

MANNKIND CORP  
Form 10-Q  
November 01, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 30, 2018

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_ .

Commission file number: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

|                                 |                     |
|---------------------------------|---------------------|
| Delaware                        | 13-3607736          |
| (State or other jurisdiction of | (I.R.S. Employer    |
| incorporation or organization)  | Identification No.) |

30930 Russell Ranch Road, Suite 300

|  |            |
|--|------------|
| Westlake Village, California             | 91362      |
| (Address of principal executive offices) | (Zip Code) |

(818) 661-5000

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(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

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

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

As of October 22, 2018, there were 159,597,573 shares of the registrant's common stock, \$0.01 par value per share, outstanding.

MANKIND CORPORATION

Form 10-Q

For the Quarterly Period Ended September 30, 2018

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## PART 1: FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## MANKIND CORPORATION AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except per share data)

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

and 119,053,414 shares issued and outstanding at September 30, 2018 and

December 31, 2017, respectively

|   |              |              |
|---|--------------|--------------|
| Additional paid-in capital                  | 2,723,232    | 2,638,992    |
| Accumulated other comprehensive loss        | (18 )        | (18 )        |
| Accumulated deficit                         | (2,930,249 ) | (2,854,898 ) |
| Total stockholders' deficit                 | (205,441 )   | (214,732 )   |
| Total liabilities and stockholders' deficit | \$ 45,356    | \$ 84,575    |

See notes to condensed consolidated financial statements.

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## MANKIND CORPORATION AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

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

See notes to condensed consolidated financial statements.

MANKIND CORPORATION AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

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

See notes to condensed consolidated financial statements.

## MANKIND CORPORATION AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

Nine Months Ended  
September 30,  
2018      2017

| CASH FLOWS FROM OPERATING ACTIVITIES:   |            |            |
|---|------------|------------|
| Net loss  | \$(77,224) | \$(84,549) |
| Adjustments to reconcile net loss to net cash (used in) provided by operating activities: |            |            |
| Depreciation, amortization and accretion  | 2,489      | 2,707      |
| Stock-based compensation expense  | 5,715      | 3,763      |
| Loss on extinguishment of debt, net   | 765        | 830        |
| (Gain) Loss on sale, abandonment/disposal or impairment of property and equipment         | (10 )      | 179        |
| (Gain) Loss on foreign currency translation   | (3,107 )   | 12,077     |
| Gain on purchase commitments  | —          | (215 )     |
| Interest on note payable to related party   | 3,345      | 2,608      |
| Change in fair value of warrant liability   | —          | (5,488 )   |
| Write-off of inventory  | 1,792      | 1,793      |
| Other, net  | 106        | 44         |
| Changes in operating assets and liabilities:  |            |            |
| Accounts receivable, net  | (74 )      | (1,502 )   |
| Receivable from Sanofi  | —          | 30,557     |
| Inventory   | (1,920 )   | (2,591 )   |
| Deferred costs from commercial product sales  | —          | (234 )     |
| Prepaid expenses and other current assets   | (5 )       | 1,303      |
| Other assets  | 200        | 166        |
| Accounts payable  | (1,169 )   | 2,099      |
| Accrued expenses and other current liabilities  | 560        | 2,889      |
| Deferred revenue  | —          | (398 )     |
| Deferred payments from collaborations   | 11,983     | (187 )     |
| Recognized loss on purchase commitments   | (6,165 )   | (648 )     |
| Net cash used in operating activities   | (62,719)   | (34,797)   |
| CASH FLOWS FROM INVESTING ACTIVITIES:   |            |            |
| Net proceeds from sale of asset held for sale   | —          | 16,651     |
| Proceeds from sale of property and equipment  | 10         | 24         |
| Net cash provided by investing activities   | 10         | 16,675     |
| CASH FLOWS FROM FINANCING ACTIVITIES:   |            |            |
| Proceeds from direct placement of common stock  | 28,000     | —          |
| Issuance cost associated with direct placement  | (1,610 )   | —          |
| Principal payments on facility financing obligation                                       | (2,000 )   | (4,000 )   |
| Borrowings on note payable to related party   | —          | 19,429     |
| Payment of employment taxes related to vested restricted stock units                      | (184 )     | (110 )     |
| Proceeds from issuance of common stock pursuant to at-the-market issuance                 | 819        | —          |
| Issuance cost of at-the-market transactions   | (33 )      | —          |



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|  |           |           |
|--|-----------|-----------|
| Proceeds from market price stock purchase plan                         | 335       | —         |
| Net cash provided by financing activities                              | 25,327    | 15,319    |
| NET DECREASE IN CASH AND CASH EQUIVALENTS AND                          |           |           |
| RESTRICTED CASH  | (37,382)  | (2,803 )  |
| CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF            |           |           |
| PERIOD   | 48,355    | 22,895    |
| CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD           | \$ 10,973 | \$ 20,092 |
| SUPPLEMENTAL CASH FLOWS DISCLOSURES:                                   |           |           |
| Interest paid in cash, net of amounts capitalized                      | \$2,895   | \$6,373   |
| NON-CASH INVESTING AND FINANCING ACTIVITIES:                           |           |           |
| Payment of note obligations through common stock issuance              | \$42,912  | \$11,000  |
| Payment of note payable to related party through common stock issuance | \$8,160   | \$—       |
| Capitalization of interest on note payable to related party            | \$—       | \$10,716  |
| Accrued but unpaid debt issuance costs                                 | \$146     | \$—       |
| Reclassification of warrant liability to Additional paid-in capital    | \$—       | \$1,893   |

See notes to condensed consolidated financial statements.

MANKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Description of Business and Significant Accounting Policies

The accompanying unaudited condensed consolidated financial statements of MannKind Corporation and its subsidiaries (“MannKind,” the “Company,” “we” or “us”), have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the “SEC”). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The information included in this quarterly report on Form 10-Q should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s annual report on Form 10-K for the fiscal year ended December 31, 2017 filed with the SEC on February 27, 2018 (the “Annual Report”).

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the three and nine months ended September 30, 2018 may not be indicative of the results that may be expected for the full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates or assumptions. Management considers many factors in selecting appropriate financial accounting policies, and in developing the estimates and assumptions that are used in the preparation of the financial statements. Management must apply significant judgment in this process. The more significant estimates reflected in these accompanying condensed consolidated financial statements include revenue recognition and gross-to-net adjustments, product return, assessing long-lived assets for impairment, clinical trial expenses, inventory costing and recoverability, recognized loss on purchase commitments, milestone rights liability, stock-based compensation and the determination of the provision for income taxes and corresponding deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Stock-Based Compensation — Share-based payments to employees, including grants of stock options, restricted stock units, performance-based awards and the compensatory elements of employee stock purchase plans, are recognized in the condensed consolidated statements of operations based upon the fair value of the awards at the grant date subject to an estimated forfeiture rate. The Company uses the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options and the compensatory elements of employee stock purchase plans. Restricted stock units are valued based on the market price on the grant date. The Company evaluates stock awards with performance conditions as to the probability that the performance conditions will be met and estimates the date at which the performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period.

