MANNKIND CORP
Form 10-Q
August 03, 2009

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**
**Form 10-Q**

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

**For the quarterly period ended June 30, 2009**

**Or**

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

**For the transition period from to .**

**Commission file number: 000-50865**

**MannKind Corporation**

*(Exact name of registrant as specified in its charter)*

| **Delaware** | **13-3607736** |
|---|---|
| *(State or other jurisdiction of incorporation or organization)* | *(I.R.S. Employer Identification No.)* |
| **28903 North Avenue Paine Valencia, California** | **91355** |
| *(Address of principal executive offices)* | *(Zip Code)* |

**(661) 775-5300**

**(***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 þ No o
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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o
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 the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No þ
As of July 23, 2009, there were 103,747,874 shares of the registrant s common stock, $.01 par value per share, outstanding.

**MANNKIND CORPORATION**
**Form 10-Q**
**For the Quarterly Period Ended June 30, 2009**
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**PART 1: FINANCIAL INFORMATION**
**ITEM 1. FINANCIAL STATEMENTS**
**MANNKIND CORPORATION AND SUBSIDIARIES**
**(A Development Stage Company)**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(Unaudited)**
**(In thousands except share data)**

| | June 30, 2009 | December 31, 2008 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 31,328 | $ 27,648 |
| Marketable securities | 2,639 | 18,844 |
| State research and development credit exchange current | | 1,500 |
| Prepaid expenses and other current assets | 4,533 | 5,983 |
| Total current assets | 38,500 | 53,975 |
| Property and equipment net | 226,221 | 226,436 |
| State research and development credit exchange receivable net of current portion | 1,850 | 1,500 |
| Other assets | 555 | 548 |
| Total | $ 267,126 | $ 282,459 |
| **LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)** | | |
| Current liabilities: | | |
| Accounts payable | $ 11,171 | $ 15,630 |
| Accrued expenses and other current liabilities | 27,718 | 37,842 |
| Total current liabilities | 38,889 | 53,472 |
| Senior convertible notes | 112,506 | 112,253 |
| Note payable to related party | 135,000 | 30,000 |
| Total liabilities | 286,395 | 195,725 |
| Commitments and contingencies | | |
| Stockholders equity (deficit): | | |
| Undesignated preferred stock, $0.01 par value - 10,000,000 shares authorized; no shares issued or outstanding at June 30, 2009 and December 31, 2008 | | |
| Common stock, $0.01 par value - 150,000,000 shares authorized; 103,646,376 and 102,008,096 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively | 1,036 | 1,020 |
| Additional paid-in capital | 1,478,908 | 1,469,497 |
| Accumulated other comprehensive income (loss) | (119) | 295 |
| Deficit accumulated during the development stage | (1,499,094) | (1,384,078) |
| Total stockholders equity (deficit) | (19,269) | 86,734 |

| | | |
|---|---|---|
| Total | $ 267,126 | $ 282,459 |

See notes to condensed consolidated financial statements.

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**MANNKIND CORPORATION AND SUBSIDIARIES**
**(A Development Stage Company)**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
**(Unaudited)**
**(In thousands, except per share data)**

| | Three months ended June 30, | | Six months ended June 30, | | Cumulative period from February 14, 1991 (date of inception) to June 30, |
|---|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 | 2009 |
| Revenue | $ | $ | $ | $ 20 | $ 2,988 |
| Operating expenses: | | | | | |
| Research and development | 39,849 | 67,574 | 82,738 | 126,019 | 1,080,220 |
| General and administrative | 13,537 | 13,290 | 28,454 | 28,930 | 274,296 |
| In-process research and development costs | | | | | 19,726 |
| Goodwill impairment | | | | | 151,428 |
| Total operating expenses | 53,386 | 80,864 | 111,192 | 154,949 | 1,525,670 |
| Loss from operations | (53,386) | (80,864) | (111,192) | (154,929) | (1,522,682) |
| Other income (expense) | 283 | (60) | 353 | | (1,589) |
| Interest expense on note payable to related party | (1,398) | | (1,990) | | (3,514) |
| Interest expense on senior convertible notes | (1,130) | (124) | (2,245) | (461) | (8,202) |
| Interest income | 27 | 1,222 | 58 | 4,143 | 36,919 |
| Loss before provision for income taxes | (55,604) | (79,826) | (115,016) | (151,247) | (1,499,068) |
| Income taxes | | | | | (26) |
| Net loss | (55,604) | (79,826) | (115,016) | (151,247) | (1,499,094) |
| Deemed dividend related to beneficial conversion feature of convertible preferred stock | | | | | (22,260) |
| Accretion on redeemable preferred stock | | | | | (952) |
| Net loss applicable to common stockholders | $ (55,604) | $ (79,826) | $ (115,016) | $ (151,247) | $ (1,522,306) |
| Net loss per share applicable to common stockholders basic and | $ (0.54) | $ (0.79) | $ (1.13) | $ (1.49) | |

| | | | | |
|---|---|---|---|---|
| diluted | | | | |
| Shares used to compute basic and diluted net loss per share applicable to common stockholders | 102,322 | 101,427 | 102,177 | 101,418 |

See notes to condensed consolidated financial statements.

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**MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company)**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(Unaudited)**
**(In thousands)**

| | Six months ended June 30, | | Cumulative Period from February 14, 1991 (Date of Inception) to June 30, |
|---|---|---|---|
| | 2009 | 2008 | 2009 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | | |
| Net loss | $ (115,016) | $ (151,247) | $ (1,499,094) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 9,233 | 3,804 | 69,647 |
| Stock-based compensation expense | 12,889 | 12,068 | 92,512 |
| Stock expense for shares issued pursuant to research agreement | | | 3,018 |
| Loss on sale, abandonment/disposal or impairment of property and equipment | | 121 | 10,706 |
| Accrued interest on investments, net of amortization of discounts | (12) | | (191) |
| In-process research and development | | | 19,726 |
| Goodwill impairment | | | 151,428 |
| Loss on available-for-sale securities | | | 229 |
| Other, net | 3 | | 1,108 |
| Changes in assets and liabilities: | | | |
| State research and development credit exchange receivable | 1,150 | 81 | (1,850) |
| Prepaid expenses and other current assets | 1,450 | 2,343 | (2,933) |
| Other assets | (7) | (1) | (555) |
| Accounts payable | (3,259) | (5,982) | 9,101 |
| Accrued expenses and other current liabilities | (11,453) | (1,174) | 22,301 |
| Other liabilities | | (24) | (2) |
| Net cash used in operating activities | (105,022) | (140,011) | (1,124,849) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | | |
| Purchase of marketable securities | (2,000) | | (792,601) |
| Sales/ maturities of marketable securities | 17,800 | | 790,565 |
| Purchase of property and equipment | (12,548) | (48,255) | (304,405) |
| Proceeds from sale of property and equipment | | 70 | 284 |
| Net cash (used in) provided by investing activities | 3,252 | (48,185) | (306,157) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | |
| Issuance of common stock and warrants | 668 | 424 | 1,141,216 |
| Collection of Series C convertible preferred stock subscriptions receivable | | | 50,000 |

| | | | |
|---|---|---|---|
| Issuance of Series B convertible preferred stock for cash | | | 15,000 |
| Cash received for common stock to be issued | | | 3,900 |
| Repurchase of common stock | | | (1,028) |
| Put shares sold to majority stockholder | | | 623 |
| Borrowings under lines of credit | | | 4,220 |
| Proceeds from notes receivables | | | 1,742 |
| Borrowings on notes payable to related party | 105,000 | | 205,000 |
| Principal payments on notes payable to principal stockholder | | | (70,000) |
| Borrowings on notes payable | | | 3,460 |
| Principal payments on notes payable | | | (1,667) |
| Proceeds from senior convertible notes | | | 111,267 |
| Payment of employment taxes related to vested restricted stock units | (218) | (59) | (1,399) |
| Net cash provided by financing activities | 105,450 | 365 | 1,462,334 |

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| | Six months ended June 30, | | Cumulative Period from February 14, 1991 (Date of Inception) to June 30, |
|---|---|---|---|
| | 2009 | 2008 | 2009 |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | $ 3,680 | $ (187,831) | $ 31,328 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 27,648 | 368,285 | |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | $ 31,328 | $ 180,454 | $ 31,328 |
| SUPPLEMENTAL CASH FLOWS DISCLOSURES: | | | |
| Cash paid for income taxes | $ | $ | $ 26 |
| Interest paid in cash | 2,761 | | 13,117 |
| Accretion on redeemable convertible preferred stock | | | (952) |
| Issuance of common stock upon conversion of notes payable | | | 3,331 |
| Increase in additional paid-in capital resulting from merger | | | 171,154 |
| Issuance of common stock for notes receivable | | | 2,758 |
| Issuance of put option by stockholder | | | (2,949) |
| Put option redemption by stockholder | | | 1,921 |
| Issuance of Series C convertible preferred stock subscriptions | | | 50,000 |
| Issuance of Series A redeemable convertible preferred stock | | | 4,296 |
| Conversion of Series A redeemable convertible preferred stock | | | (5,248) |
| Non-cash construction in progress and property and equipment | 2,814 | 14,775 | 2,814 |

In connection with the Company s initial public offering, all shares of Series B and Series C convertible preferred stock, in the amount of $15.0 million and $50.0 million, respectively, automatically converted into common stock in August 2004.

