Allison Transmission Holdings Inc
Form 10-Q
July 25, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2014

OR

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

Commission File No. 001-35456

ALLISON TRANSMISSION HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-0414014**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
One Allison Way	
Indianapolis, IN	**46222**
(Address of Principal Executive Offices)	**(Zip Code)**

(317) 242-5000

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

As of July 14, 2014, there were 176,685,429 shares of Common Stock and 1,185 shares of Non-voting Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

Allison Transmission Holdings, Inc.

Condensed Consolidated Balance Sheets

(unaudited, dollars in millions, except share data)

	June 30, 2014	December 31, 2013
ASSETS		
Current Assets		
Cash and cash equivalents	**$ 126.7**	$ 184.7
Accounts receivables net of allowance for doubtful accounts of $0.6 and $0.4	**227.0**	175.1
Inventories	**169.5**	160.4
Deferred income taxes, net	**94.9**	58.1
Other current assets	**29.4**	28.6
Total Current Assets	**647.5**	606.9
Property, plant and equipment, net	**538.2**	563.4
Intangible assets, net	**1,561.4**	1,610.8
Goodwill	**1,941.0**	1,941.0
Deferred income taxes, net	**1.1**	1.1
Other non-current assets	**82.7**	89.4
TOTAL ASSETS	**$ 4,771.9**	$ 4,812.6
LIABILITIES		
Current Liabilities		
Accounts payable	**$ 174.4**	$ 150.4
Product warranty liability	**23.2**	37.4
Current portion of long-term debt	**17.9**	17.9
Deferred revenue	**22.0**	29.2
Other current liabilities	**140.8**	152.3
Total Current Liabilities	**378.3**	387.2
Product warranty liability	**63.5**	53.1
Deferred revenue	**47.1**	43.2
Long-term debt	**2,651.5**	2,660.4
Deferred income taxes	**165.8**	76.2
Other non-current liabilities	**171.7**	153.7
TOTAL LIABILITIES	**3,477.9**	3,373.8

Commitments and contingencies (see NOTE O)		
STOCKHOLDERS EQUITY		
Common stock, $0.01 par value, 1,880,000,000 shares authorized, 176,577,025 and 183,375,436 shares issued and outstanding	**1.8**	1.8
Non-voting common stock, $0.01 par value, 20,000,000 shares authorized, 1,185 shares issued and outstanding	**0.0**	0.0
Preferred stock, $0.01 par value, 100,000,000 shares authorized, none issued and outstanding		
Paid in capital	**1,598.0**	1,631.8
Accumulated deficit	**(286.7)**	(173.8)
Accumulated other comprehensive loss, net of tax	**(19.1)**	(21.0)
TOTAL STOCKHOLDERS EQUITY	**1,294.0**	1,438.8
TOTAL LIABILITIES & STOCKHOLDERS EQUITY	**$ 4,771.9**	$ 4,812.6

The accompanying notes are an integral part of the condensed consolidated financial statements.

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Allison Transmission Holdings, Inc.

Condensed Consolidated Statements of Comprehensive Income

(unaudited, dollars in millions, except share data)

	Three months ended June 30,		Six months ended June 30,	
	2014	**2013**	**2014**	**2013**
Net sales	**$ 536.1**	$ 512.1	**$ 1,029.7**	$ 969.5
Cost of sales	**297.6**	286.0	**568.7**	545.1
Gross profit	**238.5**	226.1	**461.0**	424.4
Selling, general and administrative expenses	**85.1**	85.6	**168.3**	173.5
Engineering research and development	**21.2**	22.8	**45.7**	51.8
Operating income	**132.2**	117.7	**247.0**	199.1
Interest income	**0.2**	0.2	**0.4**	0.4
Interest expense	**(36.8)**	(33.5)	**(72.1)**	(67.6)
Other expense, net	**(0.9)**	(2.6)	**(1.3)**	(5.7)
Income before income taxes	**94.7**	81.8	**174.0**	126.2
Income tax expense	**(37.5)**	(31.3)	**(64.7)**	(48.2)
Net income	**$ 57.2**	$ 50.5	**$ 109.3**	$ 78.0
Basic earnings per share attributable to common stockholders	**$ 0.32**	$ 0.27	**$ 0.61**	$ 0.42
Diluted earnings per share attributable to common stockholders	**$ 0.31**	$ 0.26	**$ 0.59**	$ 0.41
Dividends declared per common share	**$ 0.12**	$ 0.12	**$ 0.24**	$ 0.18
Comprehensive income	**$ 57.0**	$ 44.0	**$ 111.2**	$ 68.9

The accompanying notes are an integral part of the condensed consolidated financial statements.

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Allison Transmission Holdings, Inc.

Condensed Consolidated Statements of Cash Flows

(unaudited, dollars in millions)

	Six months ended June 30, 2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	**$ 109.3**	$ 78.0
Add (deduct) items included in net income not using (providing) cash:		
Amortization of intangible assets	**49.4**	55.0
Depreciation of property, plant and equipment	**47.4**	49.7
Deferred income taxes	**61.7**	49.0
Unrealized gain on derivatives	**(8.0)**	(15.7)
Stock-based compensation	**7.3**	7.7
Excess tax benefit from stock-based compensation	**(7.8)**	(7.0)
Amortization of deferred financing costs	**4.3**	4.7
Impairment loss on investment in technology-related initiatives		2.5
Other	**0.2**	(0.2)
Changes in assets and liabilities:		
Accounts receivable	**(52.0)**	(44.2)
Inventories	**(8.8)**	(7.8)
Accounts payable	**24.0**	35.6
Other assets and liabilities	**15.0**	(22.9)
Net cash provided by operating activities	**242.0**	184.4
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions of long-lived assets	**(22.7)**	(25.8)
Investments in technology-related initiatives	**(3.8)**	(6.3)
Collateral for interest rate derivatives	**1.7**	1.3
Proceeds from disposal of assets	**0.1**	0.2
Net cash used for investing activities	**(24.7)**	(30.6)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repurchase of common stock	**(249.8)**	
Dividend payments	**(43.4)**	(33.4)
Proceeds from exercise of stock options	**22.4**	25.2
Payments on long-term debt	**(8.9)**	(11.8)
Excess tax benefit from stock-based compensation	**7.8**	7.0
Taxes paid related to net share settlement of equity awards	**(0.2)**	(3.1)
Debt financing fees	**(1.0)**	(1.6)
Net cash used for financing activities	**(273.1)**	(17.7)
Effect of exchange rate changes on cash	**(2.2)**	11.1
Net (decrease) increase in cash and cash equivalents	**(58.0)**	147.2
Cash and cash equivalents at beginning of period	**184.7**	80.2
Cash and cash equivalents at end of period	**$ 126.7**	$ 227.4
Supplemental disclosures:		
Interest paid	**$ 68.6**	$ 79.6
Income taxes paid	**$ 3.1**	$ 3.0

The accompanying notes are an integral part of the condensed consolidated financial statements.

