. United Therapeutics shall have the right to designate the chair of the ESC.

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

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

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

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

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

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

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

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

(e) Decision-Making and Dispute Resolution. For clarity, the ESC is intended primarily to be a consultative body with its decision making authority limited to the approval of material changes to the Development Plan (including the constituent development sub-plans). All decisions within the authority of the ESC shall be made by unanimous vote or

written consent, with the MannKind members of the ESC collectively having one vote and the United Therapeutics members of the ESC collectively having one vote in all decisions of the ESC. The members of the ESC shall use reasonable efforts to reach agreement on all matters. If, despite such efforts, agreement on a particular matter cannot be reached by the ESC within 10 days after the ESC first considers such matter (or such shorter or longer time as may be agreed by the Parties), then either Party may, by written notice to the other Party, have such matter referred to, on behalf of MannKind, the Chief Executive Officer of MannKind and, on behalf of United Therapeutics, the Chief Executive Officer of United Therapeutics. Such executives shall use reasonable efforts to resolve the matter referred to them within 10 days after such referral. If, despite such efforts, such executives are unable to resolve such matter within 10 days after such referral (or such shorter or longer time as may be agreed by the Parties), then, the chair of the ESC shall have the right to make the final decision with regard to the disputed matter following good faith consideration of MannKind's comments, provided that the chair of the ESC shall not have power to resolve a dispute: (i) in a manner that would require MannKind to perform activities which materially exceed the scope of, or are materially different in nature with respect to, the activities MannKind has agreed to perform under the Development Plan or has otherwise agreed in writing to perform; (ii) by overriding MannKind's rights under this Agreement; or (iii) by unilaterally determining that it has fulfilled any diligence obligations hereunder. For all purposes under this Agreement, any decision made pursuant to this Section 3.1(e) shall be deemed to be the decision of the ESC.

(f) Working Groups of the ESC. Promptly following its establishment, the ESC shall establish two working groups, one to oversee the performance of the CMC development activities ("***CMC Working Group***") and one to oversee the performance of the manufacturing technology transfer ("***Mfg Technology Transfer Working Group***"). These working groups shall periodically review their applicable activities within the Initial Development Plan and develop detailed and specific sub-plan updates as needed, which shall be submitted to the ESC for review and approval. In addition, each Party may submit requested modifications to such sub-plans to the ESC, which the ESC will reasonably consider. From time to time, the ESC may establish additional working groups as necessary to oversee particular projects or activities added to the Development Plan, as it deems necessary or advisable. Each working group shall consist of such number of representatives of each Party as the ESC determines is appropriate from time to time and shall meet with such frequency as the ESC shall determine. All decisions of each working group shall be made by unanimous vote or written consent, with the MannKind members of the working group collectively having one vote and the United Therapeutics members of the working group collectively having one vote in all decisions of the working group. If, with respect to a matter that is subject to a working group's decision-making authority, the working group cannot reach agreement, the matter shall be referred to the ESC, which shall resolve such matter in accordance with Section 3.1(e).

3.2 Scope of Governance. Notwithstanding the creation of the ESC, each Party shall retain the rights, powers and discretion granted to it hereunder, and the ESC shall not be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly agree in writing. The ESC shall not have the power to amend or modify this Agreement, and no decision of the ESC shall be in contravention of any terms and conditions of this Agreement. It is understood and agreed that issues to be formally decided by the ESC are only those specific issues that are expressly provided in this Agreement to be decided by the ESC. Notwithstanding anything to the contrary in Sections 3.1(e), any dispute regarding the interpretation of this Agreement or any alleged breach of this Agreement will be resolved in accordance with the terms of Article 14.

ARTICLE 4

DEVELOPMENT AND REGULATORY ACTIVITIES

4.1 Development Activities.

(a) United Therapeutics' Obligations.

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

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

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

(b) MannKind's Obligations.

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

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

experience as are required to accomplish such activities in accordance with the terms of the Development Plan and this Agreement.

(c) Mutual Obligations.

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

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

4.2 Regulatory Activities.

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

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

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

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

4.3 Right of Reference.

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

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

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

Development Plan that has not previously been provided hereunder and is reasonably requested by MannKind.

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

4.6 Use of Subcontractors. MannKind shall not assign, delegate, or subcontract to a Third Party any of the development or regulatory activities assigned to it under the Development Plan without the prior written approval of United Therapeutics, provided that the Parties agree that the subcontractors listed in the Initial Development Plan ("***Approved Suppliers***") shall be deemed pre-approved for the tasks indicated therein. United Therapeutics shall be free to perform its development or regulatory activities under this Agreement through one or more subcontractors. In the event that either Party elects to use subcontractors as permitted in this Section 4.6, such Party shall ensure that (a) none of the other Party's rights hereunder are diminished or otherwise adversely affected as a result of such subcontracting, and (b) the subcontractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information which are substantially the same as those undertaken by the Parties pursuant to Article 8. In the event a Party performs any of its development or regulatory activities hereunder through a subcontractor, then such Party will at all times be fully responsible for the performance and payment of such subcontractor.

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

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

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

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

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

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

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

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

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

(b) Regulatory Non-Compliance. All material information pertaining to notices from Regulatory Authorities of non-compliance with Applicable Laws in connection with products described in (i) and (ii) above, including without limitation, receipt of a warning letter

or other notice of alleged non-compliance from any Regulatory Authority relating to such products, but only to the extent in each case that such non-compliance pertains specifically to the Device component or the Processed FDKP component of the applicable product;

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

ARTICLE 5

COMMERCIALIZATION; MANUFACTURE AND SUPPLY

5.1 Commercialization of Product.

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

(i) establish the commercialization and marketing strategy and tactics (the "***Commercial Strategy***");

(ii) establishing pricing and reimbursement, including payment of applicable rebates and chargebacks;

(iii) managed care and government contracting (including contracting for Product to be available under the Government Health Care Programs);

(iv) receiving, accepting and filling orders;

(v) distribution to customers;

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

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

(viii) tracking and reporting transfers of value in connection with Product under applicable state and federal "aggregate spend"/"sunshine" reporting laws).