See notes to condensed consolidated financial statements.

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**MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company)**
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**(Unaudited)**

**1. Description of business and basis of presentation**

The accompanying unaudited condensed consolidated financial statements of MannKind Corporation and its subsidiaries (the Company ), have been prepared in accordance with generally accepted accounting principles in the United States of America ( GAAP ) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the SEC ). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These statements should be read in conjunction with the financial statements and notes thereto included in the Company s latest audited annual financial statements. The audited statements for the year ended December 31, 2008 are included in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2008 filed with the SEC on February 27, 2009 (the Annual Report ).

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the six months ended June 30, 2009 may not be indicative of the results that may be expected for the full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates or assumptions. The more significant estimates reflected in these accompanying financial statements involve accrued expenses, the valuation of stock-based compensation and the determination of the provision for income taxes and corresponding deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets.

***Business*** The Company is a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. The Company s lead product candidate, AFRESA®, is an ultra rapid-acting insulin. In March 2009, the Company submitted a new drug application ( NDA ) to the U.S. Food and Drug Administration ( FDA ) requesting approval of AFRESA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. The FDA accepted the Company s NDA for filing in May 2009. AFRESA consists of the Company s proprietary Technosphere particles onto which insulin molecules are loaded. These loaded particles are then aerosolized and inhaled deep into the lung using the Company s AFRESA inhaler.

***Basis of Presentation*** The Company is considered to be in the development stage as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, and raising capital. Since its inception through June 30, 2009, the Company has reported accumulated net losses of $1.5 billion and accumulated deficit in stockholders equity of $19.3 million, which include a goodwill impairment charge of $151.4 million, and cumulative negative cash flow from operations of $1.1 billion. It is costly to develop therapeutic products and conduct clinical trials for these products. At June 30, 2009 the Company s capital resources consisted of cash, cash equivalents, and marketable securities of $34.0 million (including a $2.0 million certificate of deposit held as collateral for foreign exchange hedging instruments) and $215.0 million of available borrowings under the loan agreement with an entity controlled by the Company s principal shareholder (see Note 11). Based upon the Company s current expectations, management believes the Company s existing capital resources will enable it to continue planned operations through the second quarter of 2010. However, the Company cannot provide assurances that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. Accordingly, the Company expects that it will need to raise additional capital, either through the sale of equity and/or debt securities, a strategic business collaboration with a pharmaceutical company or the establishment of other funding facilities, in order to continue the development and commercialization of AFRESA and other product candidates and to support its other ongoing activities.

***Fair Value of Financial Instruments*** The carrying amounts of financial instruments, which include cash equivalents, marketable securities and accounts payable, approximate their fair values due to their relatively short maturities. The fair value of the note payable to an entity controlled by the Company s principal shareholder cannot be reasonably estimated as the Company would not be able to obtain a similar credit arrangement in the current economic environment. The senior convertible notes had a carrying value of $112.5 million and $112.3 million and an estimated fair value of $71.9 million and $53.9 million as of June 30, 2009 and December 31, 2008, respectively.

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***Subsequent Events*** We have evaluated subsequent events through the date the financial statements were issued, August 3, 2009.

***Recently Issued Accounting Standards*** On April 9, 2009, the Financial Accounting Standards Board ( FASB ) issued three FASB Staff Positions ( FSP ): FSP No. FAS 157-4 *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly* ( FSP No. FAS 157-4 ); FSP No. FAS 115-2 and FAS 124-2 *Recognition and Presentation of Other-Than-Temporary Impairments* ( FSP No. FAS 115-2 and FAS 124-2 ); and FSP No. FAS 107-1 and APB 28-1 *Interim Disclosures About Fair Value of Financial Instruments* ( FSP No. FAS 107-1 and APB 28-1 ). FSP No. FAS 157-4 provides application guidance on measuring fair value when the volume and level of activity has significantly decreased and identifying transactions that are not orderly. FSP No. FAS 115-2 and FAS 124-2 provides a new other-than-temporary impairment model for debt securities only which shifts the focus from an entity s intent to hold until recovery to its intent to sell. FSP No. FAS 107-1 and APB 28-4 expands the fair value disclosures required for all financial instruments within the scope of FASB Statement No. 107 *Disclosures About Fair Value of Financial Instruments* to interim periods. All three FSPs are effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The adoption of these FSPs did not have a material impact on the Company s results of operations, financial position or cash flows.

On May 28, 2009, the FASB issued Statement of Financial Accounting Standards ( FASB Statement ) No. 165 *Subsequent Events* ( FASB Statement No. 165 ), which provides guidance on management s assessment of subsequent events. Historically, management had relied on auditing literature for guidance on assessing and disclosing subsequent events. FASB Statement No. 165 is not expected to significantly change practice because its guidance is similar to that contained in auditing guidance. The statement is effective prospectively for interim and annual periods ending after June 15, 2009. The adoption of this statement did not have a material impact on the Company s results of operations, financial position, cash flows or financial statement disclosures.

On June 29, 2009, the FASB issued FASB Statement No. 168, *FASB Accounting Statement on Codification and Hierarchy of Generally Accepted Accounting Principles- a replacement of FASB Statement No. 162* ( FASB Statement No. 168 ), which will become the source of authoritative GAAP recognized by the FASB to be applied by all nongovernmental agencies. The statement is effective for financial statements issued for interim and annual periods ending after September 15, 2009 and is not expected to have a material impact on the Company s results of operations, financial position or cash flows.

**2. Investment in securities**

The following is a summary of the available-for-sale securities classified as current assets (in thousands).

| | June 30, 2009 | | | December 31, 2008 | | |
|---|---|---|---|---|---|---|
| | Cost Basis | Gross Unrealized Loss | Fair Value | Cost Basis | Gross Unrealized Gain | Fair Value |
| Available-for-sale securities | 2,761 | (122) | 2,639 | 18,549 | 295 | 18,844 |

The Company s available-for-sale securities at June 30, 2009 consist principally of a $2.0 million certificate of deposit with a maturity greater than 90 days, held as collateral for foreign exchange hedging instruments, and a common stock investment, which is stated at fair value based on quoted prices in an active market (Level 1 in the fair value hierarchy). The Company s available-for-sale securities at December 31, 2008 consist principally of US agency securities, which are stated at fair value based on quoted prices for similar securities in active markets (Level 2 in the fair value hierarchy). The Company s policy is to maintain a highly liquid short-term investment portfolio. Proceeds from the sales and maturities of available-for-sale securities amounted to approximately $17.8 million for the six months ended June 30, 2009. Gross realized gains and losses for available-for-sale securities were insignificant and recorded as other income (expense). Gross unrealized gains and losses are included in other comprehensive income

(loss).

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**3. Accrued expenses and other current liabilities**

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

| | June 30, 2009 | December 31, 2008 |
|---|---|---|
| Salary and related expenses | $ 13,022 | $ 12,452 |
| Research and clinical trial costs | 9,022 | 13,438 |
| Accrued interest | 1,589 | 204 |
| Construction in progress | 729 | 3,327 |
| Other | 3,356 | 8,421 |
| Accrued expenses and other current liabilities | $ 27,718 | $ 37,842 |

**4. Accounting for stock-based compensation**

Total stock-based compensation expense recognized in the accompanying condensed consolidated statements of operations for the three and six months ended June 30, 2009 and 2008 was as follows (in thousands):

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| Stock-based compensation | $ 7,053 | $ 6,634 | $ 12,889 | $ 12,068 |

As of June 30, 2009, there were $9.1 million and $22.3 million of unrecognized compensation costs related to options and restricted stock units, respectively, which are expected to be recognized over the remaining weighted average vesting period of 1.9 years.

On May 21, 2009, the Company s stockholders approved an amendment to the 2004 Equity Incentive Plan to increase the number of shares of common stock available for issuance under the plan by 5,000,000 shares.

**5. Comprehensive Loss**

FASB Statement No. 130, *Reporting Comprehensive Income,* ( FASB Statement No. 130 ), requires reporting and displaying comprehensive income (loss) and its components, which, for the Company, includes net loss and unrealized gains and losses on investments and cumulative translation gains and losses. In accordance with FASB Statement No. 130, the accumulated balance of other comprehensive income (loss) is disclosed as a separate component of stockholders equity. For the three and six months ended June 30, 2009 and 2008, comprehensive loss consisted of (in thousands):

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| Net loss | $ (55,604) | $ (79,826) | $ (115,016) | $ (151,247) |
| Other comprehensive loss: | | | | |
| Unrealized loss on investments | (476) | | (417) | |
| Cumulative translation gain | 3 | | 3 | |
| Comprehensive loss | $ (56,077) | $ (79,286) | $ (115,430) | $ (151,247) |

**6. Net loss per common share**

Basic net loss per share excludes dilution for potentially dilutive securities and is computed by dividing loss applicable to common stockholders by the weighted average number of common shares outstanding during the period.

Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share for all of the periods presented in the accompanying statements of operations because the reported net loss in each of these periods results in their inclusion being antidilutive. Antidilutive securities, which consist of stock options, restricted stock units, warrants, and shares that could be issued upon conversion of the senior convertible notes, that are not included in the diluted net loss per share calculation consisted of an aggregate of 17,072,136 shares and 17,985,754 shares as of June 30, 2009 and 2008, respectively.

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**7. State research and development credit exchange receivable**

The State of Connecticut provides certain companies with the opportunity to exchange certain research and development income tax credit carryforwards for cash in exchange for forgoing the carryforward of the research and development income tax credits. The program provides for an exchange of research and development income tax credits for cash equal to 65% of the value of corporation tax credit available for exchange. Estimated amounts receivable under the program are recorded as a reduction of research and development expenses. At June 30, 2009, the estimated amount receivable under the program was $1.9 million.

**8. Property and equipment net**

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

| | Estimated Useful Life (Years) | June 30, 2009 | December 31, 2008 |
|---|---|---|---|
| Land | | $ 5,273 | $ 5,273 |
| Buildings | 39-40 | 54,927 | 53,786 |
| Building improvements | 5-40 | 112,829 | 111,346 |
| Machinery and equipment | 3-15 | 78,676 | 70,633 |
| Furniture, fixtures and office equipment | 5-10 | 5,388 | 6,622 |
| Computer equipment and software | 3 | 15,887 | 14,818 |
| Leasehold improvements | | 184 | 184 |
| Construction in progress | | 13,428 | 15,165 |
| | | 286,592 | 277,827 |
| Less accumulated depreciation and amortization | | (60,371) | (51,391) |
| Property and equipment net | | $ 226,221 | $ 226,436 |

Leasehold improvements are amortized over the shorter of the term of the lease or the service lives of the improvements.

Depreciation and amortization expense related to property and equipment for the three and six months ended June 30, 2009 and 2008 was as follows (in thousands):

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| Depreciation and amortization expense | $ 4,590 | $ 1,807 | $ 8,980 | $ 3,561 |

Capitalized interest added to property and equipment during the three and six months ended June 30, 2009 and 2008 was as follows (in thousands):

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| Capitalized Interest | $ 75 | $ 1,076 | $ 164 | $ 1,937 |

**9. Warrants**

In connection with the sale of common stock in the private placement which closed in August 2005, the Company concurrently issued warrants to purchase up to 3,426,000 shares of common stock at an exercise price of $12.228 per share. These warrants became exercisable in February 2006 and expire in August 2010. During the six months ended June 30, 2009, no warrants were exercised. As of June 30, 2009, warrants to purchase 2,882,873 shares of common stock remained outstanding.

**10. Commitments and contingencies**

***Supply Commitments*** As of June 30, 2009, the Company had a binding annual commitment for insulin purchases with Organon N.V. ( Organon ) aggregating approximately $101.6 million over the period from 2009 through 2012. If the Company terminates the supply agreement following failure to obtain or maintain regulatory approval of AFRESA or either party terminates the agreement

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following the parties inability to agree to changes to product specifications mandated after regulatory approval, the Company will be required to pay Organon a specified termination fee if Organon is unable to sell certain quantities of insulin to other parties.

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

***Litigation*** The Company is involved in various legal proceedings and other matters. In accordance with SFAS No. 5, *Accounting for Contingencies*, the Company would record a provision for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

**11. Related-party loan arrangement**

In October 2007, the Company entered into a $350.0 million loan arrangement with its principal stockholder. Under the arrangement, the Company can borrow up to a total of $350.0 million. On February 26, 2009, the promissory note underlying the loan arrangement was revised as a result of the principal stockholder being licensed as a finance lender under the California Finance Lenders Law. Accordingly, the lender was revised to The Mann Group LLC, an entity controlled by the Company s principal stockholder. This new licensing also eliminated the need for draw restrictions under the previous loan arrangement which enabled the Company to borrow up to a total of $350.0 million from time to time through and including December 31, 2011 with appropriate notice to the lender. Interest will accrue on each outstanding advance at a fixed rate equal to the one-year LIBOR rate as reported by the *Wall Street Journal* on the date of such advance plus 3% per annum and will be payable quarterly in arrears. Principal repayment is due on December 31, 2011. At any time after January 1, 2010, the lender can require the Company to prepay up to $200.0 million in advances that have been outstanding for at least 12 months. If the lender exercises this right, the Company will have until the earlier of 180 days after the lender provides written notice or December 31, 2011 to prepay such advances. In the event of a default, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at the lender s option, and the interest rate will increase to the one-year LIBOR rate calculated on the date of the initial advance or in effect on the date of default, whichever is greater, plus 5% per annum. Any borrowings under the loan arrangement will be unsecured. The loan arrangement contains no financial covenants. There are no warrants associated with the loan arrangement, nor are advances convertible into the Company s common stock.

The amount outstanding under the arrangement was $135.0 million and $30.0 million at June 30, 2009 and December 31, 2008, respectively. As of June 30, 2009, the Company had accrued interest of $1.4 million related to the amount outstanding.

**12. Senior convertible notes**

On December 12, 2006, the Company completed an offering of $115.0 million aggregate principal amount of 3.75% Senior Convertible Notes due 2013 (the Notes ), including $15.0 million aggregate principal amount of the Notes sold pursuant to the underwriters over-allotment option that was exercised in full. The Notes are governed by the terms of an indenture dated as of November 1, 2006 and a First Supplemental Indenture, dated as of December 12, 2006. The Notes bear interest at the rate of 3.75% per year on the principal amount of the Notes, payable in cash semi-annually in arrears on June 15 and December 15 of each year, beginning June 15, 2007. As of June 30, 2009 and December 31, 2008, the Company had accrued interest of $0.2 million and $0.2 million, respectively, related to the Notes. The Notes are general, unsecured, senior obligations of the Company and effectively rank junior in right of payment to all of the Company s secured debt, to the extent of the value of the assets securing such debt, and to the debt and all other

liabilities of the Company s subsidiaries. The maturity date of the Notes is December 15, 2013 and payment is due in full on that date for unconverted securities. Holders may convert, at any time prior to the close of business on the business day immediately preceding the stated maturity date, any outstanding Notes into shares of the Company s common stock at an initial conversion rate of 44.5002 shares per $1,000 principal amount of Notes, which is equal to a conversion price of approximately $22.47 per share, subject to adjustment. Except in certain circumstances, if the Company undergoes a fundamental change: (1) the Company will pay a make-whole premium on the Notes converted in connection with a fundamental change by increasing the conversion rate on such Notes, which amount, if any, will be based on the Company s common stock price and the effective date of the fundamental

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change, and (2) each holder of the Notes will have the option to require the Company to repurchase all or any portion of such holder s Notes at a repurchase price of 100% of the principal amount of the Notes to be repurchased plus accrued and unpaid interest, if any. The Company incurred approximately $3.7 million in issuance costs which are recorded as an offset to the Notes in the accompanying condensed consolidated balance sheets. These costs are being amortized to interest expense using the effective interest method over the term of the Notes.

Amortization of debt issuance expense in connection with the Notes during the three and six months ended June 30, 2009 and 2008 was as follows (in thousands):

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| Amortization expense | $ 127 | $ 122 | $ 253 | $ 243 |

**13. Income taxes**

As discussed in Note 14 to the financial statements in the Company s Annual Report, management of the Company has concluded, in accordance with applicable accounting standards, that it is more likely than not that the Company may not realize the benefit of its deferred tax assets. Accordingly, net deferred tax assets have been fully reserved.

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109* ( FIN 48 ), which clarifies the accounting and disclosure for uncertainty in tax positions, as defined. FIN 48 seeks to reduce the diversity in practice associated with certain aspects of the recognition and measurement related to accounting for income taxes. The Company is subject to the provisions of FIN 48 as of January 1, 2007. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to FIN 48. The cumulative effect, if any, of applying FIN 48 is to be reported as an adjustment to the opening balance of retained earnings in the year of adoption. The Company did not record a cumulative effect adjustment related to the adoption of FIN 48. Tax years since 1992 remain subject to examination by the major tax jurisdictions in which the Company is subject to tax.

