MANNKIND CORP
Form 10-Q
November 02, 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 September 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 October 23, 2009, there were 112,806,245 shares of the registrant s common stock, $.01 par value per share, outstanding.

**MANNKIND CORPORATION**
**Form 10-Q**
**For the Quarterly Period Ended September 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)**

| | September 30, 2009 | December 31, 2008 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 53,918 | $ 27,648 |
| Marketable securities | 2,649 | 18,844 |
| State research and development credit exchange current | 1,500 | 1,500 |
| Prepaid expenses and other current assets | 5,247 | 5,983 |
| Total current assets | 63,314 | 53,975 |
| Property and equipment net | 224,057 | 226,436 |
| State research and development credit exchange receivable net of current portion | 700 | 1,500 |
| Other assets | 584 | 548 |
| Total | $ 288,655 | $ 282,459 |
| **LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)** | | |
| Current liabilities: | | |
| Accounts payable | $ 8,801 | $ 15,630 |
| Accrued expenses and other current liabilities | 19,624 | 37,842 |
| Total current liabilities | 28,425 | 53,472 |
| Senior convertible notes | 112,635 | 112,253 |
| Note payable to related party | 150,000 | 30,000 |
| Total liabilities | 291,060 | 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 September 30, 2009 and December 31, 2008 | | |
| Common stock, $0.01 par value - 150,000,000 shares authorized; 112,783,803 and 102,008,096 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively | 1,128 | 1,020 |
| Additional paid-in capital | 1,541,223 | 1,469,497 |
| Accumulated other comprehensive income (loss) | (107) | 295 |
| Deficit accumulated during the development stage | (1,544,649) | (1,384,078) |
| Total stockholders equity (deficit) | (2,405) | 86,734 |

| | | |
|---|---|---|
| Total | $ 288,655 | $ 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 September 30, | | Nine months ended September 30, | | Cumulative period from February 14, 1991 (date of inception) to September 30, |
|---|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 | 2009 |
| Revenue | $ | $ | $ | $ 20 | $ 2,988 |
| Operating expenses: | | | | | |
| Research and development | 30,494 | 55,645 | 113,232 | 181,665 | 1,110,714 |
| General and administrative | 12,273 | 13,435 | 40,727 | 42,365 | 286,569 |
| In-process research and development costs | | | | | 19,726 |
| Goodwill impairment | | | | | 151,428 |
| Total operating expenses | 42,767 | 69,080 | 153,959 | 224,030 | 1,568,437 |
| Loss from operations | (42,767) | (69,080) | (153,959) | (224,010) | (1,565,449) |
| Other income (expense) | 149 | (7) | 503 | (7) | (1,440) |
| Interest expense on note payable to related party | (1,816) | | (3,806) | | (5,329) |
| Interest expense on senior convertible notes | (1,130) | (124) | (3,376) | (585) | (9,333) |
| Interest income | 9 | 715 | 67 | 4,858 | 36,928 |
| Loss before provision for income taxes | (45,555) | (68,496) | (160,571) | (219,744) | (1,544,623) |
| Income taxes | | | | | (26) |
| Net loss | (45,555) | (68,496) | (160,571) | (219,744) | (1,544,649) |
| 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 | $ (45,555) | $ (68,496) | $ (160,571) | $ (219,744) | $ (1,567,861) |
| | $ (0.42) | $ (0.67) | $ (1.54) | $ (2.17) | |

| | | | | |
|---|---|---|---|---|
| Net loss per share applicable to common stockholders basic and diluted | | | | |
| Shares used to compute basic and diluted net loss per share applicable to common stockholders | 108,779 | 101,647 | 104,402 | 101,495 |

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)**

| | Nine months ended September 30, | | Cumulative Period from February 14, 1991 (Date of Inception) to September 30, |
|---|---|---|---|
| | 2009 | 2008 | 2009 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | | |
| Net loss | $ (160,571) | $ (219,744) | $ (1,544,649) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 14,020 | 7,321 | 74,434 |
| Stock-based compensation expense | 17,979 | 18,849 | 97,602 |
| Stock expense for shares issued pursuant to research agreement | | | 3,018 |
| Loss on sale, abandonment/disposal or impairment of property and equipment | 62 | 121 | 10,768 |
| 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 | 5 | | 1,110 |
| Changes in assets and liabilities: | | | |
| State research and development credit exchange receivable | 800 | (294) | (2,200) |
| Prepaid expenses and other current assets | 736 | 1,887 | (3,647) |
| Other assets | (36) | (2) | (584) |
| Accounts payable | (3,994) | (12,502) | 8,366 |
| Accrued expenses and other current liabilities | (15,695) | 3,343 | 18,059 |
| Other liabilities | | (24) | (2) |
| Net cash used in operating activities | (146,706) | (201,045) | (1,166,533) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | | |
| Purchase of marketable securities | (2,000) | (63,651) | (792,601) |
| Sales/ maturities of marketable securities | 17,800 | | 790,565 |
| Purchase of property and equipment | (16,679) | (72,297) | (308,536) |
| Proceeds from sale of property and equipment | | 70 | 284 |
| Net cash used in investing activities | (879) | (135,878) | (310,288) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | |
| Issuance of common stock and warrants, net | 60,648 | 425 | 1,201,196 |