(b) Commercialization Plan. At least six (6) months prior to anticipated launch of Product, United Therapeutics shall prepare a three-year, non-binding high-level plan for the marketing, promotion and pricing of Product in the Field in the United States as well as a more detailed, non-binding one-year plan that shall contain the commercialization objectives to be achieved during the applicable Calendar Year, the launch, promotion, distribution, detailing and marketing activities to be performed in pursuit of such objectives in such Calendar Year, and a budget setting out the amounts anticipated to be expended in the performance of such activities during such Calendar Year (such three-year high level plan and more detailed one-year plan,

collectively the "***Commercialization Plan***"). Thereafter, United Therapeutics shall provide an updated Commercialization Plan to MannKind on an annual basis and shall additionally modify each such Commercialization Plan throughout the Calendar Year as it deems necessary in its sole discretion to accurately reflect United Therapeutics' then current plans for the Product, provided that any material amendments to the Commercialization Plan shall be promptly provided to MannKind. Without limiting the provisions of this Section 5.1, at MannKind's reasonable request, United Therapeutics shall periodically consult with and provide updates to MannKind regarding the Commercial Strategy and commercialization of Product in the Territory.

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

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

5.2 Manufacture and Supply.

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

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

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

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

ARTICLE 6

CONSIDERATION

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

6.2 Milestone Payments.

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

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

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

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

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

6.3 Royalty Payments.

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

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

(c) Royalty Term. On a Product-by-Product and country-by-country basis, United Therapeutics will be obligated to make royalty payments pursuant to this Section 6.3

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

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

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

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

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

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

ARTICLE 7

PAYMENTS, BOOKS AND RECORDS

7.1 Royalty Report and Payment. During the Term, within [***] days after the end of each Calendar Quarter, United Therapeutics shall deliver to MannKind a report setting forth the gross sales of Product and Net Sales in the relevant Calendar Quarter and a calculation of the payments due under Section 6.3 (a "***Royalty Report***"). Following receipt of any Royalty Report,

MannKind shall issue an invoice for the amount stated by United Therapeutics to be payable to MannKind in such Royalty Report, and payment shall be due to MannKind by United Therapeutics within [***] days of its receipt of such invoice.

7.2 Payment Method. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account in the name of MannKind designated in writing by MannKind. Payments hereunder will be considered to be made as of the day on which they are received by MannKind's designated bank.

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

7.4 Taxes.

(a) Cooperation and Coordination. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use their reasonable efforts to cooperate and coordinate with each other to achieve such objective. For the avoidance of doubt, the Parties expect that only United Therapeutics shall be responsible for the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) as a result of the sale of Products.

(b) Payment of Tax. A Party receiving a payment shall pay any and all taxes levied on such payment. If Applicable Laws require that taxes be deducted and withheld from a payment, the remitting Party shall (i) deduct those taxes from the payment; (ii) pay the taxes to the proper taxing authority; and (iii) send evidence of the obligation together with proof of payment to the other Party within 60 days following that payment.

7.5 Records. United Therapeutics shall keep, and require its Affiliates to keep, complete, true and accurate books of accounts and records for the purpose of determining the amounts payable to MannKind pursuant to this Agreement. Such books and records shall be kept for such period of time required by Applicable Laws, but no less than three years following the end of the Calendar Quarter to which they pertain. Such records shall be subject to inspection in accordance with Section 7.6.

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

inspection. The Auditor shall be obligated to execute a reasonable confidentiality agreement prior to commencing any such inspection. Inspections conducted under this Section 7.6 shall be at the expense of MannKind, unless a variation or error producing an underpayment in amounts payable exceeding 5% of the amount paid for a period covered by the inspection is established, in which case all reasonable costs relating to the inspection for such period and any unpaid amounts that are discovered shall be paid by United Therapeutics. The Parties will endeavor in such inspection to minimize disruption of United Therapeutics' normal business activities to the extent reasonably practicable.

7.7 Late Payments. In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest from the date due at a rate per annum equal to the U.S. Prime Rate (as set forth in the Wall Street Journal, Eastern Edition) for the date on which payment was due, calculated daily on the basis of a 365-day year, or similar reputable data source; provided that, in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit the Party entitled to receive such payment from exercising any other rights it may have as a consequence of the lateness of any payment.

ARTICLE 8

CONFIDENTIALITY

8.1 Confidential Information.

(a) General. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that the receiving Party (the "***Receiving Party***") shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement or any other written agreement between the Parties any confidential or proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which is disclosed to it by or on behalf of the other Party (the "***Disclosing Party***") including all information concerning Product and any other technical or business information of whatever nature (collectively, "***Confidential Information***"). For clarification, all MannKind Technology shall be Confidential Information of MannKind and all United Therapeutics Technology shall be Confidential Information of United Therapeutics. The Receiving Party shall (i) use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but in no event less than reasonable care) to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information and (ii) limit access to and use of Confidential Information to its employees, agents, consultants and other representatives (and those of its Affiliates) with a need to know such information.

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

(a) was already known to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality, at the time of disclosure;

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

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

(d) was subsequently lawfully disclosed to the Receiving Party or any of its Affiliates by a Person other than the Disclosing Party, and who, to the best knowledge of the Receiving Party, did not directly or indirectly receive such information directly or indirectly from the Disclosing Party under an obligation of confidence; or

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

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

(a) exercising its or its Affiliates' rights under this Agreement, including in the case of United Therapeutics, for the purpose of developing the Product, seeking, obtaining and maintaining Marketing Approvals of Product (including complying with the requirement of Regulatory Authorities with respect to filing for, obtaining and maintaining Marketing Approval of the Product) and manufacturing or commercializing Product;

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

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

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

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

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

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

that such Confidential Information disclosed accordingly shall only lose its confidentiality protection for purposes of such disclosure.

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

8.5 Public Announcements.

(a) Press Releases. As soon as practicable following the execution of this Agreement, the Parties will issue a joint press release announcing the existence of this Agreement. Except as required by Applicable Laws, including disclosure requirements of the SEC, the NASDAQ stock exchange or any other stock exchange on which securities issued by a Party or its Affiliates are traded, neither Party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed; provided, that it shall not be unreasonable for a Party to withhold consent with respect to any public announcement containing any of such Party's Confidential Information. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment upon the proposed text.