**14. Pfizer asset purchase**

On June 19 , 2009, the Company completed its acquisition from Pfizer Inc. ( Pfizer ) and its wholly owned subsidiary, Pfizer Manufacturing Frankfurt GmbH (the Seller ), of a portion of the Seller s inventory of bulk insulin and the Seller s and Pfizer s rights under a license to manufacture insulin for pulmonary delivery pursuant to that certain Insulin Sale and Purchase Agreement between the Company, Pfizer and the Seller dated March 6, 2009 (the Insulin Agreement ). In accordance with the terms of the Insulin Agreement, on June 19 , 2009, the Company, Pfizer and the Seller also entered into an Insulin Maintenance and Call-Option Agreement (the Option Agreement ) pursuant to which the Company agreed to maintain and store the remainder of the Seller s bulk insulin inventory (the Retained Insulin ) and acquired an option to purchase the Retained Insulin, in whole or in part, at a specified price, to the extent that the Seller has not otherwise disposed of or used the Retained Insulin. The total purchase price for this transaction including consideration payable to the Company for the storage and maintenance of the Retained Insulin was $3.0 million. The Company allocated the entire purchase price of $3.0 million to the bulk insulin purchased which has been charged to research and development expense for the period ended June 30, 2009.

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

*The following discussion contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in Part II, Item 1A Risk Factors and elsewhere in this quarterly report on Form 10-Q (this Quarterly Report ). These interim condensed consolidated financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes for the year ended December 31, 2008 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Annual Report. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.*

### OVERVIEW

We are a biopharmaceutical company focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. Our lead product candidate, AFRESA, is an ultra rapid-acting insulin. In March 2009, the Company submitted an NDA to the FDA requesting approval of AFRESA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. The FDA accepted our NDA for filing in May 2009. We believe that the performance characteristics, unique kinetics, convenience and ease of use of AFRESA may have the potential to change the way diabetes is treated.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of June 30, 2009, we have incurred a cumulative net loss of $1.5 billion and accumulated deficit in stockholders equity of $19.3 million. To date, we have not generated any product revenues and have funded our operations primarily through the sale of equity securities and convertible debt securities. As discussed below in Liquidity and Capital Resources , if we are unable to obtain additional funding, there will be substantial doubt about our ability to continue as a going concern.

We do not expect to record sales of any product prior to regulatory approval and commercialization of AFRESA. We currently do not have the required approvals to market any of our product candidates, and we may not receive such approvals. We may not be profitable even if we succeed in commercializing any of our product candidates. We expect to make substantial expenditures and to incur additional operating losses for at least the next several years as we:

- continue the clinical development of AFRESA and new inhalation systems for the treatment of diabetes;
- seek regulatory approval to sell AFRESA in the United States and other markets;
- increase our manufacturing capacity for AFRESA to meet our currently anticipated commercial production needs;
- expand our other research, discovery and development programs;
- expand our proprietary Technosphere platform technology and develop additional applications for the pulmonary delivery of other drugs; and
- enter into sales and marketing collaborations with other companies, if available on commercially reasonable terms, or develop these capabilities ourselves.

Our business is subject to significant risks, including but not limited to the risks inherent in our ongoing clinical trials and the regulatory approval process, the results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

### Research and Development Expenses

Our research and development expenses consist mainly of costs associated with the clinical trials of our product candidates that have not yet received regulatory approval for marketing and for which no alternative future use has

been identified. This includes the salaries, benefits and stock-based compensation of research and development personnel, raw materials, such as insulin purchases, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees, and depreciation of

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laboratory equipment. We track research and development costs by the type of cost incurred. We partially offset research and development expenses with the recognition of estimated amounts receivable from the State of Connecticut pursuant to a program under which we can exchange qualified research and development income tax credits for cash. Included in research and development expenses for the quarter ended June 30, 2009 were purchases of insulin totaling $5.4 million.

Our research and development staff conducts our internal research and development activities, which include research, product development, clinical development, manufacturing and related activities. This staff is located in our facilities in Valencia, California; Paramus, New Jersey; and Danbury, Connecticut. We expense our research and development costs as we incur them.

Clinical development timelines, likelihood of success and total costs vary widely. We are focused primarily on advancing AFRESA through regulatory filings. Based on the results of preclinical studies, we plan to develop additional applications of our Technosphere technology. Additionally, we anticipate that we will continue to determine which research and development projects to pursue, and how much funding to direct to each project, on an ongoing basis, in response to the scientific and clinical success of each product candidate. We cannot be certain when any revenues from the commercialization of our products will commence.

At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product candidates other than AFRESA, we are unable to estimate with any certainty the costs that we will incur in the continued development of our product candidates for commercialization. The costs required to complete the development of AFRESA will be largely dependent on the cost and efficiency of our manufacturing process and discussions with the FDA on its requirements.

**General and Administrative Expenses**

Our general and administrative expenses consist primarily of salaries, benefits and stock-based compensation for administrative, finance, business development, human resources, legal and information systems support personnel. In addition, general and administrative expenses include professional service fees and business insurance costs.

**CRITICAL ACCOUNTING POLICIES**

There have been no material changes to our critical accounting policies as described in Item 7 of our Annual Report.

**RESULTS OF OPERATIONS**

**Three and six months ended June 30, 2009 and 2008**

**Revenues**

During the three months ended June 30, 2009 and 2008, we did not recognize any revenue. We recognized no revenue during the six months ended June 30, 2009. During the six months ended June 30, 2008, we recognized $20,000 in revenue under a license agreement. We do not anticipate sales of any product prior to regulatory approval and commercialization of AFRESA.

**Research and Development Expenses**

The following table provides a comparison of the research and development expense categories for the three and six months ended June 30, 2009 and 2008 (dollars in thousands):

| | Three months ended June 30, | | | |
|---|---|---|---|---|
| | 2009 | 2008 | $ Change | % Change |
| Clinical | $ 10,619 | $ 33,874 | $ (23,255) | (69)% |
| Manufacturing | 19,890 | 20,875 | (985) | (5)% |
| Research | 4,934 | 9,745 | (4,811) | (49)% |
| Research and development tax credit | (175) | (611) | 436 | (71)% |
| Stock-based compensation expense | 4,581 | 3,691 | 890 | 24% |
| Research and development expenses | $ 39,849 | $ 67,574 | $ (27,725) | (41)% |

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| | Six months ended June 30, | | | |
|---|---|---|---|---|
| | 2009 | 2008 | $ Change | % Change |
| Clinical | $ 27,377 | $ 61,164 | $ (33,787) | (55)% |
| Manufacturing | 37,355 | 41,685 | (4,330) | (10)% |
| Research | 10,281 | 17,372 | (7,091) | (41)% |
| Research and development tax credit | (350) | (1,096) | 746 | (68)% |
| Stock-based compensation expense | 8,075 | 6,894 | 1,181 | 17% |
| Research and development expenses | $ 82,738 | $ 126,019 | $ (43,281) | (34)% |

The decrease in research and development expenses for the three and six months ended June 30, 2009, as compared to the three and six months ended June 30, 2008, was primarily due to decreased costs associated with the clinical development of AFRESA as we completed our pivotal AFRESA trials during 2008, as well as decreases in manufacturing costs associated with raw material purchases. We anticipate that our research and development expenses will continue to decrease in 2009 compared to the prior year since we have completed our pivotal AFRESA clinical trials and the expansion of our commercial manufacturing facilities during 2008, as well as due to decreased salary-related costs associated with the reduction in force in April 2009.

**General and Administrative Expenses**

The following table provides a comparison of the general and administrative expense categories for the three and six months ended June 30, 2009 and 2008 (dollars in thousands):

| | Three months ended June 30, | | | |
|---|---|---|---|---|
| | 2009 | 2008 | $ Change | % Change |
| Salaries, employee related and other general expenses | $ 11,065 | $ 10,347 | $ 718 | 7% |
| Stock-based compensation expense | 2,472 | 2,943 | (471) | (16)% |
| General and administrative expenses | $ 13,537 | $ 13,290 | $ 247 | 2% |

| | Six months ended June 30, | | | |
|---|---|---|---|---|
| | 2009 | 2008 | $ Change | % Change |
| Salaries, employee related and other general expenses | $ 23,640 | $ 23,757 | $ (117) | 0% |
| Stock-based compensation expense | 4,814 | 5,173 | (359) | (7)% |
| General and administrative expenses | $ 28,454 | $ 28,930 | $ (476) | (2)% |

General and administrative expenses for the three months ended June 30, 2009 increased as compared to the same period in the prior year primarily due to increased professional fees related to the recently completed transaction with Pfizer (See Note 14 Pfizer asset purchase, of the Notes to the accompanying financial statements). We expect general and administrative expenses to increase slightly in 2009 as a result of increased professional fees.

General and administrative expenses for the six months ended June 30, 2009 decreased as compared to the same period in the prior year primarily due to the purchase of patents from Emisphere Technologies, Inc. during the first

quarter of 2008, offset by increased professional fees related to the recently completed transaction with Pfizer (See Note 14 Pfizer asset purchase, of the Notes to the accompanying financial statements).

**Interest Income and Expense**

Interest income for the three and six months ended June 30, 2009 decreased by $1.2 million and $4.1 million, respectively, as compared to the same period in the prior year primarily due to lower market interest rates and a lower investment balance.