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Allison Transmission Holdings, Inc.

Notes to Condensed Consolidated Financial Statements

(UNAUDITED)

NOTE A. OVERVIEW

Overview

Allison Transmission Holdings, Inc. and its subsidiaries (the Company or Allison), design and manufacture commercial and defense fully-automatic transmissions.

The business was founded in 1915 and has been headquartered in Indianapolis, Indiana since inception. The Company has 13 different transmission product lines. Although approximately 77% of revenues were generated in North America in 2013, the Company has a global presence by serving customers in Europe, Asia, South America and Africa. The Company serves customers through an independent network of approximately 1,400 independent distributor and dealer locations worldwide.

Since the introduction of the Company s first fully-automatic transmission over 60 years ago, the Company s products have gained acceptance in a wide variety of applications, including on-highway trucks (distribution, refuse, construction, fire and emergency), buses (primarily school, transit and hybrid-transit), motorhomes, off-highway vehicles and equipment (primarily energy, mining and construction) and defense vehicles (wheeled and tracked). The Company has developed over 100 different product models that are used in more than 2,500 different vehicle configurations, which are compatible with more than 500 combinations of engine brands, models and ratings. The Company also sells support equipment and Allison-branded replacement parts for the Company s transmissions and remanufactured transmissions for use in the vehicle aftermarket.

NOTE B. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The condensed consolidated financial statements as of and for the three and six months ended June 30, 2014 and 2013 have been prepared in accordance with accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the condensed consolidated financial statements do not include all information and footnotes required by accounting principles generally accepted in the United States of America (GAAP) for complete financial statements. The information herein reflects all normal recurring material adjustments, which are, in the opinion of management, necessary for the fair statement of the results for the periods presented. The condensed consolidated financial statements herein consist of all wholly-owned domestic and foreign subsidiaries with all significant intercompany transactions eliminated.

These condensed consolidated financial statements present the financial position, results of operations and cash flows of the Company. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements included in the Company s Form 10-K for the year ended December 31, 2013 as filed with the Securities and Exchange Commission (SEC) on February 24, 2014. The interim period financial results for the three and six month periods presented are not necessarily indicative of results to be expected for any other interim period or for the entire year.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities and the reported amounts of revenue and expenses. Significant estimates include, but are not limited to, allowance for doubtful accounts, sales allowances, government price adjustments, fair market values and future cash flows associated with goodwill, indefinite life intangibles, long-lived asset impairment tests, useful lives for depreciation and amortization, warranty liability, determination of discount and other assumptions for pension and other postretirement benefit expense, income taxes and deferred tax valuation allowances, derivative valuation, and contingencies. The Company s accounting policies involve the application of judgments and assumptions made by management that include inherent risks and uncertainties. Actual results could differ materially from these estimates. Changes in estimates are recorded in results of operations in the period that the events or circumstances giving rise to such changes occur.

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Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued authoritative accounting guidance on a company s accounting for revenue from contracts with customers. The guidance applies to all companies that enter into contracts with customers to transfer goods, service or nonfinancial assets. The guidance requires these companies to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance also requires improved disclosures regarding the nature, timing, amount and uncertainty of revenue that is recognized. The guidance is effective prospectively for fiscal years beginning after December 15, 2016. Management is currently assessing the potential impact of the adoption of this guidance on the Company s consolidated financial statements.

In July 2013, the FASB issued authoritative accounting guidance on the presentation of an unrecognized tax benefit when net operating loss (NOL) carryforwards exist. The guidance requires presentation of an unrecognized tax benefit, or a portion of an unrecognized tax benefit, in the financial statements as a reduction to a deferred tax asset for an NOL carryforward, a similar tax loss or a tax credit carryforward. The guidance became effective for fiscal years beginning after December 15, 2013. The adoption of this guidance did not have a material effect on the Company s condensed consolidated financial statements.

In March 2013, the FASB issued authoritative accounting guidance on a parent company s accounting for the cumulative translation adjustment upon derecognition of certain subsidiaries or groups of assets within a foreign entity or of an investment in a foreign entity. The guidance clarifies that when a parent company ceases to have a controlling financial interest in a subsidiary or group of assets, the cumulative translation adjustment should be released into net income only if the sale or transfer results in the complete or substantially complete liquidation of the foreign entity in which the subsidiary or group of assets had resided. The guidance became effective for fiscal years beginning after December 15, 2013. The adoption of this guidance did not have an effect on the Company s condensed consolidated financial statements.

NOTE C. INVENTORIES

Inventories consisted of the following components (dollars in millions):

	June 30, 2014	December 31, 2013
Purchased parts and raw materials	**$ 86.4**	$ 79.7
Work in progress	**8.0**	5.7
Service parts	**45.4**	45.8
Finished goods	**29.7**	29.2
Total inventories	**$ 169.5**	$ 160.4

Inventory components shipped to third parties, primarily cores, parts to re-manufacturers, and parts to contract manufacturers, in which the Company has an obligation to buy back, are included in purchased parts and raw materials, with an offsetting liability in Other current liabilities.

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NOTE D. GOODWILL AND OTHER INTANGIBLE ASSETS

As of June 30, 2014 and December 31, 2013, the carrying amount of the Company s Goodwill was $1,941.0 million. The following presents a summary of other intangible assets (dollars in millions):

	June 30, 2014			December 31, 2013		
	Intangible assets, gross	**Accumulated amortization**	**Intangible assets, net**	**Intangible assets, gross**	**Accumulated amortization**	**Intangible assets, net**
Other intangible assets:						
Trade name	**$ 870.0**	**$**	**$ 870.0**	$ 870.0	$	$ 870.0
Customer relationships defense	**62.3**	**(26.1)**	**36.2**	62.3	(24.4)	37.9
Customer relationships commercial	**831.8**	**(400.9)**	**430.9**	831.8	(374.9)	456.9
Proprietary technology	**476.3**	**(262.9)**	**213.4**	476.3	(243.9)	232.4
Non-compete agreement	**17.3**	**(12.0)**	**5.3**	17.3	(11.1)	6.2
Patented technology defense	**28.2**	**(22.9)**	**5.3**	28.2	(21.2)	7.0
Tooling rights	**4.5**	**(4.2)**	**0.3**	4.5	(4.1)	0.4
Patented technology commercial	**260.6**	**(260.6)**		260.6	(260.6)	
Total	**$ 2,551.0**	**$ (989.6)**	**$ 1,561.4**	$ 2,551.0	$ (940.2)	$ 1,610.8

As of June 30, 2014 and December 31, 2013, the net carrying value of our Goodwill and other intangibles was $3,502.4 million and $3,551.8 million, respectively.