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

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

by a Third Party clinical collaborator, clinical site or academic or government run non-clinical site, including investigators within such institutions, to which a Party delegates the performance of non-clinical, pre-clinical or clinical research, shall be subject to the terms and conditions of the delegating Party's agreement with such Third Party to the extent inconsistent with the terms and conditions of this Section 8.6.

8.7 Prior Non-Disclosure Agreements. As of the Effective Date, the terms of this Article 8 shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) dealing with the subject of this Agreement, including without limitation the Confidentiality Agreement. Any information disclosed under such prior agreements shall be deemed disclosed under this Agreement.

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

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 Ownership of Intellectual Property.

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

(b) Inventions. As between the Parties, all right, title and interest to inventions and other subject matter (together with all intellectual property rights therein) conceived or created or first reduced to practice (in the case of patentable inventions) or made or developed (in the case of non-patentable inventions) in the course of performing activities contemplated by this Agreement ("***Inventions***") (i) by or under the authority of United Therapeutics or its Affiliates, independently of MannKind and its Affiliates, shall be owned by United Therapeutics ("***United Therapeutics Inventions***"), (ii) by or under the authority of MannKind or its Affiliates, independently of United Therapeutics and its Affiliates, shall be owned by MannKind ("***MannKind Inventions***") and (iii) that is invented jointly by personnel of United Therapeutics or its Affiliates, on the one hand, and MannKind or its Affiliates, on the other hand, shall be jointly owned by United Therapeutics and MannKind ("***Joint Inventions***"). For purposes of determining questions of inventorship for Inventions, the Parties shall apply the laws of the United States. Subject to the rights and licenses granted under this Agreement, each Party shall have the right to use, and grant licenses to use, any Joint Invention and Joint Patent without the other Party's consent and shall have no duty to account to the other Party for such use or license, and each Party hereby waives any right it may have under the laws of any country to require any such consent or accounting.

(c) Data. All Data generated in connection with development and regulatory activities performed by MannKind or United Therapeutics pursuant to this Agreement shall be owned by United Therapeutics. Notwithstanding the foregoing, MannKind shall have the right to use, make reference to and incorporate the Data in Regulatory Filings with Regulatory Authorities for products other than Product in accordance with Section 4.3(b).

9.2 Patent Prosecution and Maintenance.

(a) MannKind Patents.

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

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

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

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

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

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

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

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

(iii) Option of United Therapeutics to Prosecute and Maintain. In the event that MannKind desires to abandon or cease prosecution or maintenance of any MannKind Patent in the Territory under which United Therapeutics then has a license under this Agreement, MannKind shall provide reasonable prior written notice to United Therapeutics of such intention to abandon (which notice shall, to the extent possible, be given no later than 90 days prior to the next deadline for any action that must be taken with respect to any such MannKind Patent in the relevant patent office). In such case, MannKind shall permit United Therapeutics, at United Therapeutics' sole discretion, to continue prosecution and maintenance of such MannKind Patent in the Territory, in MannKind's name and at United Therapeutics' own expense and United Therapeutics shall provide to MannKind the rights and information described in Sections 9.2(a)(ii)(A) through (F) with respect to such MannKind Patents.

(b) United Therapeutics Patents. United Therapeutics shall be responsible, in its discretion, for the preparation, filing, prosecution and maintenance of United Therapeutics Patents (including the right to conduct any interferences, oppositions, or reexaminations thereon

and to request any reissues or patent term extensions thereof), at United Therapeutics' sole expense.

(c) Joint Patents.

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

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

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

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

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

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

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

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

(iii) Option of Other Party to Prosecute, Maintain and Enforce. In the event that the Party that is the Joint Patent Lead desires to abandon or cease prosecution or maintenance of any Joint Patent for which it is responsible, such Party shall provide reasonable prior written notice to the other Party of such intention to abandon (which notice shall, to the extent possible, be given no later than 90 days prior to the next deadline for any action that must be taken with respect to such Joint Patent in the relevant patent office and, in any case, shall be prior to abandonment). In such case, at the other Party's sole discretion, upon written notice from such other Party, such other Party may elect to continue prosecution and maintenance of any such Joint Patent at its own expense, and the Party that elected to abandon or cease prosecution or maintenance of such Joint Patent shall execute such documents and perform such acts, at its own expense, as may be reasonably necessary to effect an assignment of such Party's entire right, title, and interest in and to such Joint Patent to the other Party. Any such assignment shall be completed in a timely manner to allow such other Party to continue prosecution and maintenance of any such Joint Patent. Any Patents so assigned shall no longer be considered Joint Patents.

9.3 Infringement by Third Parties.

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

(b) MannKind Patents and Joint Patents.

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

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

(iii) If United Therapeutics fails to bring an action or proceeding that it has the right to bring and control under pursuant to Section 9.3(b)(ii) with respect to infringement that is commercially significant Competing Activity in the Territory within (A) 90 days following the notice of alleged infringement or (B) 10 days before the time limit, if any, set

forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, MannKind shall have the right (but not the obligation) to bring and control any such action at its own expense and by counsel of its own choice, and United Therapeutics shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

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

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

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

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

9.5 Consent for Settlement. Neither Party shall enter into any settlement or compromise of any action or proceeding under this Article 9 which would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement without the prior written consent of such other Party, which consent shall not be unreasonably withheld.

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

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

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

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

ARTICLE 10

REPRESENTATIONS, WARRANTIES AND COVENANTS

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

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

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

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

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

(e) Employee/Contractor Agreements. All of such Party's and its Affiliates' employees or contractors acting on its behalf pursuant to this Agreement are and will be obligated under a binding written agreement to assign to such Party or its designee all Inventions and to comply with obligations of confidentiality and non-use consistent in scope with those set forth in Article 8.

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

10.2 Representations and Warranties of MannKind. MannKind represents and warrants to United Therapeutics that, as of the Execution Date and as of the Effective Date:

(a) Scope of License.

(i) MannKind has delivered to United Therapeutics a list of MannKind Patents existing as of such date under separate cover (the "***Existing Patents***"), which list (A) is a true and complete list of all Patents Controlled by MannKind or its Affiliates as of such date that that claim or disclose Product or its components, or are necessary or reasonably useful for the development, manufacture, use, import, offer for sale, or sale of Product in the Field in the Territory, including all such Patents claiming or covering the design or utility of a Device or a Formulation, and (B) indicates the current status, date and country of filing and issuance. All official fees, maintenance fees and annuities for the MannKind Patents have been paid through such date.

