PennyMac Mortgage Investment Trust Form 10-K March 11, 2010

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2009

Or

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

For the transition period from to Commission file number: 001-34416

PennyMac Mortgage Investment Trust

(Exact name of registrant as specified in its charter)

Maryland

(State or other jurisdiction of incorporation or organization)

27-0186273 (IRS Employer Identification No.)

27001 Agoura Road, Calabasas, California

91301

(Address of principal executive offices)

(Zip Code)

(818) 224-7442

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class

Name of Each Exchange on Which Registered

Common Shares of Beneficial Interest, \$0.01 Par Value

New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ý

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 \circ 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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 o

Non-accelerated filer ý

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 Exchange Act). Yes o No ý

As of July 30, 2009, the day that trading in the registrant's common shares of beneficial interest, \$0.01 par value ("common shares") commenced on the New York Stock Exchange, the aggregate market value of the registrant's common shares held by non-affiliates was \$315,254,401 based on the closing price as reported on the New York Stock Exchange on that date.

As of March 8, 2010, there were 16,735,317 common shares of PennyMac Mortgage Investment Trust outstanding.

Documents Incorporated By Reference

DocumentDefinitive Proxy Statement for 2010 Annual Meeting of Shareholders

Parts Into Which Incorporated Part III

PENNYMAC MORTGAGE INVESTMENT TRUST FORM 10-K December 31, 2009 TABLE OF CONTENTS

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We make forward-looking statements in this Annual Report on Form 10-K ("Report") that are subject to risks and uncertainties. These forward-looking statements include information about possible or assumed future results of our business, financial condition, liquidity, results of operations, plans and objectives. When we use the words "believe," "expect," "anticipate," "estimate," "plan," "continue," "intend," "should," "may," "would," "will" or similar expressions, we intend to identify forward-looking statements. Statements regarding the following subjects, among others, are forward-looking by their nature:

our business and investment strategy;
our projected financial and operating results;
our ability to obtain future financing arrangements and the terms of such arrangements;
general volatility of the markets for mortgages and mortgage-related assets;
our expected investments;
changes in the value of our investments;
interest rate mismatches between our investments and our borrowings used to fund such purchases;
changes in interest rates and mortgage prepayment rates;
effects of interest rate caps on our adjustable-rate investments;
rates of default or decreased recovery rates on our investments;
prepayments of the mortgage and other loans underlying our mortgage-backed or other asset-backed securities;
the degree to which our hedging strategies may or may not protect us from interest rate volatility;
impact of and changes in governmental regulations, tax law and rates, accounting guidance, and similar matters;
availability of investment opportunities in our targeted assets;
availability of qualified personnel;

estimates relating to our ability to make distributions to our stockholders in the future;

our understanding of our competition; and

market trends in our industry, interest rates, the debt securities markets or the general economy.

The forward-looking statements are based on our beliefs, assumptions and expectations of our future performance, taking into account all information currently available to us. You should not place undue reliance on these forward-looking statements. These beliefs, assumptions and expectations can change as a result of many possible events or factors, not all of which are known to us. Some of these factors are described under the caption *Risk Factors* in this Report and any subsequent Quarterly Reports on Form 10-Q. If a change occurs, our business, financial condition, liquidity and results of operations may vary materially from those expressed in our forward-looking statements. Any forward-looking statement speaks only as of the date on which it is made. New risks and uncertainties arise from time to time, and it is impossible for us to predict those events or how they may affect us. Except as required by law, we are not obligated, and do not intend, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

Item 1. Business

The following description of our business should be read in conjunction with the information included elsewhere in this Report for the year ended December 31, 2009. This description contains forward-looking statements that involve risks and uncertainties. Actual results could differ significantly from the projections and results discussed in the forward-looking statements due to the factors described under the caption "Risk Factors" and elsewhere in this Report. References in this Report to "we," "our," "us," or the "Company" refer to PennyMac Mortgage Investment Trust and its consolidated subsidiaries, unless otherwise indicated.

Our Company

We are a specialty finance company that invests primarily in residential mortgage loans and mortgage-related assets. We were organized in Maryland on May 18, 2009, and commenced operations on August 4, 2009. We are managed by PNMAC Capital Management, LLC ("PCM"), a wholly-owned subsidiary of Private National Mortgage Acceptance Company, LLC ("PennyMac") and an SEC-registered investment adviser that specializes in, and focuses on, residential mortgage loans. The loans we hold in our investment portfolio are serviced on our behalf by another wholly-owned PennyMac subsidiary, PennyMac Loan Services, LLC ("PLS").

Our objective is to provide attractive risk-adjusted returns to our investors over the long-term, primarily through dividends and secondarily through capital appreciation. Our targeted investments are aimed at opportunities created by the recent market dislocations and by the historically large volume of distressed mortgage loans currently outstanding. At present, we are focused on investing in distressed mortgage loans and serving as a conduit for the acquisition and pooling of newly originated mortgage loans into mortgage-backed securitizations. The PennyMac organization was designed specifically to address the opportunities created by the recent dislocations in the markets for residential mortgage assets.