Interest expense for the three and six months ended June 30, 2009 increased by $2.4 million and $3.8 million as compared to the same period in the prior year primarily due to a decrease in capitalized interest related to the Danbury, Connecticut plant expansion and the interest expense related to amounts outstanding under the borrowing arrangement with an entity controlled by our principal stockholder (See Note 11 Related-party loan arrangement, of the Notes to the accompanying financial statements).

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## LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations primarily through the sale of equity securities and convertible debt securities.

In October 2007, we entered into a loan arrangement with our principal stockholder allowing us to borrow up to a total of $350.0 million On February 26, 2009, as a result of our principal stockholder being licensed as a finance lender under the California Finance Lenders Law, the promissory note underlying the loan arrangement was revised to reflect the lender as The Mann Group LLC, an entity controlled by our principal stockholder. This new license also eliminated the need for draw restrictions under the previous loan arrangement which enabled us to borrow up to a total of $350.0 million from time to time through and including December 31, 2011 with appropriate notice to the lender. Interest will accrue on each outstanding advance at a fixed rate equal to the one-year LIBOR rate as reported by the *Wall Street Journal* on the date of such advance plus 3% per annum and will be payable quarterly in arrears. Principal repayment is due on December 31, 2011. At any time after January 1, 2010, the lender can require us to prepay up to $200.0 million in advances that have been outstanding for at least 12 months. If the lender exercises this right, we will have until the earlier of 180 days after the lender provides written notice or December 31, 2011 to prepay such advances. In the event of a default, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at the lender s option, and the interest rate will increase to the one-year LIBOR rate calculated on the date of the initial advance or in effect on the date of default, whichever is greater, plus 5% per annum. Any borrowings under the loan arrangement will be unsecured. The loan arrangement contains no financial covenants. There are no warrants associated with the loan arrangement, nor are advances convertible into our common stock. As of June 30, 2009, the amount borrowed and outstanding under the arrangement was $135.0 million.

During the six months ended June 30, 2009, we used $105.0 million of cash for our operations compared to using $140.0 million for our operations in the six months ended June 30, 2008. We had a net loss of $115.0 million for the six months ended June 30, 2009, of which $22.1 million consisted of non-cash charges such as depreciation and amortization, and stock-based compensation. We expect our negative operating cash flow to continue at least until we obtain regulatory approval and achieve commercialization of AFRESA.

We generated $3.3 million of cash from investing activities during the six months ended June 30, 2009, compared to spending $48.2 million of cash for investing activities for the six months ended June 30, 2008. For the six months ended June 30, 2009 and 2008, $12.5 million and $48.3 million, respectively, were used to purchase machinery and equipment to expand our manufacturing operations and our quality systems that support clinical trials for AFRESA.

Our financing activities generated $105.5 million of cash for the six months ended June 30, 2009, compared to $0.4 million for the same period in 2008. For the six months ended June 30, 2009, cash from financing activities was primarily from the related party borrowings received, as well as the exercise of stock options.

As of June 30, 2009, we had $34.0 million in cash, cash equivalents and marketable securities. Although we believe our existing cash resources, including the $215.0 million remaining available under our loan arrangement with an entity controlled by our principal stockholder, will be sufficient to fund our anticipated cash requirements through the second quarter of 2010, we will require significant additional financing in the future to fund our operations and if we are unable to do so, there will be substantial doubt about our ability to continue as a going concern. Accordingly, we expect that we will need to raise additional capital, either through the sale of equity and/or debt securities, a strategic business collaboration with a pharmaceutical or biotechnology company or the establishment of other funding facilities, in order to continue the development and commercialization of AFRESA and other product candidates and to support our other ongoing activities.

We intend to use our capital resources to continue the development and commercialization of AFRESA, if approved, and to develop additional applications for our proprietary Technosphere platform technology. In addition, portions of our capital resources will be devoted to expanding our other product development programs for the treatment of different types of cancers. We are expending a portion of our capital to scale up our manufacturing capabilities in our Danbury facilities. We also intend to use our capital resources for general corporate purposes, which may include in-licensing or acquiring additional technologies.

We have held extensive discussions with a number of pharmaceutical companies concerning a potential strategic business collaboration for AFRESA. To date, we have not reached agreement with any of these companies on a collaboration and we cannot predict when, if ever, we could conclude such an agreement with a partner. There can be

no assurance that any such collaboration will be available to us on a timely basis or on acceptable terms, if at all. If we enter into a strategic business collaboration with a pharmaceutical or biotechnology company, we would expect, as part of the transaction, to receive additional capital. In addition, we expect to pursue the sale of equity and/or debt securities, or the establishment of other funding facilities. Issuances of debt or additional equity could impact the rights of our existing stockholders, dilute the ownership percentages of our existing stockholders and may impose restrictions on our operations. These restrictions could include

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limitations on additional borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing, sale or divestiture of certain intellectual property and other assets, including our Technosphere technology platform. There can be no assurance, however, that any strategic collaboration, sale of securities or sale or license of assets will be available to us on a timely basis or on acceptable terms, if at all. If we are unable to raise additional capital, we may be required to enter into agreements with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such agreements may not be on terms as commercially favorable to us.

However, we cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. If planned operating results are not achieved or we are not successful in raising additional equity financing or entering a business collaboration, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, including AFRESA development activities, or further reduction of costs for facilities and administration, and there will be substantial doubt about our ability to continue as a going concern.

**Off-Balance Sheet Arrangements**

As of June 30, 2009 we did not have any off-balance sheet arrangements.

**Contractual Obligations**

The only material change to our contractual obligations disclosed in Item 7 of our Annual Report was the additional borrowing of $105.0 million from an entity controlled by our principal stockholder during the six months ended June 30, 2009. (See Note 11 Related-party loan arrangement of the Notes to the accompanying financial statements.)

**Recent Accounting Pronouncements**

On April 9, 2009, the Financial Accounting Standards Board ( FASB ) issued three FASB Staff Positions ( FSP ): FSP No. FAS 157-4 *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly* ( FSP No. FAS 157-4 ); FSP No. FAS 115-2 and FAS 124-2 *Recognition and Presentation of Other-Than-Temporary Impairments* ( FSP No. FAS 115-2 and FAS 124-2 ); and FSP No. FAS 107-1 and APB 28-1 *Interim Disclosures About Fair Value of Financial Instruments* ( FSP No. FAS 107-1 and APB 28-1 ). FSP No. FAS 157-4 provides application guidance on measuring fair value when the volume and level of activity has significantly decreased and identifying transactions that are not orderly. FSP No. FAS 115-2 and FAS 124-2 provides a new other-than-temporary impairment model for debt securities only which shifts the focus from an entity s intent to hold until recovery to its intent to sell. FSP No. FAS 107-1 and APB 28-4 expands the fair value disclosures required for all financial instruments within the scope of FASB Statement No. 107 *Disclosures About Fair Value of Financial Instruments* to interim periods. All three FSPs are effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The adoption of these FSPs did not have a material impact on our results of operations, financial position or cash flows.

On May 28, 2009, the FASB issued Statement of Financial Accounting Standards ( FASB Statement ) No. 165 *Subsequent Events* ( FASB Statement No. 165 ), which provides guidance on management s assessment of subsequent events. Historically, management had relied on auditing literature for guidance on assessing and disclosing subsequent events. FASB Statement No. 165 includes the guidance in accounting literature and is not expected to significantly change practice because its guidance is similar to that in auditing guidance. The statement is effective prospectively for interim and annual periods ending after June 15, 2009. The adoption of this statement did not have a material impact on our results of operations, financial position or cash flows.

On June 29, 2009, the FASB issued FASB Statement No. 168, *FASB Accounting Statement on Codification and Hierarchy of Generally Accepted Accounting Principles- a replacement of FASB Statement No. 162* ( FASB Statement No. 168 ), which will become the source of authoritative GAAP recognized by the FASB to be applied by all nongovernmental agencies. The statement is effective for financial statements issued for interim and annual periods ending after September 15, 2009 and is not expected to have a material impact on our results of operations, financial position or cash flows.

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

We are exposed to market risk related to changes in interest rates impacting our short-term investment portfolio as well as the interest rate on our credit facility with an entity controlled by our principal stockholder. The interest rate on our credit facility with an entity controlled by our principal stockholder is a fixed rate equal to the one-year LIBOR rate as reported by the *Wall Street Journal* on the

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date of such advance plus 3% per annum. Our current policy requires us to maintain a highly liquid short-term investment portfolio consisting mainly of U.S. money market funds and investment-grade corporate, government and municipal debt. None of these investments is entered into for trading purposes. Our cash is deposited in and invested through highly rated financial institutions in North America. Our short-term investments at June 30, 2009 are comprised mainly of a certificate of deposit and a common stock investment. We have entered into a foreign exchange derivative hedging transaction as part of our risk management program. We continue to utilize our $350.0 million credit facility to fund operations. The interest rate is fixed at the time of the draw. If interest rates were to increase from levels at June 30, 2009 we could experience a higher level of interest expense than assumed in our current operating plan.