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

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

(iv) Neither MannKind nor any of its Affiliates has previously entered into any agreement, whether written or oral, with respect to the assignment, transfer, license,

conveyance or encumbrance of, or otherwise assigned, transferred, licensed, conveyed or encumbered its right, title, or interest in or to any Material Patent or Information (including by granting any covenant not to sue with respect thereto) that would otherwise be included in the MannKind Patents or MannKind Know-How but for such assignment, transfer, license, conveyance, or encumbrance. As used herein, "Material Patent or Information" means a Patent or item of Information which if not included in the MannKind Patents or MannKind Know-How, would be expected to have a material adverse effect on United Therapeutics' ability to develop or commercialize Product in the Field in the Territory in the manner currently conducted or proposed to be conducted.

(b) Patent Status. As of the Effective Date, (i) all issued MannKind Patents are in full force and effect and subsisting, and inventorship of each Patent is properly identified on such Patents; (ii) none of the MannKind Patents is currently involved in any interference, reissue, reexamination, or opposition proceeding; and (iii) neither MannKind nor any of its Affiliates has received any written notice from any Person, or has knowledge, of such actual or threatened proceeding.

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

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

(e) No Action or Claim. As of the Effective Date, there are no actual, pending, or alleged or threatened in writing, adverse actions, suits, claims, interferences or formal governmental investigations by or against MannKind or any of its Affiliates in or before any court, Governmental Authority involving any MannKind Know-How, MannKind Patents or Product, including in connection with the conduct of any clinical trials or manufacturing activities. As of the Effective Date, there are no material unsatisfied judgments or outstanding orders, injunctions, decrees, stipulations or awards (whether rendered by a court, an administrative agency or by an arbitrator) against MannKind with respect to any MannKind Know-How, MannKind Patents or Product.

(f) No Governmental Funding. As of the Effective Date: (i) none of the inventions claimed in the MannKind Patents has been conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by any

Governmental Authority, and (ii) the inventions claimed in the MannKind Patents are not a "subject invention" as that term is described in 35 U.S.C. Section 201(f).

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

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

(i) Regulatory Information.

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

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

(j) During the time period between the Execution Date and the Effective Date, MannKind shall promptly inform United Therapeutics in writing if MannKind or any of its Affiliates becomes aware that the representations and warranties made by MannKind pursuant to

Sections 10.1 and 10.2 as of the Execution Date are not true and correct in any material respects on and as of the Effective Date as though made on and as of the Effective Date.

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

10.4 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, OR ANY OTHER AGREEMENT CONTEMPLATED HEREUNDER, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT, VALIDITY AND ENFORCEABILITY OF PATENTS, OR THE PROSPECTS OR LIKELIHOOD OF DEVELOPMENT OR COMMERCIAL SUCCESS OF PRODUCT. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE EXPRESSLY EXCLUDED. WITHOUT LIMITING THE FOREGOING, AND WITHOUT LIMITING THE EXPRESS COVENANTS OF THE PARTIES SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION, WARRANTY OR COVENANT, EITHER EXPRESS OR IMPLIED, THAT (A) IT WILL SUCCESSFULLY DEVELOP, MANUFACTURE, COMMERCIALIZE OR CONTINUE TO DEVELOP, MANUFACTURE OR COMMERCIALIZE ANY PRODUCT IN ANY COUNTRY, OR (B) IF COMMERCIALIZED, ANY PRODUCT WILL ACHIEVE ANY PARTICULAR SALES LEVEL, WHETHER IN ANY INDIVIDUAL COUNTRY OR CUMULATIVELY THROUGHOUT THE TERRITORY.

ARTICLE 11

INDEMNIFICATION

11.1 Indemnification of MannKind. United Therapeutics shall indemnify and hold harmless each of MannKind and its Affiliates and the directors, officers, shareholders and employees of such entities and the successors and assigns of any of the foregoing (the "***MannKind Indemnitees***"), from and against any and all losses, liabilities, damages, penalties, fines, costs and expenses (including, reasonable attorneys' fees and other expenses of litigation) ("***Losses***") from any claims, actions, suits or proceedings brought by a Third Party (a "***Third Party Claims***") incurred by any MannKind Indemnitee, arising from, or occurring as a result of: (a) the development, manufacture, use, handling, storage, sale, other disposition, marketing, promotion or commercialization of Product by United Therapeutics or its Affiliates as contemplated by this Agreement; (b) gross negligence or willful misconduct of United Therapeutics or its Affiliates and (c) any material breach of any representations, warranties or covenants by United Therapeutics under Article 10 or Section 4.9 of this Agreement; except to the extent such Third Party Claims fall within the scope of the indemnification obligations of MannKind set forth in Section 11.2.

11.2 Indemnification of United Therapeutics. MannKind shall indemnify and hold harmless each of United Therapeutics and its Affiliates and the directors, officers, shareholders and employees of such entities, and the successors and assigns of any of the foregoing (the

"***United Therapeutics Indemnitees***"), from and against any and all Losses from any Third Party Claims incurred by any United Therapeutics Indemnitee, arising from, or occurring as a result of: (a) the development of Product by MannKind or its Affiliates prior to the Effective Date or during the Development Term as contemplated by this Agreement; (b) gross negligence or willful misconduct of MannKind or its Affiliates; (c) any material breach of any representations, warranties or covenants by MannKind under Article 10 or Section 4.9 of this Agreement; and (d) the Specified Matters, except to the extent such Third Party Claims (excluding Third Party Claims in relation to the Specified Matters) falls within the scope of the indemnification obligations of United Therapeutics set forth in Section 11.1.

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

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

ARTICLE 12
TERM AND TERMINATION

12.1 Term. This Agreement shall commence on the Effective Date, and unless terminated earlier as provided in this Article 12, shall continue in full force and effect until terminated pursuant to Section 12.2, 12.3, 12.4 or 12.5 (the "***Term***").