Amortization expense related to other intangible assets for the next five years and thereafter is expected to be (dollars in millions):

	2015	**2016**	**2017**	**2018**	**2019**	**Thereafter**
Amortization expense	$ 97.1	$ 92.4	$ 89.7	$ 87.2	$ 85.7	$ 189.9

NOTE E. FAIR VALUE OF FINANCIAL INSTRUMENTS

In accordance with the FASB s authoritative accounting guidance on fair value measurements, fair value is the price (exit price) that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company utilizes market data or assumptions that market participants would use in pricing the asset or liability, including assumptions about risk and the risks inherent in the inputs to the valuation technique. These inputs can be readily observable, market corroborated, or generally unobservable. The Company primarily applies the market approach for recurring fair value measurements and utilizes the best available information that maximizes the use of observable inputs and minimizes the use of unobservable inputs. The Company is able to classify fair value balances based on the observability of those inputs. The accounting guidance establishes a fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement). The three levels of the fair value hierarchy defined by the relevant guidance are as follows:

Level 1 Quoted prices are available in active markets for identical assets or liabilities as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis. Level 1 primarily consists of financial instruments such as exchange-traded derivatives, listed equities and publicly traded bonds.

Level 2 Pricing inputs are other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reported date. Level 2 includes those financial instruments that are valued using models or other valuation methodologies. These models are primarily industry standard models that consider various assumptions, including quoted forward prices for commodities, time value, volatility factors, and current market and contractual prices for the underlying instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace throughout the full term of the instrument, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

Level 3 Pricing inputs include significant inputs that are generally less observable from objective sources. These inputs may be used with internally developed methodologies that result in management s best estimate of fair value. At each balance sheet date, the Company performs an analysis of all instruments subject to authoritative accounting guidance and includes, in Level 3, all of those whose fair value is based on significant unobservable inputs. As of June 30, 2014 and December 31, 2013, the Company did not have any Level 3 financial assets or liabilities.

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The Company s assets and liabilities that are measured at fair value include cash and cash equivalents, available-for-sale securities, derivative instruments, assets held in a rabbi trust and a deferred compensation obligation. The Company s cash equivalents consist of short-term U.S. government backed securities. The Company s available-for-sale securities consist of ordinary shares of Torotrak plc (Torotrak) associated with a license and exclusivity agreement with Torotrak. Torotrak s listed shares are traded on the London Stock Exchange under the ticker symbol TRK. The Company s derivative instruments consist of interest rate swaps, foreign currency forward contracts and commodity swaps. The Company s assets held in the rabbi trust consist principally of publicly available mutual funds and target date retirement funds. The Company s deferred compensation obligation is directly related to the fair value of assets held in the rabbi trust.

The Company s valuation techniques used to calculate the fair value of cash and cash equivalents, available-for-sale securities, assets held in the rabbi trust and the deferred compensation obligation represent a market approach in active markets for identical assets that qualifies as Level 1 in the fair value hierarchy. The Company s valuation techniques used to calculate the fair value of derivative instruments represent a market approach with observable inputs that qualify as Level 2 in the fair value hierarchy.

The foreign currency contracts consist of forward rate contracts which are intended to hedge exposure of transactions denominated in certain currencies and reduce the impact of currency price volatility on the Company s financial results. The commodity contracts consist of forward rate contracts which are intended to hedge exposure of transactions involving purchases of component parts and energy to power our facilities, reducing the impact of commodity price volatility on the Company s financial results.

For the fair value measurement of foreign currency derivatives, the Company uses forward foreign exchange rates received from the issuing financial institution. These rates are periodically corroborated by comparing to third-party broker quotes. The foreign currency hedges are accounted for within the authoritative accounting guidance set forth on accounting for derivative instruments and hedging activities and have been recorded at fair value based upon quoted market rates. The fair values are included in Other current and non-current assets and liabilities in the Condensed Consolidated Balance Sheets. The Company generally does not elect to apply hedge accounting for these foreign currency contracts, and as a result, unrealized fair value adjustments and realized gains and losses are recorded in Other expense, net in the Condensed Consolidated Statements of Comprehensive Income during the period of change.

For the fair value measurement of commodity derivatives, the Company uses forward prices received from the issuing financial institution. These rates are periodically corroborated by comparing to third-party broker quotes. The commodity derivatives are accounted for within the authoritative accounting guidance set forth on accounting for derivative instruments and hedging activities and have been recorded at fair value based upon quoted market rates. The fair values are included in Other current and non-current assets and liabilities in the Condensed Consolidated Balance Sheets. The Company has either not qualified for or not elected hedge accounting treatment for these commodity contracts, and as a result, unrealized fair value adjustments and realized gains and losses are recorded in Other expense, net in the Condensed Consolidated Statements of Comprehensive Income.

For the fair value measurement of interest rate derivatives, the Company uses valuations from the issuing financial institution. The Company corroborates the valuation through the use of third-party valuation services using a standard replacement valuation model. The floating-to-fixed interest rate swaps are based on the London Interbank Offered Rate (LIBOR) which is observable at commonly quoted intervals. The fair values are included in other current and non-current assets and liabilities in the Condensed Consolidated Balance Sheets. The Company has not qualified for hedge accounting treatment for the interest rate swaps and, as a result, fair value adjustments are charged directly to Interest expense in the Condensed Consolidated Statements of Comprehensive Income.

The following table summarizes the fair value of the Company s financial assets and (liabilities) as of June 30, 2014 and December 31, 2013 (dollars in millions):

	Fair Value Measurements Using					
	Quoted Prices in Active Markets for Identical Assets (Level 1)		**Significant Other Observable Inputs (Level 2)**		**TOTAL**	
	June 30, 2014	**December 31, 2013**	**June 30, 2014**	**December 31, 2013**	**June 30, 2014**	**December 31, 2013**
Cash and cash equivalents	**$ 126.7**	$ 184.7	**$**	$	**$ 126.7**	$ 184.7
Available-for-sale securities	**11.2**	8.2			**11.2**	8.2
Rabbi trust assets	**2.7**	1.3			**2.7**	1.3
Deferred compensation obligation	**(2.7)**	(1.3)			**(2.7)**	(1.3)
Derivative assets			**0.4**	1.6	**0.4**	1.6

Derivative liabilities			**(12.2)**	(21.4)	**(12.2)**	(21.4)
Total	**$ 137.9**	$ 192.9	**$ (11.8)**	$ (19.8)	**$ 126.1**	$ 173.1

Of the available Cash and cash equivalents, approximately $125.7 million and $179.7 million was deposited in operating accounts while approximately $1.0 million and $5.0 million was invested in U.S. government backed securities as of June 30, 2014 and December 31, 2013, respectively.