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

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

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

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

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

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

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

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

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

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

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

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

Condensed Consolidated Balance Sheet

For the nine months ended September 30, 2018  
Balances without

adoption of Topic

As  
Reported Adjustments 606

Assets



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|  |               |             |                 |
|--|---------------|-------------|-----------------|
| Accounts receivable, net                       | \$2,752       | \$ 417      | \$ 3,169        |
| Deferred costs from commercial product sales   | —             | 763         | 763             |
| <b>Liabilities</b>                             |               |             |                 |
| Accrued expenses and other current liabilities |               |             |                 |
|  | \$13,434      | \$ (588 )   | \$ 12,846       |
| Deferred revenue, net                          | —             | 3,601       | 3,601           |
| <b>Equity</b>                                  |               |             |                 |
| Accumulated deficit                            | \$(2,930,249) | \$ (1,833 ) | \$( 2,932,082 ) |

Condensed Consolidated Statement of

Operations

For the nine months ended September 30, 2018

Balances without

adoption of Topic

As

Reported

Adjustments

606

|  |           |           |           |
|--|-----------|-----------|-----------|
| <b>Revenue</b>                         |           |           |           |
| Net revenue - commercial product sales | \$11,542  | \$ (778 ) | \$ 10,764 |
| <b>Expenses</b>                        |           |           |           |
| Cost of goods sold                     | \$14,406  | \$ (975 ) | \$ 13,431 |
| Net loss                               | (77,224 ) | (196 )    | (77,420 ) |

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

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

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

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires that all leasees recognize the assets and liabilities that arise from operating leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the

underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The new standard will be effective on January 1, 2019 and will result in an increase of assets and liabilities of approximately \$6.0 million.

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

## 2. Accounts Receivable

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

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

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

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

### 3. Inventories

Inventories consist of the following (in thousands):

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

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

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

### 4. Property and Equipment

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

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

|                                   |           |           |
|-----------------------------------|-----------|-----------|
| Total property and equipment, net | \$ 25,632 | \$ 26,922 |
|-----------------------------------|-----------|-----------|

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

|                      | For the Three<br>Months Ended<br>September 30,<br>2018 |        | For the Nine<br>Months Ended<br>September 30,<br>2017 |          |
|----------------------|--|--------|---|----------|
| Depreciation Expense | \$ 404   | \$ 454 | \$ 1,289  | \$ 1,350 |

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

## 5. Accrued Expenses and Other Current Liabilities

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

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

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

## 6. Related Party Arrangements

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

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

In October 2007, the Company entered into a loan arrangement (the “Mann Group Loan Arrangement”) with The Mann Group LLC (the “The Mann Group”), which has been amended from time to time. At that time, Alfred Mann, the Company’s then Chairman and Chief Executive Officer, was the managing member of The Mann Group LLC. On October 31, 2013, the promissory note underlying the Mann Group Loan Arrangement, described in the Company’s condensed consolidated balance sheets as Note Payable to Related Party, was amended to, among other things, extend the maturity date of the loan to January 5, 2020, extend the date through which the Company can borrow under the Mann Group Loan Arrangement to December 31, 2019, increase the aggregate borrowing amount under the Mann Group Loan Arrangement from \$350.0 million to \$370.0 million and provide that repayments or cancellations of principal under the Mann Group Loan Arrangement will not be available for reborrowing. At various times over the

years that the Mann Group Loan Arrangement has been outstanding, the Company and The Mann Group have agreed to exchange portions of the outstanding principal for shares of the Company's common stock.

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

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

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

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

Interest, at a fixed rate of 5.84%, is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as the Company and The Mann Group mutually agree. Under the agreement, accrued and unpaid interest may be paid-in-kind. The Mann Group can require the Company to prepay up to \$200.0 million in advances that have been outstanding for at least 12 months, less approximately \$113.2 million aggregate principal amount that has been cancelled in connection with three common stock purchase agreements. If The Mann Group exercises this right, the Company will have 90 days after The Mann Group provides written notice, or the number of days to maturity of the note if less than 90 days, to prepay such advances. However, pursuant to a letter agreement entered into in August 2010, The Mann Group has agreed to not require the Company to prepay amounts outstanding under the amended and restated promissory note if the prepayment would require the Company to use its working capital resources. In addition, The Mann Group entered into a subordination agreement with Deerfield pursuant to which The Mann Group agreed with Deerfield not to demand or accept any payment under the Mann Group Loan Arrangement until the Company's payment obligations to Deerfield under the Facility Agreement have been satisfied in full. Subject to the foregoing, in the event of a default under The Mann Group Loan Arrangement, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at The Mann Group's option, and the interest rate will increase to the one-year LIBOR calculated on the date of the initial advance or in effect on the date of default, whichever is greater, plus 5% per annum. All borrowings under the Mann Group Loan Arrangement are unsecured. The Mann Group Loan Arrangement contains no financial covenants.

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

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

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

|  | Three Months<br>Ended<br>September 30, | Nine Months<br>Ended<br>September 30, |
|--|--|---------------------------------------|
|  |  |                                       |



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|  | 2018  | 2017 | 2018   | 2017 |
|--|-------|------|--------|------|
| Amortization of debt premium           | \$ 59 | \$ — | \$ 125 | \$ — |
| Accretion expense - debt issuance cost | \$ 6  | \$ — | \$ 13  | \$ — |

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

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

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

## 7. Borrowings

Borrowings consist of the following (in thousands):

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

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

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

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

These borrowings are further described below:

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

On April 18, 2017, the Company entered into an Exchange Agreement with Deerfield pursuant to which the Company agreed to, among other things, (i) repay \$4.0 million principal amount under the Tranche B notes; (ii) exchange \$1.0 million principal amount under the Tranche B notes for 869,565 shares of the Company's common stock (the

“Tranche B Exchange Shares”); and (iii) exchange \$5.0 million principal amount under the 2019 notes for 4,347,826 shares of the Company’s common stock (together with the “Tranche B Exchange Shares,” the “April Exchange Shares”). The exchange price for the April Exchange Shares was at a discounted price of \$1.15 per share.

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

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

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

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

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

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

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

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

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

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

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

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

On June 8, 2018, the Company entered into an Exchange and Seventh Amendment to Facility Agreement with Deerfield, pursuant to which, among other things, (i) the Company issued to Deerfield 3,061,224 shares of the Company's common stock in exchange for the cancellation of (a) \$3.0 million of \$5.0 million principal amount of

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

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

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

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

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

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

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

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

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



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

The Milestone Agreement includes customary representations and warranties and covenants by the Company, including restrictions on transfers of intellectual property related to Afrezza. The Milestone Rights are subject to acceleration in the event the Company transfers its intellectual property related to Afrezza in violation of the terms of the Milestone Agreement. The Company has initially recorded the Milestone Rights at their estimated fair value.