12.2 Termination by the Parties. The Parties may terminate this Agreement in its entirety before the end of the Term as follows:

(a) by mutual written agreement of the Parties;

(b) upon written notice by a Party to the other Party if such other Party is in material breach of this Agreement and has not cured such breach within 90 days (10 days with respect to failure to pay any undisputed payment) after written notice from the terminating Party describing the breach and requesting that it be cured. Any such termination shall become effective at the end of such 90 day (10 day with respect to failure to pay any undisputed payment) period unless (i) the breaching Party has cured any such breach or default prior to the end of such period, or (ii) the Party alleged to be in breach of this Agreement disputes such breach within such ninety (90) day period, in which case the non-breaching Party shall not have the right to terminate this Agreement unless it has been determined by a court of competent jurisdiction pursuant to Article 14 that this Agreement was materially breached, and the

breaching Party fails to comply with its obligations hereunder within ninety (90) days after such determination; or

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

12.3 Additional United Therapeutics Termination Rights.

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

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

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

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

ARTICLE 13

EFFECT OF TERMINATION

13.1 Accrued Obligations. The expiration or termination of this Agreement, in whole or part, for any reason shall not release either Party from any liability or deprive either Party of any right which, at the time of such expiration or termination, has already accrued to such Party or which is attributable to a period prior to such expiration or termination, nor will any expiration

or termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement.

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

(a) Wind-down Period.

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

(ii) Commercialization. United Therapeutics and its Affiliates shall continue, to the extent that United Therapeutics and its Affiliates continue to have stocks of usable Product, to fulfill orders received from customers for Product in the Field in the Territory until up to 180 days after the effective date of termination. For clarity, United Therapeutics shall have no obligation to continue to market and promote the Product after the termination is effective. For Product sold by United Therapeutics after the effective date of a termination (i.e., after the expiration of the applicable termination notice period), United Therapeutics shall continue to pay royalties on Net Sales pursuant to Section 6.3. Notwithstanding the foregoing, United Therapeutics and its Affiliates shall cease such activities in the Territory upon 60 days written notice given by MannKind at any time after the effective date of a termination requesting that such activities (or portion thereof) cease. In the case of a termination of this Agreement in its entirety, within 30 days after MannKind has given notice to United Therapeutics requesting the cessation of activities pursuant to the provision of this Section, United Therapeutics shall notify MannKind of an estimate of the quantity of Product and its shelf life remaining in United Therapeutics' inventory and MannKind shall have the right to purchase any such quantities of Product from United Therapeutics at a price mutually agreed by the Parties. To the extent MannKind does not purchase such quantities, United Therapeutics may sell such quantities during the 180 days after the effective date of such termination within the shelf life remaining for Product.

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

(c) Transition. The Parties shall negotiate in good faith a written transition agreement pursuant to which the Parties would effectuate this Section 13.2 to coordinate the transition of relevant obligations and rights to MannKind as necessary to develop, manufacture and commercialize Product in the Territory to ensure no interruption of therapy or coverage for patients, including promptly submitting all necessary filings with Governmental Authorities. United Therapeutics shall use its reasonable efforts to cooperate with MannKind or its designee to effect a smooth and orderly transition in the development, manufacturing, sale and marketing, promotion and commercialization of Product in the Territory during the notice and the Wind-down Period. Without limiting the foregoing, United Therapeutics shall use its reasonable efforts to conduct, in an expeditious manner, any activities to be conducted under this Section 13.2. MannKind shall use diligent efforts to identify and finalize an agreement or other arrangement with a Third Party in relation to Product or, to the extent MannKind is able to take over such activities under Applicable Laws, take over, directly or through an Affiliate, all activities related to Product in the Territory, and in particular development activities on-going at the time of the effective date of the termination and the transfer of the Regulatory Filings (including the Data incorporated therein and Marketing Approvals) into the name of MannKind or MannKind's designee so that the Wind-down Period will be as limited as possible. On terms to be further clarified in the written transition agreement, United Therapeutics shall use its reasonable efforts to (i) supply API to MannKind until MannKind can establish and qualify a new supplier of API and (ii) maintain its Government Health Care Program Contracts for the Product bearing the United Therapeutics National Drug Codes ("***NDCs***") during the Wind-down Period, provided that in no event shall United Therapeutics be obligated to supply API to MannKind for a period longer than six months from the date notice of termination was given. Reasonably in advance of the date upon which MannKind or its designee begins commercialization of the Product, the Parties shall coordinate to permit MannKind to establish such agreements, and United Therapeutics shall provide to MannKind (or its designee) all information reasonably necessary to allow MannKind to report government pricing and comply with Applicable Laws. During the Wind-down Period, United Therapeutics shall work with MannKind and the applicable Government Health Care Programs to transition the Product from United Therapeutics' Government Health Care Program Contracts for the Product bearing the United Therapeutics NDC to MannKind's Government Health Care Program Contracts for the Product bearing the MannKind NDC (or the NDC of MannKind's designee) as necessary. The transition agreement shall further clarify the Parties' respective financial obligations as to allocation of any rebates, chargebacks, or Branded Prescription Drug Fees accrued with respect to Product sold or dispensed during the Wind-down Period (provided, however, that United Therapeutics shall remain solely liable for such payments as may be accrued, but not yet paid, as of the effective date of termination or expiration of this Agreement).

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

(e) Continuing Payment Obligations. Any Product sold or disposed of by United Therapeutics and its Affiliates, in accordance with this Section 13.2 shall be subject to the applicable payment obligations under Article 6.

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

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

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

(i) The Parties shall work together in good faith to adopt, and United Therapeutics shall have the final decision-making authority with respect to, a plan to wind-down the development activities in an orderly fashion, with due regard for patient safety and the rights of any subjects that are participants in any clinical trials of Product and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all Applicable Laws. United Therapeutics shall provide to MannKind (or its designee) all information reasonably necessary to allow MannKind to report government pricing and comply with Applicable Law. During the wind-down period, United Therapeutics shall work with MannKind and the applicable Government Health Care Programs to transition the Product from United Therapeutics' Government Health Care Program Contracts for the Product bearing the United Therapeutics NDC to MannKind's Government Health Care Program Contracts for the Product bearing the MannKind NDC (or the NDC of MannKind's designee) as necessary. The wind-down plan shall further clarify the Parties' respective financial obligations as to allocation of any rebates, chargebacks, or Branded Prescription Drug Fees accrued with respect to Product sold or dispensed during the Wind-down Period (provided, however, that United Therapeutics shall remain solely liable for such payments as may be accrued, but not yet paid, as of the effective date of termination of this Agreement);

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

(iii) All costs and expenses incurred from the effective date of the termination notice in winding-down the development activities with respect to the applicable Product shall be borne by MannKind; *provided, however,* that in no case shall MannKind be

obligated to pursue or support such activities for a period exceeding 6 months after the date of notice of such termination.