| | | | |
|---|---|---|---|
| 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 | 120,000 | | 220,000 |
| 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 | (6,793) | (205) | (7,974) |
| Net cash provided by financing activities | 173,855 | 220 | 1,530,739 |

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| | Nine months ended September 30, | | Cumulative Period from February 14, 1991 (Date of Inception) to September 30, |
|---|---|---|---|
| | 2009 | 2008 | 2009 |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | $ 26,270 | $ (336,703) | $ 53,918 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 27,648 | 368,285 | |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | $ 53,918 | $ 31,582 | $ 53,918 |
| SUPPLEMENTAL CASH FLOWS DISCLOSURES: | | | |
| Cash paid for income taxes | $ | $ | $ 26 |
| Interest paid in cash | 4,159 | 2,156 | 14,515 |
| 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 | 1,239 | 10,900 | 1,239 |

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 nine months ended September 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 September 30, 2009, the Company has reported accumulated net losses of $1.5 billion and accumulated deficit in stockholders equity of $2.4 million, which include a goodwill impairment charge of $151.4 million, and cumulative negative cash flow from operations of $1.2 billion. It is costly to develop therapeutic products and conduct clinical trials for these products. At September 30, 2009 the Company s capital resources consisted of cash, cash equivalents, and marketable securities of $56.6 million (including a $2.0 million certificate of deposit held as collateral for foreign exchange hedging instruments) and $200.0 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 at least the end 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, the entry into 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 $112.6

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million and $112.3 million and an estimated fair value of $89.8 million and $53.9 million as of September 30, 2009 and December 31, 2008, respectively which is calculated based on quoted prices in an active market (Level 1 in the fair value hierarchy).

***Subsequent Events*** The Company has evaluated subsequent events through the date the financial statements were issued, November 2, 2009.

***Recently Issued Accounting Standards*** On June 29, 2009, the Financial Accounting Standard Board ( 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,* or ASC 105-10, 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. 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.

**2. Investment in securities**

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

| | September 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 | $(112) | $2,649 | $18,549 | $295 | $18,844 |

The Company s available-for-sale securities at September 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 nine months ended September 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).

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

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

| | September 30, 2009 | December 31, 2008 |
|---|---|---|
| Salary and related expenses | $ 10,134 | $ 12,452 |
| Research and clinical trial costs | 3,184 | 13,438 |
| Accrued interest | 3,086 | 204 |
| Construction in progress | 555 | 3,327 |
| Other | 2,665 | 8,421 |
| Accrued expenses and other current liabilities | $ 19,624 | $ 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 nine months ended September 30, 2009 and 2008 was as follows (in thousands):

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | **2009** | **2008** | **2009** | **2008** |
| Stock-based compensation | $ 5,090 | $ 6,781 | $ 17,979 | $ 18,849 |

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As of September 30, 2009, there was $39.6 million of unrecognized compensation costs, of which $13.3 million related to options and $26.3 million related to restricted stock units, which are expected to be recognized over the remaining weighted average vesting period of 2.4 years.

**5. Comprehensive Loss**

FASB Statement No. 130, *Reporting Comprehensive Income,* or ASC 220-10-45 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 this guidance, the accumulated balance of other comprehensive income (loss) is disclosed as a separate component of stockholders equity. For the three and nine months ended September 30, 2009 and 2008, comprehensive loss consisted of (in thousands):

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| Net loss | $ (45,555) | $ (68,496) | $ (160,571) | $ (219,744) |
| Other comprehensive loss: | | | | |
| Unrealized gain/(loss) on investments | 10 | | (407) | |
| Cumulative translation gain | 2 | | 5 | |
| Comprehensive loss | $ (45,543) | $ (68,496) | $ (160,973) | $ (219,744) |

**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 18,123,648 shares and 19,607,924 shares as of September 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 September 30, 2009, the estimated amount receivable under the program was $2.2 million.