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

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

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

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

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

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

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

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

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

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

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

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

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

## 8. Collaboration Arrangements

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

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

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

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

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

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

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

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

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

The additional payments referred to above represent variable consideration for which the Company has not recognized any revenue because it is uncertain that Receptor will be able to successfully develop, manufacture or sell product related to this license. Therefore, the receipt of such payments is highly susceptible to factors outside of the Company’s influence, the uncertainty regarding the receipt of these payments is not expected to be resolved for years, and the

Company has limited experience with similar contracts. There was no change to the accounting for this contract as a result of the initial application of the new revenue guidance. See Note 1 – Description of Business and Summary of Significant Accounting Policies for additional information on the Company’s revenue recognition accounting policy.

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

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

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

## 9. Sale of Intellectual Property

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

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

## 10. Fair Value of Financial Instruments

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

Cash Equivalents and restricted cash— Cash equivalents and restricted cash consist of highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase that are readily convertible into cash. As of September 30, 2018 and December 31, 2017, the Company held \$10.4 million and \$48.4 million, respectively, of cash equivalents. For the period ended September 30, 2018, restricted cash was held in an escrow account as well as used to collateralize a letter of credit. The Company held \$0.5 million and \$4.4 million in restricted cash as of September 30, 2018 and December 31, 2017, respectively. Both are comprised of money market funds. The fair value of these money market funds was determined by using quoted prices for identical investments in an active market (Level 1 in the fair value hierarchy).

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



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

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

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

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

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

#### 11. Stock-Based Compensation Expense

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

|                                 | Three Months<br>Ended<br>September 30,<br>2018 |          | Nine Months<br>Ended<br>September 30,<br>2017 |          |
|---------------------------------|--|----------|---|----------|
| <b>Stock-based compensation</b> | \$ 1,562                                       | \$ 1,247 | \$ 5,715                                      | \$ 3,763 |

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

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

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

## 12. Commitments and Contingencies

**Guarantees and Indemnifications** — In the ordinary course of its business, the Company makes certain indemnities, commitments and guarantees under which it may be required to make payments in relation to certain transactions. The Company, as permitted under Delaware law and in accordance with its Bylaws, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at the Company's request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, the Company has a director and officer insurance policy that may enable it to recover a portion of any future amounts paid. The Company believes the fair value of these indemnification agreements is minimal. The Company has not recorded any liability for these indemnities in the accompanying condensed consolidated balance sheets. However, the Company accrues for losses for any known contingent liability, including those that may arise from indemnification provisions, when future payment is probable and the amount can be reasonably estimated. No such losses have been recorded to date.

**Litigation** — The Company is subject to legal proceedings and claims which arise in the ordinary course of its business. As of September 30, 2018, the Company believes that the final disposition of such matters will not have a material adverse effect on the financial position, results of operations or cash flows of the Company and no accrual has been recorded. The Company maintains liability insurance coverage to protect the Company's assets from losses arising out of or involving activities associated with ongoing and normal business operations. The Company records a provision for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company's policy is to accrue for legal expenses in connection with legal proceedings and claims as they are incurred.

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

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

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

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

were reduced from \$5.3 million for the period October 1, 2016 through 2018 to \$3.4 million over the same period. As of September 30, 2018, the remaining annual purchase requirements under the contract are as follows:

|      |                        |
|------|------------------------|
| 2018 | <del>4.4</del> million |
| 2019 | <del>1.6</del> million |
| 2020 | <del>5.5</del> million |
| 2021 | <del>5.5</del> million |
| 2022 | <del>9.4</del> million |
| 2023 | <del>9.4</del> million |

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

Unless terminated earlier, the term of the Insulin Supply Agreement with Amphastar expires on December 31, 2023 and can be renewed for additional, successive two year terms upon 12 months' written notice given prior to the end of the initial term or any additional two year term. The Company and Amphastar each have normal and customary termination rights, including termination for material breach that is not cured within a specific time frame or in the event of liquidation, bankruptcy or insolvency of the other party. In addition, the Company may terminate the Insulin Supply Agreement upon two years' prior written notice to Amphastar without cause or upon 30 days' prior written notice to Amphastar if a controlling regulatory authority withdraws approval for Afrezza, provided, however, in the event of a termination pursuant to either of these two scenarios, the provisions of the Insulin Supply Agreement require the Company to pay the full amount of all unpaid purchase commitments due over the initial term within 60 calendar days of the effective date of such termination. On April 2, 2018, the Company entered into a foreign currency hedging transaction to mitigate its exposure to foreign currency exchange risks. The hedging transaction hedges against short-term currency fluctuations for the remaining current year purchase requirement amount of €4.4 million and is renewable every 90 days. In 2018, the Company realized a currency loss of approximately \$0.5 million in the second quarter of 2018 and \$0.1 million in the third quarter of 2018. These amounts are recorded in cost of goods sold.

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

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

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

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

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

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

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

Future minimum lease payments are as follows:

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

### 13. Income Taxes

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets and concluded, in accordance with the applicable accounting standards, that net deferred tax assets should be fully reserved.

The Company has assessed its position with regards to uncertainty in tax positions and believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to this guidance. Tax years since 2012 remain subject to examination by the major tax jurisdictions in which the Company is subject to tax.

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

### 14. Restructuring Charges

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

### 15. Subsequent Events

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

Pursuant to the Tenth Amendment to Facility Agreement with Deerfield, on October 18, 2018, the Company repaid Deerfield \$3.0 principal million amount of 2019 notes, which payment had previously been deferred until the earlier



of October 31, 2018 and the first business day following the Company's receipt of the \$45.0 million upfront payment from United Therapeutics.

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

Statements in this report that are not strictly historical in nature are “forward-looking statements” within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would,” and similar words. We intend to identify forward-looking statements, though not all forward-looking statements contain these identifying words. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in Part II, Item 1A Risk Factors and elsewhere in this quarterly report on Form 10-Q. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. The preceding interim condensed consolidated financial statements and this Management’s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and related notes for the year ended December 31, 2017 and Management’s Discussion and Analysis of Financial Condition and Results of Operations contained in the Annual Report. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

### OVERVIEW

We are a biopharmaceutical company focused on the development and commercialization of inhaled therapeutic products for patients with diseases such as diabetes and pulmonary arterial hypertension. According to the Centers for Disease Control and Prevention, 30 million people in the United States had diabetes in 2015. Globally, the International Diabetes Federation has estimated that approximately 425 million people had diabetes in 2017 and approximately 629 million people will have diabetes by 2045. Our only approved product, Afrezza (insulin human) Inhalation Powder was approved by the U.S. Food and Drug Administration (“FDA”) in June of 2014. Afrezza became available by prescription in United States retail pharmacies in February 2015.