**ITEM 4. CONTROLS AND PROCEDURES**

**Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934, as amended, or the Securities Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our chief executive officer and chief financial officer performed an evaluation under the supervision and with the participation of our management, of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act) as of June 30, 2009. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal control over financial reporting during the fiscal quarter ended June 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

None.

**Item 1A.** ***Risk Factors***

*You should consider carefully the following information about the risks described below, together with the other information contained in this quarterly report on Form 10-Q before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this quarterly report. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. The risk factors set forth below with an asterisk (*) next to the title contain changes to the description of the risk factors previously disclosed in Item 1A to our annual report on Form 10-K. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.*

**RISKS RELATED TO OUR BUSINESS**

***We depend heavily on the successful development and commercialization of our lead product candidate, AFRESA, which is not yet approved, and our other product candidates, which are in early clinical or preclinical development.****

To date, we have not commercialized any product candidates. In March 2009, we submitted an NDA to the FDA requesting approval of AFRESA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. The FDA accepted our NDA for filing in May 2009, meaning the FDA has determined that our submission is sufficiently complete to permit a substantive review.

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Our other product candidates are generally in early clinical or preclinical development. We anticipate that in the near term, our ability to generate revenues will depend solely on the successful development and commercialization of AFRESA.

We have expended significant time, money and effort in the development of our lead product candidate, AFRESA, which has not yet received regulatory approval and which may not be approved by the FDA in a timely manner, or at all. We must receive the necessary approvals from the FDA and similar foreign regulatory agencies before AFRESA can be marketed and sold in the United States or elsewhere. Even if we were to receive regulatory approval, we ultimately may be unable to gain market acceptance of AFRESA for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, the availability of alternative treatments and cost effectiveness. If we fail to commercialize AFRESA, our business, financial condition and results of operations will be materially and adversely affected.

We are seeking to develop and expand our portfolio of product candidates through our internal research programs and through licensing or otherwise acquiring the rights to therapeutics in the areas of cancer and other indications. All of these product candidates will require additional research and development and significant preclinical, clinical and other testing prior to seeking regulatory approval to market them. Accordingly, these product candidates will not be commercially available for a number of years, if at all.

A significant portion of the research that we are conducting involves new and unproven compounds and technologies, including AFRESA, Technosphere platform technology and immunotherapy product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. Even if our research programs identify candidates that initially show promise, these candidates may fail to progress to clinical development for any number of reasons, including discovery upon further research that these candidates have adverse effects or other characteristics that indicate they are unlikely to be effective. In addition, the clinical results we obtain at one stage are not necessarily indicative of future testing results. If we fail to successfully complete the development and commercialization of AFRESA or develop or expand our other product candidates, or are significantly delayed in doing so, our business and results of operations will be harmed and the value of our stock could decline.

***We have a history of operating losses, we expect to continue to incur losses and we may never become profitable.****

We are a development stage company with no commercial products. All of our product candidates are still being developed, and all but AFRESA are still in the early stages of development. Our product candidates will require significant additional development, clinical trials, regulatory clearances and additional investment before they can be commercialized. We anticipate that AFRESA may not be approved for as long as a year or more, or at all.

We have never been profitable and, as of June 30, 2009, we had an accumulated deficit of $1.5 billion. The accumulated deficit has resulted principally from costs incurred in our research and development programs, the write-off of goodwill and general operating expenses. We expect to make substantial expenditures and to incur increasing operating losses in the future in order to further develop and commercialize our product candidates, including costs and expenses to complete clinical trials, seek regulatory approvals and market our product candidates, including AFRESA. This accumulated deficit may increase significantly as we continue development and clinical trial efforts.

Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders equity. As of June 30, 2009, we had an accumulated deficit in stockholders equity of $19.3 million. Our ability to achieve and sustain profitability depends upon obtaining regulatory approvals for and successfully commercializing AFRESA, either alone or with third parties. We do not currently have the required approvals to market any of our product candidates, and we may not receive them. We may not be profitable even if we succeed in commercializing any of our product candidates. As a result, we cannot be sure when we will become profitable, if at all.

***If we fail to raise additional capital our financial condition and business would suffer.****

It is costly to develop therapeutic product candidates and conduct clinical trials for these product candidates. Although we are currently focusing on AFRESA as our lead product candidate, we have begun to conduct clinical trials for additional product candidates. Our existing capital resources will not be sufficient to support the expense of fully commercializing AFRESA or developing any of our product candidates.

Based upon our current expectations, we believe that our existing capital resources, including the loan arrangement with an entity controlled by our principal stockholder, will enable us to continue planned operations through the second quarter of 2010. However, we cannot assure you that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. Accordingly, we plan to raise additional capital, either through the sale of equity and/or debt securities, a strategic business collaboration, or the establishment of other funding facilities, in order to continue the

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development and commercialization of AFRESA and other product candidates and to support our other ongoing activities. However, it may be difficult for us to raise additional capital through the sale of equity and/or debt securities. As of June 30, 2009, we had an accumulated deficit in stockholders equity of $19.3 million which may affect our ability to raise additional capital. The amount of additional funds we need will depend on a number of factors, including:

- the rate of progress and costs of our clinical trials and research and development activities, including costs of procuring clinical materials and expanding our own manufacturing facilities;
- our success in establishing strategic business collaborations and the timing and amount of any payments we might receive from any collaboration we are able to establish;
- actions taken by the FDA and other regulatory authorities affecting our products and competitive products;
- our degree of success in commercializing AFRESA;
- the emergence of competing technologies and products and other adverse market developments;
- the timing and amount of payments we might receive from potential licensees;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others;
- the costs of discontinuing projects and technologies or decommissioning existing facilities, if we undertake those activities; and
- the costs of performing additional clinical trials to demonstrate safety and efficacy if our current trials do not deliver results sufficient for FDA approval and commercialization.

We have raised capital in the past primarily through the sale of equity and debt securities. We may in the future pursue the sale of additional equity and/or debt securities, or the establishment of other funding facilities. Issuances of additional debt or equity securities or the conversion of any of our currently outstanding convertible debt securities into shares of our common stock could impact your rights as a holder of our common stock and may dilute your ownership percentage. Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets, including our Technosphere technology platform. We cannot offer assurances, however, that any strategic collaborations, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case.

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, credit facilities, licensing arrangements and/or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, including AFRESA commercialization, or further reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will be substantial doubt about our ability to continue as a going concern.

***The current financial crisis and deteriorating economic conditions may have an adverse impact on the loan facility with an entity controlled by our principal stockholder, which we currently cannot predict.***

As widely reported, economic conditions in the United States and globally have been deteriorating. Financial markets in the United States, Europe and Asia have been experiencing a period of unprecedented turmoil and upheaval characterized by extreme volatility and declines in security prices, severely diminished liquidity and credit availability, inability to access capital markets, the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government and other governments. We cannot predict the impact of these events on the loan facility with an entity controlled by our

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principal stockholder. If we are unable to draw on this financial resource, our business and financial condition will be adversely affected.

***If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, our business would be harmed and the market price of our common stock could decline.***

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

- the rate of progress, costs and results of our clinical trial and research and development activities, which will be impacted by the level of proficiency and experience of our clinical staff;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our ability to access sufficient, reliable and affordable supplies of components used in the manufacture of our product candidates, including insulin and other materials for AFRESA;
- the costs of expanding and maintaining manufacturing operations, as necessary;
- the extent of scheduling conflicts with participating clinicians and clinical institutions;
- the receipt of approvals by our competitors and by us from the FDA and other regulatory agencies; and other actions by regulators.

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

***We face substantial competition in the development of our product candidates and may not be able to compete successfully, and our product candidates may be rendered obsolete by rapid technological change.***

A number of established pharmaceutical companies have or are developing technologies for the treatment of diabetes. We also face substantial competition for the development of our other product candidates.

Many of our existing or potential competitors have, or have access to, substantially greater financial, research and development, production, and sales and marketing resources than we do and have a greater depth and number of experienced managers. As a result, our competitors may be better equipped than we are to develop, manufacture, market and sell competing products. In addition, gaining favorable reimbursement is critical to the success of AFRESA. Many of our competitors have existing infrastructure and relationships with managed care organizations and reimbursement authorities which can be used to their advantage.

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

We also expect to face increasing competition from universities and other non-profit research organizations. These institutions carry out a significant amount of research and development in the areas of diabetes and cancer. These institutions are becoming increasingly

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aware of the commercial value of their findings and are more active in seeking patent and other proprietary rights as well as licensing revenues.

***If we fail to enter into a strategic collaboration with respect to AFRESA, we may not be able to execute on our business model.****

We have held extensive discussions with a number of pharmaceutical companies concerning a potential strategic business collaboration for AFRESA. To date, we have not reached agreement with any of these companies on a collaboration and we cannot predict when, if ever, we could conclude such an agreement with a partner. There can be no assurance that any such collaboration will be available to us on a timely basis or on acceptable terms, if at all. If we are not able to enter into a collaboration on terms that are favorable to us, we may be unable to undertake and fund product development, clinical trials, manufacturing and marketing activities at our own expense. Accordingly, we may have to substantially reduce our development efforts, which would delay or otherwise impede the commercialization of AFRESA.