Our primary focus is on investing in distressed residential mortgage loans. Our definition of distressed mortgages includes performing and non-performing loans. The investment objective for performing loans is value enhancement through effective "high touch" servicing, which is based on significant levels of borrower outreach and contact, and the ability to implement long-term, sustainable loan modification and restructuring programs that keep borrowers in their homes. Alternatively, for non-performing loans and real estate assets, the ability to effect property resolution in a timely, orderly and economically efficient manner is essential to generating attractive returns.

We invest in distressed mortgage loans at discounts to their unpaid principal balances. We then seek to maximize the value of the mortgage loans that we acquire through proprietary and federally sponsored (such as the U.S. Department of Housing and Urban Development's Home Affordable Modification Program, or "HAMP") loan modification programs, special servicing and other initiatives focused on keeping borrowers in their homes. We believe that by using these methods, we can provide borrowers with long-term solutions that address their willingness and ability to pay their mortgage loans. We expect these methods to increase our portfolio of performing loans, reduce default rates and enhance the value of the loans in our portfolio. Once we have improved the credit quality of a portfolio, we intend to monetize the enhanced value through various disposition strategies.

We believe that there is currently a need, particularly among smaller lenders, to find outlets for government and government-sponsored entity ("GSE") eligible loans or to achieve liquidity through other means. We believe that PCM can utilize its expertise and relationships to capitalize on these opportunities on our behalf. Under current market conditions, these opportunities include the purchase from smaller mortgage lenders of newly originated mortgage loans that are eligible for (a) sale to participating GSEs such as Federal Home Loan Mortgage Corporation ("Freddie Mac") and the

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Federal National Mortgage Association ("Fannie Mae"), (b) securitization through Government National Mortgage Association ("Ginnie Mae") (Freddie Mac, Fannie Mae and Ginnie Mae are each referred to as an "Agency" and, collectively, as the "Agencies"), or jumbo conventional loans underwritten to Agency standards. Our manager, PCM, is in the process of building a conduit operation to enable us to pursue these opportunities.

We intend to elect and qualify to be taxed as a Real Estate Investment Trust ("REIT") for U.S. federal income tax purposes and to maintain our exclusion from regulation under the Investment Company Act of 1940, as amended (the "Investment Company Act"). Therefore, we will be required to invest a substantial majority of our assets in loans secured by mortgages on real estate and real estate related assets. Subject to maintaining our REIT qualification and our Investment Company Act exclusion, we do not have any limitations on the amounts we may invest in any of our targeted asset classes.

As our manager, PCM conducts activities including developing our investment strategies, sourcing and acquiring mortgage loans and mortgage-related assets for our investment portfolio, and developing the appropriate approach to be taken by PLS for each loan as it performs its specialty servicing. As our loan servicer, PLS services the mortgage loans we acquire, including traditional servicing and workout activities, and executes the portfolio strategies developed by PCM. As part of its execution of PCM's portfolio strategy, PLS may modify or refinance loans in our investment portfolio and originate loans to finance the sale of real estate we acquire in settlement of our loans.

Our internet address is www.pennymacmortgageinvestmenttrust.com. We make available free of charge, on or through the investor relations section of our web site, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as well as proxy statements, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC").

Our Manager and Its Operating Platform

We are externally managed and advised by PCM pursuant to a management agreement. PCM was established in March 2008 and is an SEC-registered investment adviser that specializes in, and focuses on, residential mortgage loans. PCM also serves as the investment manager to two private fund vehicles, which we refer to as the PennyMac funds, with investment objectives and policies that are substantially similar to ours. PCM managed assets totaling \$693.5 million, including our assets, which totaled \$324.4 million, as of December 31, 2009. The PennyMac funds also had \$214.7 million of uncalled capital commitments as of December 31, 2009.

PCM is responsible for administering our business activities and day-to-day operations. Pursuant to the terms of the management agreement, PCM provides us with our senior management team, including our officers, along with appropriate support personnel. PCM is subject to the supervision and oversight of our board of trustees and has the functions and authority specified in the management agreement.

We also have a loan servicing agreement with PLS, pursuant to which PLS provides primary servicing and special servicing for our portfolio of residential mortgage loans. The workout-oriented servicing platform of PLS includes significant borrower contacts, which we refer to as "high touch," and is designed to enable us to effectively implement programs that address borrower needs and maximize the value of our portfolio. PLS was established in February 2008 and also provides primary servicing and special servicing to the PennyMac funds and entities in which they have invested. PLS acted as the servicer for loans with an aggregate unpaid principal balance of approximately \$2.6 billion as of December 31, 2009.

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Our senior management team has extensive experience in the residential mortgage industry and expertise across each of the critical capabilities that we believe is required to successfully acquire and manage mortgage loans, including sourcing, valuation, due diligence, portfolio strategy, servicing (including modification and refinance fulfillment) and secondary marketing of restructured and re-performing loans. Our senior management team is supported by a dedicated team of employees at PLS and PCM.