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

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

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

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

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

Our business is subject to significant risks, including but not limited to our need to raise additional capital to fund our operations, our ability to successfully commercialize Afrezza and manufacture sufficient quantities of Afrezza and the risks inherent in our ongoing clinical trials and the regulatory approval process for our product candidates. Additional significant risks also include the results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

### CRITICAL ACCOUNTING POLICES

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

### RESULTS OF OPERATIONS

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

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

|   | Nine Months Ended September 30, |      |              |             |
|---|---------------------------------|------|--------------|-------------|
|   | 2018                            | 2017 | \$<br>Change | %<br>Change |
| Net revenue - commercial product sales: |                                 |      |              |             |

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

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

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

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

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

#### Expenses

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

#### Costs of Goods Sold

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

#### Research and Development Expenses

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

#### Selling Expenses

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

#### General and Administrative Expenses

Our general and administrative expenses include payroll, employee benefits and stock-based compensation expense, severance expense, and other headcount-related expenses associated with executives, finance, legal, facilities, human

resources and other administrative personnel, certain taxes, professional services, and legal and other administrative fees.

#### Gain or Loss on Foreign Currency Translation

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

## Other Income (Expense)

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

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

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

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

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

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

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

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

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

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

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

## LIQUIDITY AND CAPITAL RESOURCES

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

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

\$18.7 million principal amount of 2021 notes bearing interest at 5.75% per annum and maturing on October 23, 2021, which are convertible;

•The following amounts under the Facility Financing Obligation with Deerfield:

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

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

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

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

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

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

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

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

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

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

While we have been able to timely make our required interest payments to date, we cannot guarantee that we will be able to do so in the future. If we fail to pay interest on the 2021 notes and the Facility Financing Obligation or if we fail to repay or repurchase the 2021 notes, Facility Financing Obligation, or borrowings under The Mann Group Loan Arrangement, we will be in default under the applicable instrument for such indebtedness, and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the note holders initiating bankruptcy proceedings or causing us to cease operations altogether.

In connection with the execution of the Facility Agreement, on July 1, 2013, we issued Milestone Rights to the Milestone Purchasers. The Milestone Rights provide the Milestone Purchasers certain rights to receive payments of up to \$90.0 million, of which \$75.0 million remain payable, upon the occurrence of specified strategic and sales milestones, including the achievement of specified net sales figures. In addition, the Facility Agreement includes customary representations, warranties and covenants, including, a restriction on the incurrence of additional indebtedness, and a financial covenant which requires our cash and cash equivalents to be at least \$20.0 million as of October 31, 2018 and December 31, 2018 and \$25.0 million as of the end of each fiscal quarter after December 31, 2018. We have met the required conditions as of the specified dates. See Note 12 — Commitments and Contingencies and Note 7 — Borrowings for further information related to the Facility Agreement.

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

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

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

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

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

Future Liquidity Needs.



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

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

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

#### Off-Balance Sheet Arrangements

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

#### Contractual Obligations

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

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

#### Interest Rate Risk

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

The interest rate on amounts borrowed under The Mann Group Loan Arrangement is fixed at 5.84%. As of September 30, 2018, we also have debt related to the 2021 notes at a fixed interest rate of 5.75%, debt related to the 2019 notes at a fixed interest rate of 9.75% and debt related to the Tranche B notes at a fixed interest rate of 8.75%.

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

If a change in interest rates equal to 10% of the interest rates on September 30, 2018 were to have occurred, this change would not have had a material effect on the value of our short-term investment portfolio.

#### Foreign Currency Exchange Risk

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

### ITEM 4. CONTROLS AND PROCEDURES

#### Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of September 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, we have concluded, as of such date, that our disclosure controls and procedures were effective.

#### Changes in Internal Control over Financial Reporting

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

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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

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

#### Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this quarterly report on Form 10-Q before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this quarterly report. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. The risk factors set forth below marked with an asterisk (\*) did not appear as separate risk factors in, or contain changes to the similarly titled risk factors included in, Item 1A of the Annual Report. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.

#### RISKS RELATED TO OUR BUSINESS

We will need to raise additional capital to fund our operations, and there is substantial doubt about our ability to continue as a going concern.\*

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

- The degree to which Afrezza is commercially successful;
- The degree to which we are able to generate revenue from our Technosphere drug delivery platform;
- The costs of developing and commercializing Afrezza on our own in the United States, including the costs of expanding our commercialization capabilities;
- The costs of finding regional collaboration partners for the development and commercialization of Afrezza in foreign jurisdictions;
- The demand by any or all of the holders of our debt instruments to require us to repay or repurchase such debt securities if and when required;
- Our ability to repay or refinance existing indebtedness, and the extent to which our notes with conversion options or any other convertible debt securities we may issue are converted into or exchanged for shares of our common stock;

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- The rate of progress and costs of our clinical studies and research and development activities;
- The costs of procuring raw materials and operating our manufacturing facilities;
- Our obligation to make milestone payments pursuant to the Milestone Agreement;
- Our success in establishing strategic business collaborations or other sales or licensing of assets, and the timing and amount of any payments we might receive from any such transactions;
- Actions taken by the FDA and other regulatory authorities affecting Afrezza and our product candidates and competitive products;
- The emergence of competing technologies and products and other market developments;
  - The costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others;
- The level of our legal and litigation expenses; and
- The costs of discontinuing projects and technologies, and/or decommissioning existing facilities, if we undertake any such activities.

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

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will continue to be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and up to total loss of investment to our stockholders and other security holders. As of the date hereof, we have not obtained a solvency opinion or otherwise conducted a valuation of our properties to determine whether our debts exceed the fair value of our property within the meaning of applicable solvency laws. If we are or become insolvent, holders of our common stock or other securities may lose the entire value of their investment.

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

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

We have expended significant time, money and effort in the development of our only approved product, Afrezza. We anticipate that in the near term our prospects and ability to generate significant revenues will heavily depend on our ability to successfully commercialize Afrezza in the United States. In addition, we anticipate that revenues from our existing or future licensing arrangements for our Technosphere platform technology that involve license, milestone, royalty or other payments to us will depend on our ability to achieve the performance obligations specified in such arrangements.



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

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

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

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

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

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

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

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

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

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

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

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

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

We have sought to develop our product candidates through our internal research programs. All of our product candidates will require additional research and development and, in some cases, significant preclinical, clinical and other testing prior to seeking regulatory approval to market them. Accordingly, these product candidates will not be commercially available for a number of years, if at all. Further research and development on these programs will require significant financial resources. Given our limited financial resources and our focus on development and commercialization of Afrezza, we will not be able to advance these programs unless we are able to enter into collaborations with third parties to fund these programs or to obtain funding to enable us to continue these programs.