**8. Property and equipment net**

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

| | Estimated Useful Life (Years) | September 30, 2009 | December 31, 2008 |
|---|---|---|---|
| Land | | $ 5,273 | $ 5,273 |
| Buildings | 39-40 | 54,993 | 53,786 |
| Building improvements | 5-40 | 113,197 | 111,346 |
| Machinery and equipment | 3-15 | 79,776 | 70,633 |
| Furniture, fixtures and office equipment | 5-10 | 5,371 | 6,622 |
| Computer equipment and software | 3 | 15,849 | 14,818 |
| Leasehold improvements | | 172 | 184 |
| Construction in progress | | 13,715 | 15,165 |
| | | 288,346 | 277,827 |
| Less accumulated depreciation and amortization | | (64,289) | (51,391) |
| Property and equipment net | | $ 224,057 | $ 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 nine months ended September 30, 2009 and 2008 was as follows (in thousands):

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| Depreciation and amortization expense | $ 4,658 | $ 3,393 | $ 13,638 | $ 6,954 |

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

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| Capitalized Interest | $ 77 | $ 1,078 | $ 240 | $ 3,016 |

**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 nine months ended September 30, 2009, no warrants were exercised. As of September 30, 2009, warrants to purchase 2,882,873 shares of common stock remained outstanding.

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**10. Commitments and contingencies**

***Supply Commitments*** As of September 30, 2009, the Company had a binding annual commitment for insulin purchases with Organon N.V. ( Organon ) aggregating approximately $103 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 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 general accounting guidance for recording 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. 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 $150.0 million and $30.0 million at September 30, 2009 and December 31, 2008, respectively. As of September 30, 2009, the Company had accrued interest of $1.8 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 ). 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 September 30, 2009 and December 31, 2008, the Company had accrued interest of $1.3 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

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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 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 nine months ended September 30, 2009 and 2008 was as follows (in thousands):

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| Amortization expense | $ 129 | $ 124 | $ 382 | $ 367 |

**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* or ASC 740-10-25 ( 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 was 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. Common stock offering**

On August 5, 2009, the Company sold 8.4 million shares of common stock comprised of 1.0 million shares to its principal stockholder at a price per share of $8.11 and 7.4 million shares to other investors at a price per share of $7.07. The sale of common stock resulted in aggregate net proceeds to the Company of approximately $59.7 million after deducting offering expenses.

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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, 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. 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 September 30, 2009, we have incurred a cumulative net loss of $1.5 billion and accumulated deficit in stockholders equity of $2.4 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 in the future, there will be substantial doubt about our ability to continue as a going concern.

We have held extensive discussions with a number of pharmaceutical companies concerning a potential strategic business collaboration for AFRESA. On October 6, 2009, we announced that we do not expect to complete a partnership until after we receive a response from the FDA regarding our NDA for AFRESA. We cannot predict when, if ever, we could conclude 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.

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.

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**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, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees, and depreciation of 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 September 30, 2009 were purchases of insulin totaling $2.6 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 or if 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 additional FDA requirements, if any.

**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 nine months ended September 30, 2009 and 2008**

**Revenues**

During the three months ended September 30, 2009 and 2008, we did not recognize any revenue. We recognized no revenue during the nine months ended September 30, 2009. During the nine months ended September 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 nine months ended September 30, 2009 and 2008 (dollars in thousands):

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| | Three months ended September 30, | | | |
|---|---|---|---|---|
| | 2009 | 2008 | $ Change | % Change |
| Clinical | $ 8,467 | $ 27,044 | $ (18,577) | (69%) |
| Manufacturing | 15,907 | 18,434 | (2,527) | (14%) |
| Research | 3,791 | 6,549 | (2,758) | (42%) |
| Research and development tax credit | (754) | (375) | (379) | 101% |
| Stock-based compensation expense | 3,083 | 3,993 | (910) | (23%) |
| Research and development expenses | $ 30,494 | $ 55,645 | $ (25,151) | (45%) |

| | Nine months ended September 30, | | | |
|---|---|---|---|---|
| | 2009 | 2008 | $ Change | % Change |
| Clinical | $ 35,843 | $ 88,208 | $ (52,365) | (59%) |
| Manufacturing | 53,262 | 60,119 | (6,857) | (11%) |
| Research | 14,073 | 23,921 | (9,848) | (41%) |
| Research and development tax credit | (1,104) | (1,471) | 367 | (25%) |
| Stock-based compensation expense | 11,158 | 10,888 | 270 | 2% |
| Research and development expenses | $ 113,232 | $ 181,665 | $ (68,433) | (38%) |

The decrease in research and development expenses for the three and nine months ended September 30, 2009, as compared to the three and nine months ended September 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. The decrease in research expenses reflects reduced salary-related and other research costs as a result of a reduction in force that we implemented in April 2009. 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 expenses resulting from the April 2009 reduction in force.