We will face similar challenges as we seek to develop our other product candidates. Our current strategy for developing, manufacturing and commercializing our other product candidates includes evaluating the potential for collaborating with pharmaceutical and biotechnology companies at some point in the drug development process and for these collaborators to undertake the advanced clinical development and commercialization of our product candidates. It may be difficult for us to find third parties that are willing to enter into collaborations on economic terms that are favorable to us, or at all. Failure to enter into a collaboration with respect to any other product candidate could substantially increase our requirements for capital and force us to substantially reduce our development effort.

***If we enter into collaborative agreements with respect to AFRESA and if our third-party collaborators do not perform satisfactorily or if our collaborations fail, development or commercialization of AFRESA may be delayed and our business could be harmed.***

We currently rely on clinical research organizations and hospitals to conduct, supervise or monitor some or all aspects of clinical trials involving AFRESA. Further, we may also enter into license agreements, partnerships or other collaborative arrangements to support the financing, development and marketing of AFRESA. We may also license technology from others to enhance or supplement our technologies. These various collaborators may enter into arrangements that would make them potential competitors. These various collaborators also may breach their agreements with us and delay our progress or fail to perform under their agreements, which could harm our business. If we enter into collaborative arrangements, we will have less control over the timing, planning and other aspects of our clinical trials, and the sale and marketing of AFRESA and our other product candidates. We cannot offer assurances that we will be able to enter into satisfactory arrangements with third parties as contemplated or that any of our existing or future collaborations will be successful.

***Continued testing of AFRESA or another product candidate may not yield successful results, and even if it does, we may still be unable to commercialize that product candidate.****

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

- safety and efficacy results obtained in our nonclinical and initial clinical testing may be inconclusive or may not be predictive of results obtained in later-stage clinical trials or following long-term use, and we may as a result be forced to stop developing product candidates that we currently believe are important to our future;
- the data collected from clinical trials of our product candidates may not be sufficient to support FDA or other regulatory approval;
- after reviewing test results, we or any potential collaborators may abandon projects that we previously believed were promising; and
- our product candidates may not produce the desired effects or may result in adverse health effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

We conducted a pivotal Phase 3 safety study of AFRESA to evaluate pulmonary function, with multiple uses per day, over a period of two years. Forecasts about the effects of the use of drugs, including AFRESA, over terms longer than

the clinical trials or in much larger populations may not be consistent with the clinical results. If use of AFRESA results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our ability to market and sell AFRESA, may narrow the

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approved indications for use or otherwise require restrictive product labeling or marketing, or may require further clinical trials, which may be time-consuming and expensive and may not produce favorable results.

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

***If we are unable to transition successfully from a development company to a company that commercializes therapeutics, our business would suffer.****

We require a well-structured plan to make the transition from the development-stage to being a company with commercial operations. We have a number of executive personnel, particularly in clinical development, regulatory and manufacturing production, including personnel with significant Phase 3-to-commercialization experience. In order to implement our commercialization strategy, we will need to:

- align our management structure to accommodate the increasing complexity of our operations;
- develop comprehensive and detailed commercialization, clinical development and regulatory plans; and
- implement standard operating procedures.

If we are unable to accomplish these measures in a timely manner, we would be at considerable risk of failing to develop the manufacturing capabilities necessary for FDA inspection and commercial operations.

***If our suppliers fail to deliver materials and services needed for the production of AFRESA in a timely and sufficient manner, or they fail to comply with applicable regulations, our business and results of operations would be harmed and the market price of our common stock could decline.****

For AFRESA to be commercially viable, we need access to sufficient, reliable and affordable supplies of insulin, our AFRESA inhaler, the related cartridges and other materials. In November 2007, we entered into a long-term supply agreement with N.V. Organon. In June 2009, we purchased from Pfizer, Inc. a portion of its inventory of bulk insulin and acquired an option to purchase the remainder of Pfizer s insulin inventory, in whole or in part, at a specified price to the extent that Pfizer has not otherwise disposed of or used the retained insulin.

We have obtained FDKP, the precursor raw material for AFRESA, from two sources, both of which are major chemical manufacturers with facilities in Europe and North America. We have recently completed a successful validation campaign of FDKP at commercial scale. We can also utilize our in-house chemical manufacturing plant for supplemental capacity. We believe both manufacturers have the capacity to supply our current clinical and future commercial requirements. We have obtained our AFRESA inhaler and cartridges from two large plastic molding companies.

We must rely on our suppliers to comply with relevant regulatory and other legal requirements, including the production of insulin in accordance with the FDA s current good manufacturing practice, or cGMP, for drug products, and the production of AFRESA inhaler and related cartridges in accordance with the FDA s cGMP for medical devices, known as the Quality System Regulation, or QSR. The supply of all of these materials may be limited or the manufacturer may not meet relevant regulatory requirements, and if we are unable to obtain these materials in sufficient amounts, in a timely manner and at reasonable prices, or if we should encounter delays or difficulties in our relationships with manufacturers or suppliers, the development or manufacturing of AFRESA may be delayed. Any such events would delay market introduction and subsequent sales of AFRESA and, if so, our business and results of operations will be harmed and the market price of our common stock may decline.

***We have never manufactured AFRESA or any other product candidate in commercial quantities, and if we fail to develop an effective manufacturing capability for our product candidates or to engage third-party manufacturers with this capability, we may be unable to commercialize these products.****

We use our Danbury, Connecticut facility to formulate AFRESA, fill plastic cartridges with AFRESA and blister package the cartridges for our clinical trials. This facility is still undergoing the rigorous testing and regulatory inspection processes that are expected to result in approval to manufacture commercially. The manufacture of pharmaceutical products requires significant

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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 AFRESA at our Danbury facility, it would have to undergo an acceptable pre-approval inspection by the FDA. If we engage a third-party manufacturer, we would need to transfer our technology to that third-party manufacturer and gain FDA approval, potentially causing delays in product delivery. In addition, our third-party manufacturer may not perform as agreed or may terminate its agreement with us.

Additionally, when we manufacture commercial material on a significantly larger production scale than the production scale for clinical trial materials, we may be required by the FDA to establish that the results obtained from the clinical trials may reasonably be extrapolated to such commercial material. We are in the process of compiling documentation to show correlation to the clinical-scale production materials.

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 acceptable quality, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and quality on a timely basis, we would likely be unable to meet demand for such 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 a chemical that 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 completed the final stages of the soil cleanup plan in the third quarter of 2008 which cost approximately $2.25 million. We have 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. We are currently pursuing collection of the clean-up costs and expenses from the seller or the party responsible for the contamination. If we are unable to collect the full amount of these costs and expenses, 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.***

Our products will be used by a large number of healthcare professionals who require substantial education and support. For example, a broad base of physicians, including primary care physicians and endocrinologists, treat

patients with diabetes. A large sales force will be required in order to educate these physicians about the benefits and advantages of AFRESA and to provide adequate support for them. Therefore, we plan to enter into collaborations with one or more pharmaceutical companies to market, distribute and sell AFRESA, 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. Because we lack experience in selling pharmaceutical products to the diabetes market, we would be at a disadvantage compared to our potential competitors, all of

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whom have substantially more resources and experience than we do. For example, several other companies selling products to treat diabetes have existing sales forces in excess of 1,500 sales representatives. We, acting alone, 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. Also, we would not be able to match our competitor s spending levels for pre-launch marketing preparation, including medical education. 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.***

AFRESA and our other product candidates are new and unproven. Even if any of our product candidates obtains 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 AFRESA 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 other 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 consumers 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 AFRESA 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

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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 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 AFRESA 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 AFRESA. 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 AFRESA 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 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 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.

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***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, terrorism, and an enhanced risk of natural and other disasters such as fires, power and telecommunications failures, mudslides, 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, 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 errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. 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.

**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 AFRESA, 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 at a pre-NDA meeting, we conducted a study, prior to submitting our NDA, that assessed the

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bioequivalency of the inhaler used in our clinical trials to date with the modified version of the same inhaler that we intend to use for commercial purposes. The FDA did not request any other trials prior to NDA submission. However, we cannot be certain if or when the FDA might request additional studies, under what conditions such studies might be requested, or what the size or length of any such studies might be. The clinical 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 AFRESA. 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. 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 AFRESA, 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 essentially all of the risks associated with the FDA approval processes. Some of those agencies also must approve prices of the products. Approval of a product by the FDA does not ensure approval of the same product by the health authorities of other countries. In addition, changes in regulatory policy in the United States or in foreign countries for product approval during the period of product development and regulatory agency review of each submitted new application may cause delays or rejections.