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

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

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

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

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

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

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

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

\$71.5 million principal amount of indebtedness under The Mann Group Loan Arrangement maturing on January 5, 2020, bearing interest at a fixed rate of 5.84% per annum compound quarterly payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, except that the lender has agreed to defer interest payments until July 1, 2018 unless otherwise permitted under the subordination agreement with Deerfield, and such interest payments are subject to additional deferral beyond July 1, 2018 until our payment obligations to Deerfield have been satisfied in full.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the terms of our indebtedness when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2021 notes, or certain Major Transactions as defined in the Facility Agreement in respect of the 2019 Notes and the Tranche B notes, the holders of the respective debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. While we have been able to timely make our required interest payments to date, we cannot guarantee that we will be able to do so in the future. If we fail to pay interest on the 2021 notes, 2019 notes, or Tranche B notes, or if we fail to repay or repurchase the 2021 notes, 2019 notes, Tranche B notes, or the loans under The Mann Group Loan Arrangement when required, we will be in default under the instrument for such debt securities or loans, and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the note holders initiating bankruptcy proceedings or causing us to cease operations altogether.

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

Our obligations under the Facility Agreement, including any indebtedness under the 2019 notes and the Tranche B notes, and the Milestone Agreement are secured by substantially all of our assets, including our intellectual property, accounts receivables, equipment, general intangibles, inventory (excluding the insulin inventory) and investment property, and all of the proceeds and products of the foregoing. Our obligations under the Facility Agreement and the Milestone Agreement are also secured by a certain mortgage on our facility in Danbury, Connecticut. The Facility Agreement includes customary representations, warranties and covenants by us, including restrictions on our ability to incur additional indebtedness, grant certain liens, engage in certain mergers and acquisitions, make certain distributions and make certain voluntary prepayments. Events of default under the Facility Agreement include: our failure to timely make payments due under the Facility Financing Obligation; inaccuracies in our representations and warranties to Deerfield; our failure to comply with any of our covenants under any of the Facility Agreement, Milestone Agreement or certain other related security agreements and documents entered into in connection with the Facility Agreement, subject to a cure period with respect to most covenants; our insolvency or the occurrence of certain bankruptcy-related events; certain judgments against us; the suspension, cancellation or revocation of governmental authorizations that are reasonably expected to have a material adverse effect on our business; the acceleration of a specified amount of our indebtedness; our cash and cash equivalents falling below \$20.0 million as of October 31, 2018 and December 31, 2018 or \$25.0 million as of the end of each fiscal quarter after December, 31, 2018. There have been no events of default under the Facility Financing Obligation. If we fail to timely pay accrued interest under The Mann Group Loan Arrangement when required, we will be in default under The Mann Group Loan Arrangement. If one or more events of default under the Facility Agreement occurs and continues beyond any applicable cure period, the holders of the Facility Financing Obligation may declare all or any portion of the Facility Financing Obligation to be immediately due and payable. The Milestone Agreement includes customary representations and warranties and covenants by us, including restrictions on transfers of intellectual property related to Afrezza. The milestones are subject to acceleration in the event we transfer our intellectual property related to Afrezza in violation of the terms of the Milestone Agreement.

There can be no assurance that we will be able to comply with the covenants under any of the foregoing agreements, and we cannot predict whether the holders of the Facility Financing Obligation would demand repayment of the outstanding balance of the Facility Financing Obligation as applicable or exercise any other remedies available to such holders if we were unable to comply with these covenants. The covenants and restrictions contained in the foregoing agreements could significantly limit our ability to respond to changes in our business or competitive activities or take advantage of business opportunities that may create value for our stockholders and the holders of our other securities. In addition, our inability to meet or otherwise comply with the covenants under these agreements could have an adverse impact on our financial position and results of operations and could result in an event of default under the terms of our other indebtedness, including our indebtedness under the 2021 notes. In the event of certain future defaults under the foregoing agreements for which we are not able to obtain waivers, the holders of the 2021 notes and Facility Financing Obligation may accelerate all of our repayment obligations, and, with respect to the Facility Financing Obligation, take control of our pledged assets, potentially requiring us to renegotiate the terms of our indebtedness on terms less favorable to us, or to immediately cease operations. If we enter into additional debt arrangements, the terms of such additional arrangements could further restrict our operating and financial flexibility. In the event we must cease operations and liquidate our assets, the rights of any holders of our outstanding secured debt would be senior to the rights of the holders of our unsecured debt and our common stock to receive any proceeds from the liquidation.

If we do not achieve our projected development goals in the timeframes we expect, our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities could decline.

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

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

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

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

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

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

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

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

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

- Safety and efficacy results obtained in our nonclinical and early clinical testing may be inconclusive or may not be predictive of results that we may obtain in our future clinical studies or following long-term use, and we may as a result be forced to stop developing a product candidate or alter the marketing of an approved product;
- The analysis of data collected from clinical studies of our product candidates may not reach the statistical significance necessary, or otherwise be sufficient to support FDA or other regulatory approval for the claimed indications;

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•After reviewing clinical data, we or any collaborators may abandon projects that we previously believed were promising; and

•Our product candidates may not produce the desired effects or may result in adverse health effects or other characteristics that preclude regulatory approval or limit their commercial use once approved.

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

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

For the commercial manufacture of Afrezza, we need access to sufficient, reliable and affordable supplies of insulin, our Afrezza inhaler, the related cartridges and other materials. Currently, the only approved source of insulin for Afrezza is manufactured by Amphastar. We must rely on our suppliers, including Amphastar, to comply with relevant regulatory and other legal requirements, including the production of insulin and FDKP in accordance with the FDA's cGMP for drug products, and the production of the Afrezza inhaler and related cartridges in accordance with QSRs. The supply of any of these materials may be limited or any of the manufacturers may not meet relevant regulatory requirements, and if we are unable to obtain any of these materials in sufficient amounts, in a timely manner and at reasonable prices, or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, the production of Afrezza may be delayed. Likewise, if Amphastar ceases to manufacture or is otherwise unable to deliver insulin for Afrezza, we will need to locate an alternative source of supply and the production of Afrezza may be delayed. If any of our suppliers is unwilling or unable to meet its supply obligations and we are unable to secure an alternative supply source in a timely manner and on favorable terms, our business, financial condition, and results of operations may be harmed and the market price of our common stock and other securities may decline.

If we fail as an effective manufacturing organization or fail to engage third-party manufacturers with this capability, we may be unable to support commercialization of this product.