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

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

(d) Termination Assistance. United Therapeutics and its Affiliates may continue to sell its inventory of Product in the Territory for up to 12 months after the effective date of the termination or offer MannKind to purchase the inventories of Product at a price mutually agreed by the Parties. MannKind may to the extent permitted by the applicable Third Party, assume such supply or distribution agreement. MannKind shall provide such other assistance, at no cost to United Therapeutics, as may be reasonably necessary or useful for United Therapeutics to terminate the development or commercialization of the applicable Product in the applicable countries of the Territory.

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

13.4 Rights Upon Bankruptcy. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction in the Territory or where a Party is situated (collectively, the **"Bankruptcy Laws"**), licenses of rights to "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided in such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided in the Bankruptcy Laws and the other Party elects to retain its rights hereunder as provided in the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a Title 11 trustee), shall provide to the other Party copies of all Information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws.

13.5 Return of Confidential Information. Upon termination or expiration of this Agreement, except to the extent that a Party retains a license from the other Party as contemplated by this Article 13, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only subject to a continuing confidentiality obligations.

13.6 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any rights or obligation accruing prior to such expiration or termination. In addition, upon expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall terminate, except those described in the following Articles and Sections: Sections 2.3 (last sentence only); 6.4(b) (for a period of up to three (3) years from the end of the Calendar Quarter in which termination occurs, but in any event not more than (3) years from the end of the Calendar Quarter in which the last Quarterly Report was submitted); 7.6 (for a period of three (3) years from end of the Calendar Quarter in which termination or expiration occurs); 9.1; 9.3(b), 9.3(d) and 9.5 (in each case with respect to any infringement action being prosecuted as of the effective date of termination); 10.4; and 11.1 – 11.3, and Articles 1, 8, 12, 13 (and sections referenced therein), 14 and 15.

ARTICLE 14

DISPUTE RESOLUTION AND GOVERNING LAW

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

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

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

14.4 Governing Law. This Agreement, and all questions regarding the existence, validity, interpretation, breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law.

ARTICLE 15

GENERAL PROVISIONS

15.1 Intervening Events. If the performance of any part of this Agreement by either Party (other than making payment when due) is prevented, restricted, interfered with or delayed by any reason or cause beyond the reasonable control of such Party (including: fire, flood, embargo, power shortage or failure, acts of war, insurrection, riot, terrorism, strike, lockout or other labor disturbance, acts of God or any acts, omissions or delays in acting of the other Party) (an "***Intervening Event***"), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such Intervening Event, provided that the affected Party shall use its substantial efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. If either Party becomes aware that such an Intervening Event has occurred, is imminent or likely, it will immediately notify the other Party. The Party which is subject to such Intervening Event shall exert all reasonable efforts to overcome it. Such Party will keep the other informed as to the progress of overcoming such Intervening Event.

15.2 Waiver of Breach. The failure of either Party at any time or times to require performance of any provision of this Agreement shall in no manner affect its rights at a later time to enforce such rights. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

15.3 Performance by Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligation. Either Party may use one or more of its Affiliates to perform its obligation hereunder, provided that the Parties will remain liable hereunder for the prompt payment and performance of all their respective obligations hereunder.

15.4 Modification. No amendment or modification of any provision of this Agreement shall be effective unless in a prior writing signed by both Parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by both Parties hereto.

15.5 Severability. In the event any provision of this Agreement should be held invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate, in good faith and enter into a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties. All other provisions of this Agreement shall remain in full force and effect in such jurisdiction. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

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

15.7 Language. The language of this Agreement and all activities to be pursued under this Agreement is English. Any and all documents proffered by one Party to the other in fulfillment of any provision of this Agreement shall only be in compliance if in English. Any translation of this Agreement in another language shall be deemed for convenience only and shall never prevail over the original English version. This Agreement is established in the English language.

15.8 Notices. Any notice or communication required or permitted under this Agreement shall be in writing in the English language, delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by internationally-recognized courier or sent by registered or certified mail, postage prepaid to the following addresses of the Parties (or such other address for a Party as may be at any time thereafter specified by like notice):

To MannKind:

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

To United Therapeutics:

United Therapeutics Corporation
1040 Spring Street, Silver Spring,
Maryland 20910
Telephone:202-483-7000
Facsimile: 202-483-4005
Attention: General Counsel

with a copy to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
Telephone: (858) 550-6000
Facsimile: (858) 550-6420
Attention: L. Kay Chandler, Esq.

with a copy to:

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

Any such notice shall be deemed to have been given: (a) when delivered if personally delivered; (b) on the next Business Day after dispatch if sent by confirmed facsimile or by internationally-recognized overnight courier; and/or (c) on the third Business Day following the date of mailing if sent by mail or nationally recognized courier. Notices hereunder will not be deemed sufficient if provided only between or among each Party's representatives on the ESC.

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

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

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

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

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

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

15.11 Assignment. This Agreement shall not be assignable or otherwise transferred, nor may any right or obligations hereunder be assigned or transferred, by either Party to any Third Party without the prior written consent of the other Party; except either Party may assign or otherwise transfer this Agreement (including, for clarity, with respect to the Option) without the consent of the other Party to an entity that acquires all or substantially all of the business or assets of the assigning Party relating to the subject matter of this Agreement, whether by merger, acquisition or otherwise. In addition, either Party shall have the right to assign this Agreement to an Affiliate upon written notice to the non-assigning Party; *provided, however,* the assigning Party hereby guarantees the performance of this Agreement by such Affiliate. Subject to the foregoing, this Agreement shall inure to the benefit of each Party, its successors and permitted assigns. Any assignment of this Agreement in contravention of this Section 15.11 shall be null and void.