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NOTE F. DEBT

Long-term debt and maturities are as follows (dollars in millions):

	June 30, 2014	December 31, 2013
Long-term debt:		
Senior Secured Credit Facility Term B-2 Loan, variable, due 2017	**$ 423.5**	$ 423.5
Senior Secured Credit Facility Term B-3 Loan, variable, due 2019	**1,774.6**	1,783.5
Senior Notes, fixed 7.125%, due 2019	**471.3**	471.3
Total long-term debt	**2,669.4**	2,678.3
Less: current maturities of long-term debt	**17.9**	17.9
Total long-term debt less current portion	**$ 2,651.5**	$ 2,660.4

As of June 30, 2014, the Company had $423.5 million of indebtedness associated with Allison Transmission, Inc. s (ATI), the Company s wholly-owned subsidiary, Senior Secured Credit Facility Term B-2 Loan due 2017 (Term B-2 Loan) and $1,774.6 million of indebtedness associated with ATI s Senior Secured Credit Facility Term B-3 Loan due 2019 (Term B-3 Loan) (together the Term B-2 Loan, Term B-3 Loan and revolving credit facility defined as the Senior Secured Credit Facility). The Company also had indebtedness of $471.3 million of ATI s 7.125% senior cash pay notes due May 2019 (7.125% Senior Notes).

The fair value of the Company s long-term debt obligations as of June 30, 2014 was $2,705.8 million. The fair value is based on quoted Level 1 market prices of the Company s debt as of June 30, 2014. It is not expected that the Company would be able to repurchase a significant amount of its debt at these levels. The difference between the fair value and carrying value of the long-term debt is driven primarily by trends in the financial markets.

Senior Secured Credit Facility

The Senior Secured Credit Facility is collateralized by a lien on substantially all assets of the Company including all of ATI s capital stock and all of the capital stock or other equity interest held by the Company, ATI and each of the Company s existing and future U.S. subsidiary guarantors (subject to certain limitations for equity interests of foreign subsidiaries and other exceptions set forth in the terms of the Senior Secured Credit Facility). In the second quarter of 2014, ATI entered into an amendment with the term loan lenders under its Senior Secured Credit Facility to refinance Term B-2 Loan. The interest rate margin applicable to such refinanced loan is at the Company s option, either (a) 2.75% over the LIBOR or (b) 1.75% over the greater of the prime lending rate provided by the British Banking Association or the federal funds effective rate published by the Federal Reserve Bank of New York plus 0.50%. The Company recorded $0.3 million of new deferred financing fees in the condensed consolidated financial statements. Interest on the Term B-3 Loan, as of June 30, 2014, is equal to the LIBOR (which may not be less than 1.00%) plus 2.75% based on the Company s total leverage ratio. As of June 30, 2014, these rates were approximately 2.91% and 3.75% on the Term B-2 Loan and Term B-3 Loan, respectively, and the weighted average rate on the Senior Secured Credit Facility was approximately 3.59%. The Senior Secured Credit Facility requires minimum quarterly principal payments on the Term B-2 Loan and Term B-3 Loan as well as prepayments from certain net cash proceeds of non-ordinary course asset sales and casualty and condemnation events and from a percentage of excess cash flow, if applicable. Due to voluntary prepayments, the Company has fulfilled all Term B-2 Loan required quarterly payments through its maturity date of 2017. The minimum required quarterly principal payment on the Term B-3 Loan is $4.5 million and remains through its maturity date of 2019. As of June 30, 2014, there had been no payments required for certain net cash proceeds of non-ordinary course asset sales and casualty and condemnation events. The remaining principal balance on each loan is due upon maturity.

The Senior Secured Credit Facility also provides for revolving credit borrowings. In the first quarter of 2014, ATI increased the revolving commitments available under the revolving portion of the Senior Secured Credit Facility to $465.0 million, net of an allowance for up to $75.0 million in outstanding letters of credit commitments. The increase was treated as a modification of debt under GAAP, and thus the Company recorded $0.6 million of new deferred financing fees in the condensed consolidated financial statements. Throughout the six months ended June 30, 2014, the Company made one withdrawal and payment on the revolving credit facility as part of its debt management plans. The maximum amount outstanding at any time on the revolving credit facility was $40.0 million, and the entire balance was repaid within the quarter it was borrowed. As of June 30, 2014, the Company had $453.0 million available under the revolving credit facility, net of $12.0 million in letters of credit. Revolving credit borrowings bear interest at a variable base rate plus an applicable margin based on the Company s total

leverage ratio. As of June 30, 2014, this rate would have been between approximately 2.16% and 4.25%. In addition, there is an annual commitment fee, based on the Company s total leverage ratio, which as of June 30, 2014, was equal to 0.375% of the average unused revolving credit borrowings available under the Senior Secured Credit Facility. Revolving credit borrowings are payable at the option of the Company throughout the term of the Senior Secured Credit Facility with the balance due in January 2019.

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The revolving portion of the Senior Secured Credit Facility requires the Company to maintain a specified maximum total senior secured leverage ratio of 5.50x when revolving loan commitments remain outstanding at the end of a fiscal quarter. On March 12, 2014, however, the revolving lenders holding a majority of the revolving loan commitments permanently waived and agreed that no event of default would result from any non-compliance so long as there were no revolving loans outstanding as of the last day of any fiscal quarter. As of June 30, 2014, the Company had no revolving loans outstanding, however the Company would have been in compliance with the maximum total senior secured leverage ratio, achieving a 3.11x ratio. Additionally within the terms of the Senior Secured Credit Facility, a senior secured leverage ratio at or below 3.50x results in the elimination of excess cash flow payments on the Senior Secured Credit Facility for the applicable year. The Senior Secured Credit Facility also provides certain financial incentives based on our total leverage ratio. A total leverage ratio at or below 4.00x results in a 25 basis point reduction to the applicable margin on the revolving credit facility, and a total leverage ratio at or below 3.50x results in a 12.5 basis point reduction to the revolving credit facility commitment fee and an additional 25 basis point reduction to the applicable margin on the revolving credit facility. A total leverage ratio at or below 3.25x results in a 25 basis point reduction to the applicable margin on our Term B-3 Loan. These reductions would remain in effect as long as the Company achieves a total leverage ratio at or below the related threshold. As of June 30, 2014, the total leverage ratio was 3.82x.

In addition, the Senior Secured Credit Facility, among other things, includes customary restrictions (subject to certain exceptions) on the Company s ability to incur certain indebtedness, grant certain liens, make certain investments or declare or pay certain dividends. As of June 30, 2014, the Company is in compliance with all covenants under the Senior Secured Credit Facility.

NOTE G. DERIVATIVES

The Company is exposed to certain financial risk from volatility in interest rates, foreign exchange rates and commodity prices. The risk is managed through the use of financial derivative instruments including interest rate swaps, foreign currency forward contracts and commodity swaps. The Company s current derivative instruments are used strictly as an economic hedge and not for speculative purposes. As necessary, the Company adjusts the values of the derivative instruments for counter-party or credit risk.