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

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



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

Afrezza, and other products that we may develop in the future, may not gain market acceptance among physicians, patients, third-party payors and the healthcare community. Failure to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

The degree of market acceptance of Afrezza and other products that we may develop in the future depends on many factors, including the:

- Approved labeling claims;
- Effectiveness of efforts by us or any future marketing partner to educate physicians about the benefits and advantages of Afrezza or our other products and to provide adequate support for them, and the perceived advantages and disadvantages of competitive products;
- Willingness of the healthcare community and patients to adopt new technologies;
- Ability to manufacture the product in sufficient quantities with acceptable quality and cost;
- Perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits compared to competing products or therapies;
- Convenience and ease of administration relative to existing treatment methods;
- Coverage and pricing and reimbursement relative to other treatment therapeutics and methods; and
- Marketing and distribution support.

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

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

Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of government and other third-party payors to contain or reduce the costs of healthcare through various means. For example, in certain foreign markets the pricing of prescription pharmaceuticals is subject to governmental control. In the United States, there have been several congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion, and members of Congress and the Trump administration have stated that they will address such costs through new legislative and administrative measures. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that there will continue to be a number of federal and state proposals to implement similar and/or additional governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services may take in response to any drug pricing and reimbursement reform proposals or legislation. Such reforms may limit our ability to generate revenues from sales of Afrezza or other products that we may develop in the future and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of any future marketing partner for Afrezza, and companies that are prospective collaborators for our product candidates, our ability to commercialize Afrezza and our product candidates under development may be adversely affected.

In the United States and elsewhere, sales of prescription pharmaceuticals still depend in large part on the availability of coverage and adequate reimbursement to the consumer from third-party payors, such as governmental and private

insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. The market for Afrezza and our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. In addition, because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that

approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing more products to market, we cannot be certain that any such products would be considered cost-effective or that coverage and adequate reimbursement to the consumer would be available. Patients will be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

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

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

Healthcare legislation may make it more difficult to receive revenues.

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

- An annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- A 2.3% medical device excise tax on certain transactions, including many U.S. sales of medical devices, which currently includes and we expect will continue to include U.S. sales of certain drug-device combination products, which has been suspended for calendar years 2016 through 2019;
- An increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- A licensure framework for follow-on biological products;
- Expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- A new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% commencing January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- Extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

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Expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;

Expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

New requirements to report annually to the Centers for Medicare & Medicaid Services ("CMS") certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any "payments or transfers of value" made or distributed to prescribers, teaching hospitals and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year;

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- A new requirement to annually report drug samples that certain manufacturers and authorized distributors provide to physicians; and
- A new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and, following passage of the BBA, will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the “ATRA”), which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. These new laws and initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

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

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

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

•The federal Anti-Kickback Statute (as amended by PPACA, which modified the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the Statute or specific intent to violate it to have committed a violation), which constrains our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

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Federal civil and criminal false claims laws, including without limitation the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government, and under PPACA, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal false claims laws;

HIPAA, which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or falsifying, concealing, or covering up a material fact in connection with the delivery of or payment for health care benefits;

HIPAA, as amended by HITECH, and their respective implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information. In addition, the European Union, or EU, has established its own data security and privacy legal framework, including but not limited to Directive 95/46/EC, or the Data Protection Directive. The Data Protection Directive was replaced in May 2018 with the European General Data Protection Regulation, or GDPR, which contains provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We anticipate that over time we may expand our business operations to include additional operations in the EU, including potentially conducting preclinical and clinical trials. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR.

The federal physician sunshine requirements under PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; and state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities.

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



If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.\*

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

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

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

The testing, manufacturing, marketing and sale of Afrezza and any clinical testing of our product candidates expose us to potential product liability claims. A product liability claim may result in substantial judgments as well as consume significant financial and management resources and result in adverse publicity, decreased demand for a product, injury to our reputation, withdrawal of clinical studies volunteers and loss of revenues. We currently carry worldwide product liability insurance in the amount of \$10.0 million. Our insurance coverage may not be adequate to satisfy any liability that may arise, and because insurance coverage in our industry can be very expensive and difficult to obtain, we cannot assure you that we will seek to obtain, or be able to obtain if desired, sufficient additional coverage. If losses from such claims exceed our liability insurance coverage, we may incur substantial liabilities that we may not have the resources to pay. If we are required to pay a product liability claim our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities may decline.

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

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

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

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

If our internal controls over financial reporting are not considered effective, our business, financial condition and market price of our common stock and other securities could be adversely affected.

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

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

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

From time to time, the Financial Accounting Standards Board ("FASB"), either alone or jointly with other organizations, promulgates new accounting principles that could have an adverse impact on our financial position, results of operations or reported cash flows. In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606). The standard requires a company to recognize revenue to depict the transfer of goods or services when transferred to customers in the amount that reflects the consideration it expects to be entitled to receive in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In March 2016, the FASB issued additional ASUs which clarified certain aspects of the new guidance. We adopted the new standard for the year beginning January 1, 2018. We had the

option to either apply the new standard retrospectively for all prior reporting periods presented (full retrospective) or retrospectively with the cumulative effect of initially applying the new standard recognized at the date of initial application (modified retrospective). We have elected to apply the new standard using the modified retrospective approach with the cumulative effect of initial application recognized as of January 1, 2018. Based on the impact of adopting the new standard, the cumulative effect adjustment was approximately a \$1.9 million decrease to the opening balance of accumulated deficit. Any difficulties in implementing this standard, or in adopting or implementing any other new accounting standard, and to update or modify our internal controls as needed on a timely basis, could result in our failure to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us. Finally, if we were to change our critical accounting estimates, including those related to the recognition of collaboration revenue and other revenue sources, our operating results could be significantly affected.

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

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

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

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

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

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

business, operating results and financial condition.

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

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



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

Our research and development and commercialization of Afrezza work involves the controlled storage and use of hazardous materials, including chemical and biological materials. In addition, our manufacturing operations involve the use of a chemical that may form an explosive mixture under certain conditions. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations (i) governing how we use, manufacture, store, handle and dispose of these materials (ii) imposing liability for costs of cleaning up, and damages to natural resources from past spills, waste disposals on and off-site, or other releases of hazardous materials or regulated substances, and (iii) regulating workplace safety. Moreover, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated, and in the event of an accident, we could be held liable for any damages that may result, and any liability could fall outside the coverage or exceed the limits of our insurance. Currently, our general liability policy provides coverage up to \$1.0 million per occurrence and \$2.0 million in the aggregate and is supplemented by an umbrella policy that provides a further \$20.0 million of coverage; however, our insurance policy excludes pollution liability coverage and we do not carry a separate hazardous materials policy. In addition, we could be required to incur significant costs to comply with environmental laws and regulations in the future. Finally, current or future environmental laws and regulations may impair our research, development or production efforts or have an adverse impact on our business, results of operations and financial condition.