15.12 No Partnership or Joint Venture. Nothing in this Agreement or any action which may be taken pursuant to its terms is intended, or shall be deemed, to establish a joint venture or partnership between United Therapeutics and MannKind. Neither Party to this Agreement shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party.

15.13 Interpretation. The captions to the several Articles and Sections of this Agreement are not a part of this Agreement but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) the word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction are mutually exclusive; (c) the words "herein," "hereof" and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Article or Section or other subdivision; (d) references in this Agreement to "days" shall mean calendar days; (e) the singular shall include the plural and vice versa; and (f) masculine, feminine and neuter pronouns and expressions shall be interchangeable. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP consistently applied, but only to the extent consistent with its usage and the other definitions in this Agreement.

15.14 Counterparts; Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

15.15 Limitation of Liability. EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 8, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE OR RIGHT GRANTED HEREUNDER; *provided, however,* that this Section 15.15 shall not be construed to limit either Party's indemnification obligations with respect to Third Party Claims under Article 11.

15.16 Antitrust Filings. Each of MannKind and United Therapeutics shall use its reasonable best efforts to (i) file, as soon as practicable after the date of this Agreement, all notices, reports and other documents required to be filed by such Party, pursuant to the Antitrust Laws, with any Governmental Authority (the "***Filings***") with respect to this Agreement and the transactions contemplated hereby, (ii) submit promptly any additional information requested by any such Governmental Authority, and (iii) obtain termination or expiration of the waiting period under the HSR Act and those associated with any other of the Filings which the parties reasonably conclude must be obtained prior to making the rights and obligations of this Agreement effective, and (iv) prevent the entry in any action brought by a Governmental Authority or any other Person that would prohibit, make unlawful or delay the making of the rights and obligations of this Agreement effective. Without limiting the generality of the foregoing, each of MannKind and United Therapeutics agrees to prepare and make appropriate filings under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder (the "***HSR Act***") relating to this Agreement and the transactions contemplated hereby as soon as reasonably practicable, but in any event within 15 Business Days after the Execution Date unless otherwise agreed to in writing by the parties (the "***HSR Filing Date***"). The Parties will notify each other promptly of any oral communication with, and provide copies of written communications with, any Governmental Authority in connection with any filings made pursuant to this Section 15.16. Each Party shall cooperate reasonably with the other Party in connection with any such filing (including, to the extent permitted by Applicable Laws, providing copies of all such documents to the non-filing Party prior to filing and considering all reasonable additions, deletions or changes suggested in connection therewith) and in connection with resolving any investigation or other inquiry of any Governmental Authority under any Antitrust Laws with respect to any such filing. No Party hereto shall independently participate in any meeting, teleconference, or other written or oral communication with any Governmental Authority in respect of any such filing, investigation or other inquiry without giving the other Party prior notice of the meeting and, to the extent permitted by such Governmental Authority, the opportunity to attend and/or participate. To the extent permitted by Applicable Laws, and subject to all applicable privileges (including the attorney client privilege), each Party shall consult and cooperate reasonably with the other Party, and shall consider in good faith the views of each other, in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, opinions and proposals made or submitted by or on behalf of any Party hereto in connection with proceedings under or relating to the HSR Act or other Antitrust Laws. Each Party may, as it deems advisable and necessary, reasonably designate any competitively sensitive material provided to the other Parties under this paragraph as "outside counsel only." Such materials and the information contained therein shall be given only to the outside legal counsel of the recipient and will not be disclosed by such outside legal counsel to employees, officers, or directors of the recipient, unless express written

permission is obtained in advance from the source of the materials. United Therapeutics will pay all fees, payable to any Governmental Authority, associated with Filings. Other than the provisions of this Section 15.16, the rights and obligations of the Parties under this Agreement shall not become effective until the waiting period provided by the HSR Act, and those associated with any other of the Filings which the Parties reasonably conclude must be obtained prior to making the rights and obligations of this Agreement effective, shall have terminated or expired (the date of such termination or expiration shall be the "***Effective Date***" of this Agreement). On the Effective Date, MannKind shall deliver to United Therapeutics a written certification (the "***Closing Certificate***") from an officer of MannKind that MannKind's representations and warranties in Article 10 are accurate in all material respects as of the date of the Effective Date. Upon the occurrence of the Effective Date, all provisions of this Agreement shall become effective automatically without the need for further action by the Parties. In the event that any such clearance associated with the Filings is not obtained within [***] days after the Execution Date (or such later date as agreed in writing by the Parties), this Agreement may be terminated by either Party. Notwithstanding anything to the contrary contained in this Agreement and in this Section 15.16, nothing in this Agreement shall require United Therapeutics or its Subsidiaries to agree or propose to (i) sell, hold separate, license or otherwise dispose of any assets or conduct their business in a specified manner, (ii) permit or agree to the sale, holding separate, licensing or other disposition of, any assets of MannKind, or (iii) take or refrain from taking any action that would result in any modification, amendment, or change to this Agreement. Notwithstanding anything to the contrary contained in this Agreement, if the Effective Date does not occur United Therapeutics shall reimburse MannKind for [***] percent ([***]%) of all reasonable and documented out-of-pocket fees, costs, and expenses incurred by MannKind in connection with this Section 15.16 after the Execution Date, up to a maximum reimbursement amount of $[***] in the aggregate.

ARTICLE 16

COMPLIANCE WITH LAW

16.1 Export Laws. Notwithstanding anything to the contrary contained herein, all obligations of MannKind and United Therapeutics are subject to prior compliance with export and import regulations and such other laws and regulations in effect in such jurisdictions or any other relevant country as may be applicable, and to obtaining all necessary approvals required by the applicable agencies of the governments of any relevant countries. MannKind and United Therapeutics shall cooperate with each other and shall provide assistance to the other as reasonably necessary to obtain any required approvals.

16.2 Securities Laws. Each of the Parties acknowledges that it is aware that the securities laws of the United States and the securities laws of other countries prohibit any person who has material non-public information about a publicly listed company from purchasing or selling securities of such company or from communicating such information to any person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell such securities. Each Party agrees to comply with such securities laws make its Affiliates, employees and agents aware of the existence of such securities laws and their need to comply with such laws.