Interest Rate

The Company is subject to interest rate risk related to the Senior Secured Credit Facility and enters into interest rate swap contracts that are based on the LIBOR to manage a portion of this exposure. The Company has not elected hedge accounting treatment for these derivatives, and as a result, fair value adjustments are charged directly to Interest expense in the Condensed Consolidated Statements of Comprehensive Income. A summary of the Company s interest rate derivatives as of June 30, 2014 and December 31, 2013 follows (dollars in millions):

	June 30, 2014		**December 31, 2013**	
	Notional Amount	**Fair Value**	**Notional Amount**	**Fair Value**
3.75% Interest Rate Swap H, due August 2014	**$ 350.0**	**$ (1.1)**	$ 350.0	$ (7.2)
3.77% Interest Rate Swap I, due August 2014	**350.0**	**(1.1)**	350.0	(7.2)
2.96% Interest Rate Swap J, due August 2014	**125.0**	**(0.3)**	125.0	(2.0)
3.05% Interest Rate Swap K, due August 2014	**125.0**	**(0.3)**	125.0	(2.0)
3.44% Interest Rate Swap L, due August 2019*	**75.0**	**(1.7)**	75.0	(0.4)
3.43% Interest Rate Swap M, due August 2019*	**100.0**	**(2.3)**	100.0	(0.4)
3.37% Interest Rate Swap N, due August 2019*	**75.0**	**(1.6)**	75.0	(0.2)
3.19% Interest Rate Swap O, due August 2019*	**75.0**	**(1.2)**	75.0	0.2
3.08% Interest Rate Swap P, due August 2019*	**75.0**	**(0.9)**	75.0	0.4
2.99% Interest Rate Swap Q, due August 2019*	**50.0**	**(0.5)**	50.0	0.4
2.98% Interest Rate Swap R, due August 2019*	**50.0**	**(0.5)**	50.0	0.4

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unable to provide us with goods or services at the agreed-upon price, our facilities expansion could be delayed or its costs increased.

We have never manufactured our Technosphere Insulin System or any other product candidate in commercial quantities. As our product candidates move through the regulatory process, we will need to either develop the capability of manufacturing on a commercial scale or engage third-party manufacturers with this capability, and we cannot offer assurances that we will be able to do either successfully. 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. In addition, before we would be able to produce commercial quantities of Technosphere Insulin at our Danbury facility, it would have to undergo a pre-approval inspection by the FDA. The expansion process and preparation for the FDA s pre-approval inspection for commercial production at the Danbury facility could take an additional six months or longer. If we use a third-party supplier to formulate Technosphere Insulin or produce raw material, the transition could also require significant start-up time to qualify and implement the manufacturing process. If we engage a third-party manufacturer, 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 clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, entail higher costs and result in our being unable to effectively commercialize our products. Furthermore, if we or a third-party manufacturer fail to deliver the required commercial quantities of any product on a timely basis and at commercially reasonable prices, 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 on a timely basis, we would likely be unable to meet demand for such products and we would lose potential revenues.

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

Our research and development work involves the controlled storage and use of hazardous materials, including chemical, radioactive and biological materials. In addition, our manufacturing operations involve the use of CBZ-lysine, which is stable and non-hazardous under normal storage conditions, but 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 governing how we use, manufacture, store, handle and dispose of these materials. 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 million per occurrence and $2 million in the aggregate and is supplemented by an umbrella policy that provides a further $4 million of coverage; however, our insurance policy excludes pollution 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.

When we purchased the facilities located in Danbury, Connecticut in 2001, there was a soil cleanup plan in process. As part of the purchase, we obtained an indemnification from the seller related to the remediation of the soil for all known environmental conditions that existed at the time the seller acquired the property. The seller is, in turn, indemnified for these known environmental conditions by the previous owner. We initiated the final stages of the soil cleanup plan which we estimate will cost approximately $1.5 to $3.0 million to complete by the end of 2007. We also received an indemnification from the seller for environmental conditions created during its ownership of the property and for environmental problems unknown at the time that the seller acquired the property. These additional indemnities are limited to the purchase price that we paid for the Danbury facilities. In the event that any cleanup costs are imposed on us and we are unable to collect the full amount of these costs and expenses from the seller or the party responsible for the contamination, we may be required to pay these costs and our business and results of operations

may be harmed.

If we fail to enter into collaborations with third parties, we would be required to establish our own sales, marketing and distribution capabilities, which could impact the commercialization of our products and harm our business.

A broad base of physicians, including primary care physicians, internists and endocrinologists, treat patients with diabetes. A large sales force will be required in order to educate and support these physicians. Therefore, we plan to enter into collaborations with one or more pharmaceutical companies to market, distribute and sell our Technosphere Insulin System, if it is approved. If we fail to enter into collaborations, we would be required to establish our own direct sales, marketing and distribution capabilities. Establishing these capabilities can be time-consuming and expensive and we estimate that establishing a specialty sales force would cost more than $35 million. Because of our size, we would be at a disadvantage to our potential competitors, all of which either are or have collaborated with large pharmaceutical companies that have substantially more resources than we do. As a result, we would not initially be able to field a sales force as large as our competitors or provide the same degree of market research or marketing support.

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In addition, our competitors would have a greater ability to devote research resources toward expansion of the indications for their products. We cannot assure you that we will succeed in entering into acceptable collaborations, that any such collaboration will be successful or, if not, that we will successfully develop our own sales, marketing and distribution capabilities.

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

Technosphere Insulin System and our other product candidates are new and unproven. Even if any of our product candidates obtain regulatory approvals, it may not gain market acceptance among physicians, patients, third-party payers and the healthcare community. Failure to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

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

- claims for which FDA approval can be obtained, including superiority claims;
- perceived advantages and disadvantages of competitive products;
- willingness and ability of patients and the healthcare community to adopt new technologies;
- ability to manufacture the product in sufficient quantities with acceptable quality and at an acceptable cost;
- perception of patients and the healthcare community, including third-party payers, regarding the safety, efficacy and benefits of the product compared to those of competing products or therapies;
- convenience and ease of administration of the product relative to existing treatment methods;
- pricing and reimbursement of the product relative to existing treatment therapeutics and methods; and
- marketing and distribution support for the product.

Physicians will not recommend a product until clinical data or other factors demonstrate the safety and efficacy of the product as compared to other treatments. Even if the clinical safety and efficacy of our product candidates is established, physicians may elect not to recommend these product candidates for a variety of factors, including the reimbursement policies of government and third-party payers and the effectiveness of our competitors in marketing their therapies. Because of these and other factors, any product that we may develop may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

If third-party payers do not reimburse customers for our products, our products might not be used or purchased, which would adversely affect our revenues.

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

In the United States and elsewhere, sales of prescription pharmaceuticals still depend in large part on the availability of reimbursement to the consumer from third-party payers, such as governmental and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. In addition, because each third-party payer individually approves reimbursement, obtaining these approvals is a time-consuming and costly process. We would be required to provide scientific and clinical support for the use of any product to each third-party payer separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing one or more products to market, we cannot be certain that any such products would be

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considered cost-effective or that reimbursement to the consumer would be available, in which case our business and results of operations would be harmed and the market price of our common stock could decline.