When we purchased the facilities located in Danbury, Connecticut in 2001, a soil and groundwater investigation and remediation was being conducted by a former site operator (the responsible party) under the oversight of the Connecticut Department of Environmental Protection, which is not completed. The responsible party will make all filings necessary to achieve closure for the environmental remediation conducted at the site, and has agreed to indemnify us for any future costs and expenses we may incur that are directly related to the final closure. If we are unable to collect these future costs and expenses, if any, from the responsible party, our business, financial condition and results of operations may be harmed.

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

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

## RISKS RELATED TO GOVERNMENT REGULATION

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

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

- Product design, development, manufacture and testing;
- Product labeling;
- Product storage and shipping;

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- Pre-market clearance or approval;
- Advertising and promotion; and
- Product sales and distribution.

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

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

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

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

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

Even if we comply with regulatory requirements, we may not be able to obtain the labeling claims necessary or desirable for product promotion. We may also be required to undertake post-marketing studies. For example, as part of the approval of Afrezza, the FDA required that we complete a clinical trial to evaluate the potential risk of pulmonary malignancy with Afrezza. To date, we have not enrolled any subjects in this trial.

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

We are subject to stringent, ongoing government regulation.\*

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

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

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

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

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

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

Our suppliers are subject to FDA inspection.

We depend on suppliers for insulin and other materials that comprise Afrezza, including our Afrezza inhaler and cartridges. Each supplier must comply with relevant regulatory requirements and is subject to inspection by the FDA. Although we conduct our own inspections and review and/or approve investigations of each supplier, there can be no assurance that the FDA, upon inspection, would find that the supplier substantially complies with the QSR or cGMP requirements, where applicable. If we or any potential third-party manufacturer or supplier fails to comply with these requirements or comparable requirements in foreign countries, regulatory authorities may subject us to regulatory action, including criminal prosecutions, fines and suspension of the manufacture of our products.

If we are required to find a new or additional supplier of insulin, we will be required to evaluate the new supplier's ability to provide insulin that meets regulatory requirements, including cGMP requirements as well as our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and commercialization of Afrezza.

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

If other pharmaceutical companies announce that they observed frequent adverse events in their studies involving insulin therapies, we may be subject to class warnings in the label for Afrezza. In addition, the public perception of Afrezza might be adversely affected, which could harm our business, financial condition and results of operations and cause the market price of our common stock and other securities to decline, even if the concern relates to another company's products or product candidates.

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

## RISKS RELATED TO INTELLECTUAL PROPERTY

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

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

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

these patents will be subjected to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated.

In addition, in certain countries, including the United States, applications are generally published 18 months after the application's priority date. In any event, because publication of discoveries in scientific or patent literature often trails behind actual discoveries, we cannot be certain that we were the first inventor of the subject matter covered by our pending patent applications or that we were the first to file patent applications on such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act ("AIA"), or the Leahy-Smith Act, the United States moved to a first inventor to file system. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.



Moreover, the term of a patent is limited and, as a result, the patents protecting our products expire at various dates. For example, some patents providing protection for Afrezza inhalation powder have terms extending into 2020, 2026, 2028, 2029, and 2030. In addition, patents providing protection for our inhaler and cartridges have terms extending into 2023, 2031 and 2032, and we have method of treatment claims that extend into 2026, 2029, 2030 and 2031. As and when these different patents expire, Afrezza could become subject to increased competition. As a consequence, we may not be able to recover our development costs.

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

We also rely on unpatented technology, trade secrets, know-how and confidentiality agreements. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. These agreements provide that all inventions developed by the individual on behalf of us must be assigned to us and that the individual will cooperate with us in connection with securing patent protection on the invention if we wish to pursue such protection. We also execute confidentiality agreements with outside collaborators. There can be no assurance, however, that our inventions and assignment agreements and our confidentiality agreements will provide meaningful protection for our inventions, trade secrets, know-how or other proprietary information in the event of unauthorized use or disclosure of such information. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business, results of operations and financial condition could be adversely affected.

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

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

Interference proceedings brought by the USPTO, may be necessary to determine the priority of inventions with respect to our pre-AIA patent applications or those of our collaborators or licensors. Additionally, the Leahy-Smith Act has greatly expanded the options for post-grant review of patents that can be brought by third parties. In particular Inter Partes Review (“IPR”), available against any issued United States patent (pre-and post-AIA), has resulted in a higher rate of claim invalidation, due in part to the much reduced opportunity to repair claims by amendment as compared to re-examination, as well as the lower standard of proof used at the USPTO as compared to the federal courts. With the passage of time an increasing number of patents related to successful pharmaceutical products are being subjected to IPR. Moreover, the filing of IPR petitions has been used by short-sellers as a tool to help drive down stock prices. We may not prevail in any litigation, post-grant review, or interference proceedings in which we are involved and, even if we are successful, these proceedings may result in substantial costs and be a distraction to our management. Further, we may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully

as in the United States.

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

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

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

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

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

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

Although we own a number of domestic and foreign patents and patent applications relating to Afrezza, we have identified certain third-party patents having claims that may trigger an allegation of infringement in connection with the commercial manufacture and sale of Afrezza. We do not believe that Afrezza infringes on any patents. However, if a court were to determine that Afrezza was infringing any of these patent rights, we would have to establish with the court that these patents are invalid or unenforceable in order to avoid legal liability for infringement of these patents. However, proving patent invalidity or unenforceability can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in a non-infringement or invalidity action we will have to either acquire the third-party patents outright or seek a royalty-bearing license. Royalty-bearing licenses effectively increase production costs and therefore may materially affect product profitability. Furthermore, should the patent holder refuse to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and/or design around the patents, if possible. In either event, our business, financial condition and results of operations would be harmed and our profitability could be materially and adversely impacted.

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

these results to be negative, the market price of our common stock and other securities may decline.

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

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

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

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

#### RISKS RELATED TO OUR COMMON STOCK

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

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

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

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

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

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

Between January 1, 2014 and September 30, 2018, our closing stock price as reported on The Nasdaq Global Market has ranged from \$0.71 to \$54.80, adjusted for the reverse stock split that occurred during this period. The trading price of our common stock is likely to continue to be volatile. The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks, and this trend may continue.