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 approval has had an impact on and, notwithstanding the voluntary withdrawal of the product from the market by its manufacturer, could still impact the development and registration of AFRESA in different ways. For example, Exubera may be used as a reference for safety and efficacy evaluations of AFRESA, and the approval standards set for Exubera may be applied to other products that follow including AFRESA.

On March 16, 2009, we submitted an NDA for AFRESA, which the FDA accepted for review on May 16, 2009. The FDA has advised us that it will regulate AFRESA as a combination product because of the complex nature of the system that includes the combination of a new drug (AFRESA) and a new medical device (the AFRESA inhaler used to administer the insulin). The FDA indicated that the review of our drug marketing application for AFRESA will involve three separate review groups of the FDA: (1) the Metabolic and Endocrine Drug Products Division; (2) the Pulmonary Drug Products Division; and (3) the Center for Devices and Radiological Health, which 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. We can make no assurances at this time about what impact FDA review by multiple groups will have on the timeliness of the FDA s review or the approvability of our product or whether we are correct in our understanding of how AFRESA 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 AFRESA 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 AFRESA.

We are developing AFRESA as a new treatment for diabetes utilizing unique, proprietary components. As a combination product, any changes to either the AFRESA inhaler, or AFRESA, 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, such as our next generation inhaler, could require us to undertake additional clinical trials and other studies, which could significantly delay the development and commercialization of AFRESA. Our product

candidates that are currently in development for the treatment of cancer also face similar obstacles and costs.
We also must obtain approval from the FDA for the trade name of our product. The FDA has informed us that the name AFRESA may be too similar to other drugs on the market and that we may want to propose another trade name for our product.

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Our first generation inhaler is being reviewed for approval as part of the NDA for AFRESA. No assurances exist that we will not be required to obtain separate device clearances or approval for use of our inhaler with AFRESA. 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 AFRESA, 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 AFRESA or any other product candidates until we have obtained regulatory approval. Until we prepared and filed our NDA for AFRESA, we had 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 or could require potentially costly post-marketing follow-up clinical trials. Regulatory authorities may limit the segments of the diabetes population to which we or others may market AFRESA or limit the target population for our other product candidates. Based on currently available clinical studies, we believe that AFRESA 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 or any other advantages of AFRESA will be agreed to by the FDA or otherwise included in product labeling or advertising and, as a result, AFRESA may not have our expected competitive advantages when compared to other insulin products.

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 United States 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 United States 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

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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 AFRESA.****

Our insulin supplier for purposes of the NDA filing 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 AFRESA. We also depend on suppliers for other materials that comprise AFRESA, including our AFRESA 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 AFRESA. 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.

***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 AFRESA 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 AFRESA. As well, the public perception of AFRESA 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 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 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

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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 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 courts must determine the scope of coverage afforded by a patent and the courts do not always arrive at uniform conclusions.

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

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

Moreover, certain components of AFRESA and/or our DNA-based cancer vaccines may be manufactured outside the United States and imported into the United States. As such, third parties could file complaints under 19 U.S.C. Section 337(a)(1)(B), or a 337 action, with the International Trade Commission, or the ITC. A 337 action can be

expensive and would consume time and other resources. There is a risk that the ITC would decide that we are infringing a third party s patents and either enjoin us from importing the infringing products or parts thereof into the United States or set a bond in an amount that the ITC considers would offset our competitive advantage from the continued importation during the statutory review period. The bond could be up to 100% of the value

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of the patented products. We may not prevail in any legal action, and a required license under the patent may not be available on acceptable terms, or at all, resulting in a permanent injunction preventing any further importation of the infringing products or parts thereof into the United States. We also may not be able to develop a non-infringing product design on commercially reasonable terms, or at all.

Although we own a number of domestic and foreign patents and patent applications relating to AFRESA and cancer vaccine products under development, we have identified certain third-party patents having claims relating to pulmonary insulin delivery that may trigger an allegation of infringement upon the commercial manufacture and sale of AFRESA. We have also identified third-party patents disclosing methods of use and compositions of matter related to DNA-based cancer 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 our 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.

**RISKS RELATED TO OUR COMMON STOCK**

***Our stock price is volatile.***

The current turbulence in the U.S. and global financial markets could adversely affect our stock price and our ability to raise additional capital through the sale of equity and/or debt securities. 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;

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- general economic, political or stock market conditions;
- announcements by us or our competitors concerning clinical trial results, acquisitions, strategic alliances, technological innovations, newly approved commercial products, product discontinuations, or other developments;
- the availability of critical materials used in developing and manufacturing AFRESA or other product candidates;
- developments or disputes concerning our patents or proprietary rights;
- the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;
- announcements by us concerning our financial condition or operating performance;
- changes in securities analysts estimates of our financial condition or operating performance;
- 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; and
- discussion of AFRESA, 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.

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 Stock 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.****

At July 23, 2009, Mr. Mann beneficially owned approximately 47.3% of our outstanding shares of capital stock. We believe members of Mr. Mann s family beneficially owned at least an additional 1% 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 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 United States 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, the Technion-Israel Institute of

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Technology, and at Purdue University, 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.***

Substantially all of the outstanding shares of our common stock 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.

**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 second quarter of 2009.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

Our 2009 Annual Meeting of Stockholders was held on May 21, 2009.

The following matters were voted on at our 2009 Annual Meeting of Stockholders:

1. The election of eight nominees to serve on our board of directors until the 2010 Annual Meeting of Stockholders. The following eight individuals were elected to our board of directors by the votes indicated:

| | Affirmative Votes | Votes Withheld | Votes Abstaining |
|---|---|---|---|
| Alfred E. Mann | 63,320,958 | 5,823,899 | 2,824 |
| Hakan S. Edstrom | 63,320,958 | 5,823,899 | 2,824 |
| Abraham E. Cohen | 62,722,001 | 6,421,706 | 3,974 |
| Ronald Consiglio | 63,320,458 | 5,824,399 | 2,824 |
| Michael Friedman, M.D. | 62,722,001 | 6,421,706 | 3,974 |
| Kent Kresa | 62,722,501 | 6,421,206 | 3,974 |
| David H. MacCallum | 63,320,458 | 5,824,399 | 2,824 |
| Henry L. Nordhoff | 63,320,458 | 5,824,399 | 2,824 |

2. To approve an increase in the maximum number of shares of common stock that may be issued under MannKind s 2004 Equity Incentive Plan from 14,000,000 shares to 19,000,000 shares. The increase in the maximum number of shares of common stock under MannKind s 2004 Equity Incentive Plan was approved by the following vote: 61,011,192 votes for and 8,131,245 votes against, with 5,244 votes abstaining.

3. The ratification of Deloitte & Touche LLP as independent auditor for the fiscal year ending December 31, 2009 was approved by the following vote: 54,877,014 votes for and 14,259,622 votes against, with 11,045 votes abstaining.

**ITEM 5. OTHER INFORMATION**

None.

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## ITEM 6. EXHIBITS

| Exhibit Number | Description of Document |
|---|---|
| 3.1(1) | Restated Certificate of Incorporation. |
| 3.2(2) | Certificate of Amendment of Amended and Restated Certificate of Incorporation. |
| 3.3(3) | Amended and Restated Bylaws. |
| 4.1(4) | Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated November 1, 2006. |
| 4.2(5) | First Supplemental Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated December 12, 2006. |
| 4.3(5) | Form of 3.75% Senior Convertible Note due 2013. |
| 4.4(1) | Form of common stock certificate. |
| 4.5(1) | Registration Rights Agreement, dated October 15, 1998 by and among CTL ImmunoTherapies Corp., Medical Research Group, LLC, McLean Watson Advisory Inc. and Alfred E. Mann, as amended. |
| 10.1(6) | 2004 Equity Incentive Plan, as amended. |
| 10.2(7) | Insulin Maintenance and Call-Option Agreement, by and among Pfizer Manufacturing Frankfurt GmbH, Pfizer Inc. and MannKind, dated June 19, 2009. |
| 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.

(2) Incorporated by reference to MannKind s quarterly report on Form 10-Q, filed with the SEC on August 9, 2007.

(3) Incorporated by reference to MannKind s current report on Form 8-K, filed with the SEC on November 19, 2007.

(4) Incorporated by reference to MannKind s registration statement on Form S-3 (File No. 333-138373) filed with the SEC on November 2, 2006.

(5) Incorporated by reference to MannKind s current report on Form 8-K filed with the SEC on December 12, 2006.

(6) Incorporated by reference to MannKind s current report on Form 8-K, filed with the SEC on June 9, 2009.

(7) The form of this agreement was included as part of Exhibit 2.2 to MannKind s quarterly report on Form 10-Q filed with the SEC on May 4, 2009 and is incorporated herein by reference. Confidential treatment has been granted with respect to certain portions of this agreement. Omitted portions have been filed separately with the SEC.

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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: August 3, 2009

MANNKIND CORPORATION

By: /s/ Matthew J. Pfeffer
Matthew J. Pfeffer
*Corporate Vice President and Chief Financial Officer*
*(Principal Financial and Accounting Officer)*