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 our Technosphere Insulin System and our other product candidates expose us to potential product liability claims. A product liability claim may result in substantial judgments as well as consume significant financial and management resources and result in adverse publicity, decreased demand for a product, injury to our reputation, withdrawal of clinical trial volunteers and loss of revenues. We currently carry worldwide liability insurance in the amount of $10 million. We believe these limits are reasonable to cover us from potential damages arising from current and previous clinical trials of our Technosphere Insulin System. In addition, we carry local policies per trial in each country in which we conduct clinical trials that require us to carry coverage based on local statutory requirements. We intend to obtain product liability coverage for commercial sales in the future if our Technosphere Insulin System is approved. However, we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise, and because insurance coverage in our industry can be very expensive and difficult to obtain, we cannot assure you that we will be able to obtain sufficient coverage at an acceptable cost, if at all. If losses from such claims exceed our liability insurance coverage, we may ourselves incur substantial liabilities. If we are required to pay a product liability claim, we may not have sufficient financial resources to complete development or commercialization of any of our product candidates and, if so, our business and results of operations would be harmed and the market price of our common stock may decline.

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

In order to commercialize our product candidates successfully, we will be required to expand our work force, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, and sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel. 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.

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 our product candidates 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 our product candidates.

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

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

We have been sued by our former Chief Medical Officer. As a result of this litigation, we may incur material costs and suffer other consequences, which may adversely affect us. *

In May 2005, Dr. Cheatham filed a complaint against us in the California Superior Court. The complaint alleges causes of action for wrongful termination in violation of public policy, breach of contract and retaliation in connection with the termination of

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Dr. Cheatham s employment. In the complaint, Dr. Cheatham seeks compensatory, punitive and exemplary damages in excess of $2.0 million as well as reimbursement of attorneys fees. In June 2005, we answered the complaint and also filed a cross-complaint against Dr. Cheatham, alleging claims for libel per se, trade libel, breach of contract, breach of the implied covenant of good faith and fair dealing and breach of the duty of loyalty. In July 2005, Dr. Cheatham filed a demurrer and motion to strike our cross-complaint under California s anti-SLAPP statute. In September 2005, the California Superior Court overruled Dr. Cheatham s demurrer and denied his motion to strike our cross-complaint. In November 2005, Dr. Cheatham appealed the Court s ruling denying his motion to strike. In July 2006, we filed a motion for summary judgment , or in the alternative, for summary adjudication, requesting dismissal before trial of Dr, Cheatham s claims against us. In October 2006, the Superior Court denied the motion. In December 2006, the Court of Appeal affirmed in part and reversed in part the Superior Court s order denying Dr. Cheatham s motion to strike. Subsequently, Dr. Cheatham filed a notice of dismissal of the retaliation cause of action, and we filed a notice of dismissal of the remaining claims under the cross complaint. In April 2007, Dr. Cheatham through his counsel advised us that Dr. Cheatham intended to file a new lawsuit against us alleging that we refused to enter into a contract with Dr. Cheatham s current employer because of the pending litigation and claiming that such refusal was wrongful and legally actionable. On April 16, 2007, we filed a complaint for declaratory relief in the Circuit Court of Howard County, Mary land seeking a declaration from the Maryland court that we had not engaged in wrongful or legally actionable conduct, that Dr. Cheatham had suffered no damages and that we could in the future choose not to enter into a contract or otherwise conduct business with Dr. Cheatham s employer simply because of the pending litigation with Dr. Cheatham. Dr. Cheatham who had not filed the new lawsuit as of the date of this report has until May 23, 2007 to answer our complaint. The trial in the California Superior Court commenced on April 30, 2007 and as of the date of this report was continuing.

The litigation will result in costs and divert management s attention and resources, any of which could adversely affect our business, results of operations or financial position. We are also concerned that, despite the findings by an independent counsel following an investigation and despite the endorsement of the independent counsel s report by our board of directors, investors could give undue weight to Dr. Cheatham s allegations, resulting in damage to our reputation, or the FDA could begin an investigation, either of which could adversely affect the trading price of our common stock. To date, we have not been notified of any investigation by the FDA. If we are not successful in this litigation, we could be forced to make a significant settlement or judgment payment to Dr. Cheatham, which could adversely affect our business, results of operations or financial position.

Our facilities that are located in Southern California may be affected by man-made or natural disasters.

Our headquarters and some of our research and development activities are located in Southern California, where they are subject to a risk of man-made disasters such as terrorism and an enhanced risk of natural and other disasters such as power and telecommunications failures, mudslides, fires and earthquakes. An act of terrorism, fire, earthquake or other catastrophic loss that causes significant damage to our facilities or interruption of our business could harm our business. We do not carry insurance to cover losses caused by earthquakes, and the insurance coverage that we carry for fire damage and for business interruption may be insufficient to compensate us for any losses that we may incur.

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

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

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our internal controls over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a

company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls in the future. A material weakness in our internal controls over financial reporting would require management and our independent registered public accounting firm to evaluate our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business and on the market price of our common stock.

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RISKS RELATED TO REGULATORY APPROVALS

Our product candidates must undergo rigorous nonclinical and clinical testing and we must obtain regulatory approvals, which could be costly and time-consuming and 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 our product candidates, including our Technosphere Insulin System, 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 regulation of comparable foreign regulatory authorities are wide-ranging and govern, among other things:

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

Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. Based on our discussions with the FDA and on our understanding of the interactions between the FDA and other pharmaceutical companies developing inhaled insulin delivery systems, we expect, among other requirements, that we will need safety data covering at least two years from patients treated with our Technosphere Insulin System and that we must complete an additional six-month carcinogenicity study of Technosphere Insulin in rodents in order to obtain approval. We cannot be certain when or under what conditions we will undertake further clinical trials. The clinical trials of our product candidates may not be completed on schedule, the FDA or foreign 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 trials may not be sufficient to support regulatory approval of our various product candidates, including our Technosphere Insulin System. Even if we believe the data collected from our clinical trials are sufficient, the FDA has substantial discretion in the approval process and may disagree with our interpretation of the data. For example, even if we meet the statistical criteria for non-inferiority with respect to the primary endpoint in a pivotal clinical study (Study 102) of our Technosphere Insulin System, the FDA may deem the results uninterpretable because of issues related to the open-label, non-inferiority design of the study. 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.

The requirements governing the conduct of clinical trials and manufacturing and marketing of our product candidates, including our Technosphere Insulin System, 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 trial designs. Foreign regulatory approval processes include 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.