**General and Administrative Expenses**

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

| | Three months ended September 30, | | | |
|---|---|---|---|---|
| | 2009 | 2008 | $ Change | % Change |
| Salaries, employee related and other general expenses | $ 10,266 | $ 10,647 | $ (381) | (4%) |
| Stock-based compensation expense | 2,007 | 2,788 | (781) | (28%) |
| General and administrative expenses | $ 12,273 | $ 13,435 | $ (1,162) | (9%) |

| | Nine months ended |
|---|---|

| | September 30, | | | |
|---|---|---|---|---|
| | 2009 | 2008 | $ Change | % Change |
| Salaries, employee related and other general expenses | $ 33,906 | $ 34,404 | $ (498) | (1%) |
| Stock-based compensation expense | 6,821 | 7,961 | (1,140) | (14%) |
| General and administrative expenses | $ 40,727 | $ 42,365 | $ (1,638) | (4%) |

General and administrative expenses for the three months ended September 30, 2009 decreased as compared to the same period in the prior year primarily due to decreased salary related costs resulting from the April 2009 reduction in force.

General and administrative expenses for the nine months ended September 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 during the second quarter and partnership efforts during the third quarter of 2009. Overall, we expect general and administrative expenses to decrease in 2009 as a result of decreased professional fees.

**Interest Income and Expense**

Interest income for the three and nine months ended September 30, 2009 decreased by $0.7 million and $4.8 million, respectively, as compared to the same period in the prior year primarily due to a lower investment balance and lower market interest rates.

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Interest expense for the three and nine months ended September 30, 2009 increased by $2.8 million and $6.6 million as compared to the same period in the prior year primarily due to 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) and a decrease in capitalized interest related to the completion of the Danbury, Connecticut plant expansion.

**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. 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 September 30, 2009, the amount borrowed and outstanding under the arrangement was $150.0 million.

During the nine months ended September 30, 2009, we used $146.7 million of cash for our operations compared to using $201.0 million for our operations in the nine months ended September 30, 2008. We had a net loss of $160.6 million for the nine months ended September 30, 2009, of which $32.0 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 used $0.9 million of cash in investing activities during the nine months ended September 30, 2009, compared to $135.9 million for the nine months ended September 30, 2008. For the nine months ended September 30, 2009 and 2008, $16.7 million and $72.3 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 $173.9 million of cash for the nine months ended September 30, 2009, compared to $0.2 million for the same period in 2008. For the nine months ended September 30, 2009, cash from financing activities was primarily from the common stock offering completed in August 2009, related party borrowings received, as well as the exercise of stock options.

As of September 30, 2009, we had $56.6 million in cash, cash equivalents and marketable securities. Although we believe our existing cash resources, including the $200.0 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 at least the end 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, the entry into 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.

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We have held extensive discussions with a number of pharmaceutical companies concerning a potential strategic business collaboration for AFRESA. On October 6, 2009, we announced that we do not expect to complete a partnership until after we receive a response from the FDA regarding our NDA for AFRESA. We cannot predict when, if ever, we could conclude 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 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 September 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 $120.0 million from an entity controlled by our principal stockholder during the nine months ended September 30, 2009. (See Note 11 Related-party loan arrangement of the Notes to the accompanying financial statements.)

**Recent Accounting Pronouncements**

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,* or ASC 105-10, 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. The adoption of this standard did not have a material impact on our results of operations, financial position, cash flows or financial statement disclosures.

**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 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 September 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 September 30, 2009 we could experience a higher level of interest expense than assumed in our current operating plan.

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## 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 September 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 September 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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## 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 determined that our submission is sufficiently complete to permit a substantive review.

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.

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***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 cannot be certain when AFRESA may be approved, or if it will be approved.

We have never been profitable and, as of September 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 September 30, 2009, we had an accumulated deficit in stockholders equity of $2.4 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 at least the end 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, the entry into a strategic business collaboration, 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. However, it may be difficult for us to raise additional capital through the sale of equity and/or debt securities. As of September 30, 2009, we had an accumulated deficit in stockholders equity of $2.4 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;

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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.

***Deteriorating global 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, 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 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;

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- 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 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 an agreement with any of these companies on a collaboration. On October 6, 2009, we announced that we do not expect to complete a partnership until after we receive a response from the FDA regarding our NDA for AFRESA. We cannot predict when, if ever, we could conclude 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 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

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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.

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 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.

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***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. We have a long-term agreement with N.V. Organon for the supply of insulin. Recently, 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 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 could 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 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

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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 are intended to be used by a large number of healthcare professionals who will 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 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

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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