16.3 Certain Payments. Each of the Parties acknowledges that it is aware that the United States and other countries have stringent laws which prohibit persons directly or indirectly to make unlawful payments to, and for the benefit of, government officials and related parties to secure approvals or permission for their activities. Each Party agrees that it will make no such prohibited payments, it will not indirectly make or have made such payments and it will

make its Affiliates, employees and agents aware of the existence of such laws and their need to comply with such laws.

16.4 Conduct of Activities. As to all matters contained in this Agreement, each Party shall conduct the activities allocated to it in compliance in all material respects with all Applicable Laws and in accordance with generally accepted scientific standards, good clinical and manufacturing practices and applicable industry ethical codes, applicable under the laws and regulations of the country in which such activities are conducted or of the country in which a Regulatory Filing is made. Without limiting the foregoing, each Party agrees as follows:

(a) In the performance of its obligations under this Agreement, such Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws, and shall obtain and maintain all licenses, permits, approvals and other authorizations applicable to it in order to enable it to perform its respective obligations hereunder.

(b) Such Party and, to its knowledge, its and its Affiliates' employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a Public Official or Entity or other Person for purpose of obtaining or retaining business for or with, or directing business to, any Person, including either Party (it being understood that such Party, and to its knowledge, its and its Affiliates' employees and contractors, has not directly or indirectly promised, offered or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a Public Official or Entity or any other person in connection with the performance of such Party's obligations under this Agreement, and shall not, directly or indirectly, engage in any of the foregoing).

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

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

(e) In connection with the performance of its obligations under this Agreement, such Party shall comply and shall cause its and its Affiliates' employees and

contractors to comply with such Party's own anti-corruption and anti-bribery policy, a copy of which has been provided or made available to the other Party.

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

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

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

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

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

[Signature Page Follows]

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

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

SECOND AMENDMENT
TO
SPECIALTY PHARMACY NETWORK AGREEMENT

This Second Amendment to Specialty Pharmacy Network Agreement (this "**Amendment**") is made as of the date the last Party executes this Amendment (the "**Amendment Effective Date**"), by and between Accredo Health Group, Inc. ("**Specialty Pharmacy**"), and United Therapeutics Corporation ("**UT**"). Specialty Pharmacy and UT are each referred to in this Agreement as a "**Party**," collectively, the "**Parties**."

WHEREAS, the Parties entered into that certain Specialty Pharmacy Network Agreement dated as of January 1, 2018, as may be amended (the "**Agreement**"); and

WHEREAS, the Parties entered into that certain Master Services Agreement dated December 18, 2013 as amended (the "**MSA**"); and

WHEREAS, the Parties now wish to amend the Agreement to include no charge TYVASO DPI training equipment as further described below.

NOW THEREFORE, in consideration of the mutual agreements and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. *Attachment A*. Attachment A of the Agreement is hereby deleted in its entirety and is replaced with the Attachment A attached to this Amendment.

2. *Attachment H.* A new Attachment H, BluHale® PRO Device and TYVASO DPI™ Demonstration Kit ("Training Equipment"), shall be added to the Agreement as a new Attachment H to the Agreement.

3. Except as amended and supplemented hereby, all of the terms and conditions of the Agreement shall remain and continue in full force and effect and apply hereto.

IN WITNESS WHEREOF, each of the undersigned, duly authorized, has executed this Amendment, effective as of the Amendment Effective Date.

Accredo Health Group, Inc.	**United Therapeutics Corporation**
By: /s/ Bill Martin	By: /s/ Kevin Gray
Print Name: Bill Martin	Print Name: Kevin Gray
Title: Chief Commercial Officer	Title: SVP Strategic Operations
Date: 06/08/2022 | 10:40 AM CDT	Date: 13-Jun-2022 | 5:30:09 PM EDT

EXHIBIT 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Martine Rothblatt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of United Therapeutics 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2022

/s/ MARTINE ROTHBLATT

By: Martine Rothblatt, Ph.D.

Title: *Chairperson and Chief Executive Officer*

(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, James C. Edgemond, certify that:

1. I have reviewed this quarterly report on Form 10-Q of United Therapeutics 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2022

/s/ JAMES C. EDGEMOND

By: James C. Edgemond

Title: *Chief Financial Officer and Treasurer*

(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended June 30, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Martine Rothblatt, Chairperson and Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 3, 2022

/s/ MARTINE ROTHBLATT

Martine Rothblatt, Ph.D.

Chairperson and Chief Executive Officer

(Principal Executive Officer)

United Therapeutics Corporation

THE FOREGOING CERTIFICATION IS BEING FURNISHED SOLELY PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 AND IS NOT BEING FILED AS PART OF THE FORM 10-Q OR AS A SEPARATE DISCLOSURE DOCUMENT.

A SIGNED ORIGINAL OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, OR OTHER DOCUMENT AUTHENTICATING, ACKNOWLEDGING, OR OTHERWISE ADOPTING THE SIGNATURE THAT APPEARS IN TYPED FORM WITHIN THE ELECTRONIC VERSION OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, HAS BEEN PROVIDED TO UNITED THERAPEUTICS CORPORATION AND WILL BE RETAINED BY UNITED THERAPEUTICS CORPORATION AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended June 30, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, James C. Edgemond, Chief Financial Officer and Treasurer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 3, 2022

/s/ JAMES C. EDGEMOND

James C. Edgemond

Chief Financial Officer and Treasurer

(Principal Financial and Accounting Officer)

United Therapeutics Corporation

THE FOREGOING CERTIFICATION IS BEING FURNISHED SOLELY PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 AND IS NOT BEING FILED AS PART OF THE FORM 10-Q OR AS A SEPARATE DISCLOSURE DOCUMENT.

A SIGNED ORIGINAL OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, OR OTHER DOCUMENT AUTHENTICATING, ACKNOWLEDGING, OR OTHERWISE ADOPTING THE SIGNATURE THAT APPEARS IN TYPED FORM WITHIN THE ELECTRONIC VERSION OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, HAS BEEN PROVIDED TO UNITED THERAPEUTICS CORPORATION AND WILL BE RETAINED BY UNITED THERAPEUTICS CORPORATION AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.