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. We are not aware of any precedent for the successful commercialization of products based on our technology. On January 26, 2006, the FDA approved the first pulmonary insulin product, Exubera. This may impact

the development and registration of our Technosphere Insulin System in many ways, including: the approval of Exubera may increase the difficulty of enrolling patients in our clinical trials; Exubera may be viewed as standard of care by the FDA and used as a reference for the safety/efficacy evaluations of our Technosphere Insulin System; and the approval standards set for Exubera may be applied to other products that follow including our Technosphere Insulin System. The FDA has advised us that it will regulate our Technosphere Insulin System as a combination product because of the complex nature of the system that includes the combination of a new drug (Technosphere Insulin) and a new medical device (the MedTone inhaler used to administer the insulin). The FDA indicated that the review of a future drug marketing application for our Technosphere Insulin System will involve three separate review groups of the FDA: (1) the Metabolic and Endocrine Drug Products Division; (2) the Pulmonary

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Drug Products Division; and (3) the Center for Devices and Radiological Health within the FDA that reviews medical devices. We currently understand that the Metabolic and Endocrine Drug Products Division will be the lead group and will obtain consulting reviews from the other two FDA groups. The FDA has not made an official final decision in this regard, however, and we can make no assurances at this time about what impact FDA review by multiple groups will have on the review and approval of our product or whether we are correct in our understanding of how our Technosphere Insulin System will be reviewed and approved.

Also, 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 the FDA 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. FDA review of our Technosphere Insulin System as a combination product therapy may lengthen the product development and regulatory approval process, increase our development costs and delay or prevent the commercialization of our Technosphere Insulin System.

We are developing our Technosphere Insulin System as a new treatment for diabetes utilizing unique, proprietary components. As a combination product, any changes to either the MedTone inhaler, the Technosphere material or the insulin, including new suppliers, could possibly result in FDA requirements to repeat certain clinical studies. This means, for example, that switching to an alternate delivery system could require us to undertake additional clinical trials and other studies, which could significantly delay the development and commercialization of our Technosphere Insulin System. Our product candidates that are currently in development for the treatment of cancer also face similar obstacles and costs.

We currently expect that our inhaler will be reviewed for approval as part of the NDA for our Technosphere Insulin System. No assurances exist that we will not be required to obtain separate device clearances or approval for use of our inhaler with our Technosphere Insulin System. This may result in our being subject to medical device review user fees and to other device requirements to market our inhaler and may result in significant delays in commercialization. Even if the device component is approved as part of our NDA for our Technosphere Insulin System, numerous device regulatory requirements still apply to the device part of the drug-device combination.

We have only limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain timely approvals from the FDA or foreign regulatory agencies, if at all.

We will not be able to commercialize our Technosphere Insulin System or any other product candidates until we have obtained regulatory approval. We have no experience as a company in late-stage regulatory filings, such as preparing and submitting NDAs, which may place us at risk of delays, overspending and human resources inefficiencies. Any delay in obtaining, or inability to obtain, regulatory approval could harm our business.

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

Even if we comply with regulatory requirements, we may not be able to obtain the labeling claims necessary or desirable for product promotion. We may also be required to undertake post-marketing trials. 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 trials, changes in labeling of, or indications of use for, our products and/or additional marketing applications may be required. If we encounter any of the foregoing problems, our business and results of operations will be harmed and the market price of our common stock may decline.

Even if we obtain regulatory approval for our product candidates, such approval may be limited and we will be subject to stringent, ongoing government regulation.

Even if regulatory authorities approve any of our product candidates, they could approve less than the full scope of uses or labeling that we seek or otherwise require special warnings or other restrictions on use or marketing. Regulatory authorities may limit the segments of the diabetes population to which we or others may market our

Technosphere Insulin System or limit the target population for our other product candidates. Based on currently available clinical studies, we believe that our Technosphere Insulin System may have certain advantages over currently approved insulin products including its approximation of the natural early insulin secretion normally seen in healthy individuals following the beginning of a meal. Nonetheless, there are no assurances that these and other advantages, if any, of our Technosphere Insulin System have clinical significance or can be confirmed in head-to-head clinical trials against appropriate approved comparator insulin drug products. Such comparative clinical trials are required to make these types of superiority claims in labeling or advertising. These aforementioned observations and others may therefore not be capable of substantiation in comparative clinical trials prior to our NDA submission, if at all, or otherwise may not be suitable for inclusion in product labeling or advertising and, as a result, our Technosphere Insulin System may not have competitive advantages when compared to other insulin products.

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The manufacture, marketing and sale of these product candidates will be subject to stringent and ongoing government regulation. The FDA may also withdraw product approvals if problems concerning safety or efficacy of the product occur following approval. In response to questions that have been raised about the safety of certain approved prescription products, including the lack of adequate warnings, the FDA and U.S. Congress are currently considering new regulatory and legislative approaches to advertising, monitoring and assessing the safety of marketed drugs, including legislation providing the FDA with authority to mandate labeling changes for approved pharmaceutical products, particularly those related to safety. We also cannot be sure that the current FDA and U.S. Congressional initiatives pertaining to ensuring the safety of marketed drugs or other developments pertaining to the pharmaceutical industry will not adversely affect our operations.

We also are required to register our establishments and list our products with the FDA and certain state agencies. We and any third-party manufacturers or suppliers must continually adhere to federal regulations setting forth requirements, known as cGMP (for drugs) and QSR (for medical devices), and their foreign equivalents, which are enforced by the FDA and other national regulatory bodies through their facilities inspection programs. If our facilities, or the facilities of our manufacturers or suppliers, cannot pass a preapproval plant inspection, the FDA will not approve the marketing of our product candidates. In complying with cGMP and foreign regulatory requirements, we and any of our potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that our products meet applicable specifications and other requirements. QSR requirements also impose extensive testing, control and documentation requirements. State regulatory agencies and the regulatory agencies of other countries have similar requirements. In addition, we will be required to comply with regulatory requirements of the FDA, state regulatory agencies and the regulatory agencies of other countries concerning the reporting of adverse events and device malfunctions, corrections and removals (e.g., recalls), promotion and advertising and general prohibitions against the manufacture and distribution of adulterated and misbranded devices. Failure to comply with these regulatory requirements could result in civil fines, product seizures, injunctions and/or criminal prosecution of responsible individuals and us. Any such actions would have a material adverse effect on our business and results of operations.

Our insulin supplier does not yet supply human recombinant insulin for an FDA-approved product and will likely be subject to an FDA preapproval inspection before the agency will approve a future marketing application for our Technosphere Insulin System.

Our insulin supplier sells its product outside of the United States. However, we can make no assurances that our insulin supplier will be acceptable to the FDA. If we were required to find a new or additional supplier of insulin, we would be required to evaluate the new supplier s ability to provide insulin that meets our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and future commercialization of our Technosphere Insulin System. We also depend on suppliers for other materials that comprise our Technosphere Insulin System, including our MedTone inhaler and cartridges. All of our device suppliers must comply with relevant regulatory requirements including QSR. It also is likely that major suppliers will be subject to FDA preapproval inspections before the agency will approve a future marketing application for our Technosphere Insulin System. At the present time our insulin supplier is certified to the ISO9001:2000 Standard. There can be no assurance, however, that if the FDA were to conduct a preapproval inspection of our insulin supplier or other suppliers, that the agency would find that the supplier substantially comply 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.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the indicated uses for which the product candidate may be marketed or contain requirements for potentially costly post-marketing follow-up clinical trials.