The volatility of pharmaceutical and biotechnology stocks often does not relate to the operating performance of the companies represented by the stock. Our business and the market price of our common stock may be influenced by a large variety of factors, including:

- Our ability to obtain marketing approval for Afrezza outside of the United States and to find collaboration partners for the commercialization of Afrezza in foreign jurisdictions;
  - Our future estimates of Afrezza sales, prescriptions or other operating metrics;
  - Our ability to successfully commercialize our Technosphere drug delivery platform;
  - The progress of preclinical and clinical studies of our product candidates and of post-approval studies of Afrezza required by the FDA;
  - The results of preclinical and clinical studies of our product candidates;
  - General economic, political or stock market conditions, especially for emerging growth and pharmaceutical market sectors;
  - Legislative developments;
  - Announcements by us, our collaborators, or our competitors concerning clinical study results, acquisitions, strategic alliances, technological innovations, newly approved commercial products, product discontinuations, or other developments;
  - The availability of critical materials used in developing and manufacturing Afrezza or other product candidates;
  - Developments or disputes concerning our relationship with any of our current or future collaborators or third party manufacturers;
  - Developments or disputes concerning our patents or proprietary rights;
  - The expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;
    - Announcements by us concerning our financial condition or operating performance;
  - Changes in securities analysts' estimates of our financial condition or operating performance;
  - Sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
  - Our ability, or the perception of investors of our ability, to continue to meet all applicable requirements for continued listing of our common stock on The Nasdaq Stock Market, and the possible delisting of our common stock if we are unable to do so;
  - The status of any legal proceedings or regulatory matters against or involving us or any of our executive officers and directors; and
  - Discussion of Afrezza, our other product candidates, competitors' products, or our stock price by the financial and scientific press, the healthcare community and online investor communities such as chat rooms. In particular, it may be difficult to verify statements about us and our investigational products that appear on interactive websites that permit users to generate content anonymously or under a pseudonym and statements attributed to company officials may, in fact, have originated elsewhere.
- Any of these risks, as well as other factors, could cause the market value of our common stock and other securities to decline.

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

Our common stock is currently listed on The Nasdaq Global Market, which has qualitative and quantitative listing criteria. If we are unable to meet any of the Nasdaq listing requirements in the future, such as the corporate governance requirements, the minimum closing bid price requirement, or the minimum market value of listed securities requirement, Nasdaq could determine to delist our common stock. A delisting of our common stock could adversely affect the market liquidity of our common stock, decrease the market price of our common stock, adversely affect our ability to obtain financing for the continuation of our operations and result in the loss of confidence in our company. In 2016, we received a notice of non-compliance from the Listing Qualifications Department of the Nasdaq Stock Market with respect to the \$1.00 minimum closing bid price requirement. Although we regained compliance

with the minimum closing bid price requirement after effecting a reverse stock split in March 2017 there can be no assurance that we will be able to meet the minimum closing bid price requirement or other listing requirements in the future.



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

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

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

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

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

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

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

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

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

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

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

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

Exhibit

Number Description of Document

- 3.1 Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2016).
- 3.2 Certificate of Amendment of Amended and Restated Certificate of Incorporation of MannKind Corporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on March 2, 2017).
- 3.3 Certificate of Amendment of Amended and Restated Certificate of Incorporation of MannKind Corporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on December 13, 2017).
- 3.4 Amended and Restated Bylaws (incorporated by reference to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on November 19, 2007).
- 4.1 Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
- 4.2 Form of common stock certificate (incorporated by reference to Exhibit 4.2 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2017).
- 4.3 Form of 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
- 4.4 Form of Amended and Restated 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to Exhibit 4.7 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
- 4.5 Form of Tranche B Senior Secured Note due 2019 (incorporated by reference to Exhibit 4.8 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50856), filed with the SEC on May 12, 2014).
- 4.6 Milestone Rights Purchase Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to Exhibit 99.3 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
- 4.7 Guaranty and Security Agreement, dated as of July 1, 2013, by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to Exhibit 99.4 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
- 4.8 Facility Agreement, dated as of July 1, 2013, by and among MannKind Corporation, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
- 4.9

First Amendment to Facility Agreement and Registration Rights Agreement, dated as of February 28, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 10.39 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).

- 4.10 Second Amendment to Facility Agreement and Registration Rights Agreement, dated as of August 11, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 4.14 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 10, 2014).
- 4.11 Exchange and Third Amendment to Facility Agreement, dated June 29, 2017 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on June 29, 2017).
- 4.12 Fourth Amendment to Facility Agreement, dated October 23, 2017 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on October 23, 2017).

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Exhibit

Number Description of Document

- 4.13 Fifth Amendment to Facility Agreement, dated January 15, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on January 18, 2018).
- 4.14 Sixth Amendment to Facility Agreement, dated January 18, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on January 18, 2018).
- 4.15 Exchange and Seventh Amendment to Facility Agreement, dated June 8, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on June 11, 2018).
- 4.16 Exchange and Eighth Amendment to Facility Agreement, dated July 12, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 13, 2018).
- 4.17 Ninth Amendment to Facility Agreement, dated September 5, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 5, 2018).
- 4.18 Tenth Amendment to Facility Agreement, dated September 26, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 27, 2018).
- 4.19 Indenture, by and between MannKind and U.S. Bank (dated October 30, 2017 (incorporated by reference to Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on October 30, 2017).
- 4.20 Form of 5.75% Convertible Senior Subordinated Exchange Note due 2021 (incorporated by reference to Exhibit A of Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on October 30, 2017).
- 4.21 Form of Warrant to Purchase Common Stock issued November 16, 2015 (incorporated by reference to Exhibit 4.17 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 15, 2016).
- 4.22 Amended and Restated Promissory Note made by MannKind in favor of The Mann Group LLC, dated March 11, 2018 (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on March 12, 2018).
- 4.23

Form of Common Stock Purchase Warrant issued April 9, 2018 (incorporated by reference to Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on April 6, 2018).

- 10.1\* MannKind Corporation 2018 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to MannKind's registration statement Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).
- 10.2\* Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the MannKind 2018 Equity Incentive Plan (incorporated by reference to Exhibit 99.2 to MannKind's registration statement on Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).
- 10.3\* Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the MannKind 2018 Equity Incentive Plan (incorporated by reference to Exhibit 99.3 to MannKind's registration statement on Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).
- 10.4\* MannKind Corporation 2004 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 99.4 to MannKind's registration statement Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).
- 10.5 Exchange and Eighth Amendment to Facility Agreement, dated July 12, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 13, 2018).

Exhibit

Number Description of Document

- 10.6 Ninth Amendment to Facility Agreement, dated September 5, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 5, 2018).
- 10.7 Tenth Amendment to Facility Agreement, dated September 26, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 27, 2018).
- 10.8\*\* License and Collaboration Agreement, dated September 3, 2018 by and between MannKind and United Therapeutics Corporation.
- 10.9\*\* Research Agreement, dated September 3, 2018 by and between MannKind and United Therapeutics Corporation.
- 31.1 Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 31.2 Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 32.1 Certification of the Chief Executive Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
- 32.2 Certification of the Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
- 101 Interactive Data Files pursuant to Rule 405 of Regulation S-T.

\*Indicates management contract or compensatory plan.

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



SIGNATURE

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

Dated: November 1,  
2018

MANKIND CORPORATION

By: /s/ MICHAEL E. CASTAGNA  
Michael E. Castagna  
Chief Executive Officer

(on behalf of the registrant and as the registrant's Principal Executive Officer)

By: /s/ STEVEN B. BINDER  
Steven B. Binder  
Chief Financial Officer

(on behalf of the registrant and as the registrant's Principal Financial and Accounting Officer)