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

At present, there are a number of clinical trials being conducted by us and other pharmaceutical companies involving insulin delivery systems. If we discover that our lead product candidate is associated with a significantly increased frequency of adverse events, or if other pharmaceutical companies announce that they observed frequent adverse events in their trials involving the pulmonary delivery of insulin, we could encounter delays in the timing of our clinical trials or difficulties in obtaining the approval of our Technosphere Insulin System. As well, the public perception of our lead product candidates might be adversely affected, which could harm our business and results of operations and cause the market price of our common stock to decline, even if the concern relates to another company s products or product candidates.

There are also a number of clinical trials being conducted by other pharmaceutical companies involving compounds similar to, or competitive with, our other product candidates. Adverse results reported by these other companies in their clinical trials could delay or prevent us from obtaining regulatory approval or negatively impact public perception of our product candidates, which could harm our

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business and results of operations and cause the market price of our common stock to decline.

RISKS RELATED TO INTELLECTUAL PROPERTY

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

Our commercial success depends, in large part, on our ability to obtain and maintain intellectual property protection for our technology. Our ability to do so will depend on, among other things, complex legal and factual questions, and it should be noted that the standards regarding intellectual property rights in our fields are still evolving. We attempt to protect our proprietary technology through a combination of patents, trade secrets, know-how 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 similar alternative technologies.

Moreover, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be afforded by our patents. A third party may challenge the validity or enforceability of a patent after its issuance by various proceedings such as oppositions in foreign jurisdictions or re-examinations in the United States. 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. We also execute confidentiality agreements with outside collaborators. There can be no assurance, however, that these agreements will provide meaningful protection for our inventions, trade secrets, know-how or other proprietary information in the event of unauthorized use or disclosure of such information. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business, results of operations and financial condition could be adversely affected.

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

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

Interference proceedings brought by the U.S. Patent and Trademark Office, or USPTO, may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. We may not prevail in any litigation or interference proceeding in which we are involved. Even if we do prevail, these proceedings can be very expensive and distract our management.

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

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

Over the past three decades the number of patents issued to biotechnology companies has expanded dramatically. As a result it is not always clear to industry participants, including us, which patents cover the multitude of biotechnology product types. Ultimately, the

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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. For example, in August 2006, Novo Nordisk filed a lawsuit against Pfizer claiming that Pfizer s product Exubera infringes certain patents owned by Novo Nordisk that cover inhaled insulin treatment for diabetes. In its lawsuit, Novo Nordisk is seeking compensatory damages and permanent injunctive relief. Novo Nordisk had also filed a motion for a preliminary injunction, and while it was not granted, it could have substantially impacted Pfizer s ability to commercialize Exubera while the lawsuit is in progress had it been granted.

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.

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

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

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

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

We have not selected trade names for some of our products and product candidates; therefore, we have not filed trademark registrations for our potential trade names for those products in all jurisdictions, nor can we assure that we will be granted registration of those potential trade names for which we have filed. Although we intend to defend any opposition to our trademark registrations, no assurance can be given that any of our trademarks will be registered in

the United States or elsewhere or 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.

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RISKS RELATED TO OUR COMMON STOCK

Our stock price is volatile.

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

- the progress and results of our clinical trials;
- announcements by us or our competitors concerning their clinical trial results, acquisitions, strategic alliances, technological innovations and newly approved commercial products;
- the availability of critical materials used in developing and manufacturing our Technosphere Insulin System or other product candidates;
- developments or disputes concerning our patents or proprietary rights;
- developments in our litigation with our former Chief Medical Officer;
- the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;
- changes in securities analysts estimates of our financial and operating performance;
- general market conditions and fluctuations for emerging growth and pharmaceutical market sectors;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- discussion of our Technosphere Insulin System, 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; and
- general economic, political or stock market conditions.

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

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

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

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

Our Chief Executive Officer and principal stockholder can individually control our direction and policies, and his interests may be adverse to the interests of our other stockholders. After his death, his stock will be left to

his funding foundations for distribution to various charities, and we cannot assure you of the manner in which those entities will manage their holdings. *

Mr. Mann has been our primary source of financing to date. At March 31, 2007, Mr. Mann beneficially owned approximately 41.1% of our outstanding shares of capital stock. We believe members of Mr. Mann s family beneficially owned at least an additional 1.4% of our outstanding shares of common stock, although Mr. Mann does not have voting or investment power with respect to these shares. By virtue of his holdings, Mr. Mann can and will continue to be able to effectively control the election of the members of our board of directors, our management and our affairs and prevent corporate transactions such as mergers, consolidations or the sale of all

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or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders or cause a transaction that we or our other stockholders may view as unfavorable.

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

The future sale of our common stock or the conversion of our senior convertible notes into common stock could negatively affect our stock price. *

As of March 31, 2007, we had approximately 73.4 million shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock may decline. Likewise the issuance of additional shares of our common stock upon the conversion of some or all of our senior convertible notes could adversely affect the trading price of our common stock. In addition, the existence of these notes may encourage short selling of our common stock by market participants. Furthermore, if we were to include in a company-initiated registration statement shares held by our stockholders pursuant to the exercise of their registrations rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

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 may decline and our existing stockholders may experience significant dilution.

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

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

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

We have paid no cash dividends on any of our capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition,

results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, the success of your investment in our common stock will likely depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value after the offering or even maintain the price at which you purchased your shares, and you may not realize a return on your investment in our common stock.

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

There were no sales of equity securities by us that were not registered under the Securities Act of 1933, as amended, during the first quarter of 2007.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

On April 4, 2007, MannKind Corporation entered into a contractor agreement with Torcon, Inc. related to the expansion of our manufacturing facility in Danbury, Connecticut. The sum of the cost of work and the contractor s fee is guaranteed by the contractor not to exceed $114.0 million.

ITEM 6. EXHIBITS

Exhibit Number	Description of Document
3.1(1)	Restated Certificate of Incorporation
3.2(1)	Amended and Restated Bylaws.
31.1	Certification of the Chief Executive Officer Pursuant to Rules 13a-14(a) or 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) or 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32	Certifications of the Chief Executive Officer and Chief Financial Officer Pursuant to Rules 13a-14(b) or 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350).

(1) Incorporated by reference to MannKind s registration statement on Form S-1 (File No. 333-115020), filed with the SEC on April 30, 2004, as amended.

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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: May 10, 2007

MANNKIND CORPORATION

By: /s/ Richard L. Anderson
Richard L. Anderson
Corporate Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

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