We have no employees, and we do not pay our officers any cash compensation. Rather, under the management agreement, we pay PCM management fees quarterly in arrears, which include a "base" component and an "incentive" component. We pay PLS fees for servicing our loans, and we reimburse PCM for certain direct costs incurred on our behalf and for certain overhead expenses.

Our management fees are calculated on a quarterly basis as follows:

The base management fee is calculated at the annual rate of 1.5% of shareholders' equity, which is defined as follows for purposes of calculating the base management fee:

the sum of the net proceeds from any issuances of our equity securities since inception (weighted for the time outstanding during the measurement period); plus

our retained earnings at the end of the quarter (without taking into account any non-cash equity compensation expense incurred in current or prior periods); less

any amount we pay for repurchases of our common shares (weighted for the time held during the measurement period); excluding

any unrealized gains, losses or other non-cash items that have impacted our shareholders' equity as reported in our financial statements, regardless of whether those items are included in other comprehensive income or loss or net income; and excluding

one-time events pursuant to changes in accounting principles generally accepted in the U.S. ("U.S. GAAP") and certain other non-cash charges after discussions between PCM and our independent trustees and approval by a majority of our independent trustees.

The performance incentive fee is calculated at 20% per annum of the amount by which "core earnings," on a rolling four-quarter basis and before the incentive fee, exceeds an 8% "hurdle rate."

"Core earnings," for purposes of determining the amount of the performance incentive fee, is defined as U.S. GAAP net income (loss) adjusted to exclude non-cash equity compensation expense, unrealized gains and losses or other non-cash items recognized during the period, any conditional payment amounts relating to our initial public offering ("IPO") paid to PCM and the underwriters of our IPO, and any one-time events pursuant to changes in U.S. GAAP and certain other non-cash charges after discussions between PCM and our independent trustees and approval by a majority of our independent trustees.

The "hurdle rate" is calculated as the product of (1) the weighted average of the issue price per share of all of our public offerings multiplied by the weighted average number of shares outstanding (including, for the avoidance of doubt, restricted share units) in the four quarter period and (2) 8%. During our first four quarters, core earnings will be calculated based on the annualized results of each of the preceding quarters.

PLS's loan servicing activities include collecting principal, interest and escrow account payments, if any, with respect to mortgage loans, as well as managing loss mitigation, which may include, among other things, collection activities, loan workouts, modifications and refinancings,

foreclosures, short sales and financings to facilitate sales of real estate acquired in settlement of loans.

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Investment Strategy

Our objective is to provide attractive risk-adjusted returns to our investors over the long-term, primarily through dividends and secondarily through capital appreciation. We seek to achieve this objective by investing in mortgage loans, a substantial portion of which may be distressed and acquired at discounts to their unpaid principal balances. We seek to maximize the value of the mortgage loans that we acquire through proprietary loan modification programs, special servicing and other initiatives focused on keeping borrowers in their homes. Where this is not possible, such as in the case of non-performing mortgage loans, we seek to effect property resolution in a timely, orderly and economically efficient manner. We also invest in mortgage-related securities and other mortgage-related, real estate and financial assets. It is anticipated that a substantial portion of our investments will not be rated by any rating agency.

The pools of loans that we acquire consist primarily of U.S. residential mortgage loans. These loans may be performing, sub-performing and non-performing, of varying credit quality, including subprime, Alt-A and prime. PCM, in its sole discretion, determines the size, loan type, credit quality and the composition of our portfolio of loans.

We rely on PennyMac's expertise in identifying pools of distressed mortgage loans and other assets for acquisition. PCM's sourcing and evaluation processes for potential acquisitions of residential mortgage loans and for mortgage-related assets are substantially similar. PCM makes investment decisions based on various factors, including expected cash yield, relative value, risk-adjusted returns, current and projected credit fundamentals, current and projected macroeconomic considerations, current and projected supply and demand, market risk, portfolio diversification, liquidity and availability and terms of financing, as well as maintaining our REIT qualification and our exclusion from registration under the Investment Company Act. The evaluation process with respect to residential mortgage-backed securities ("RMBS") and other mortgage-backed securities ("MBS") also includes relative value analyses based on yield, credit rating, average life, effective duration, option-adjusted spreads, prepayment assumptions and credit exceptions.

PCM and its affiliates evaluate new opportunities based on their relative expected returns compared to comparable assets held in our portfolio. Investment decisions with regard to the acquisition or disposition of any of our targeted assets are made by PCM's investment committee.

Our assets are not subject to any geographic, diversification or concentration limitations except that we will be concentrated in residential mortgage-related investments. There are no limitations on the maturity, duration or credit rating of our assets.

We reevaluate our investment strategy as market conditions change with a view toward maximizing the returns from our investment portfolio and identifying dislocations in the mortgage market.

Targeted Asset Classes

We invest primarily in residential mortgage loans and mortgage-related assets. Based on current market conditions, our primary focus initially is on distressed mortgage loans and, to a lesser extent, on other mortgage-related assets. Over time, our targeted asset classes may change as a result of changes in the opportunities that are available in the market. In addition, we may not invest in certain of the investments described below if we believe those types of investments will not provide us with attractive opportunities or if we believe other types of our targeted assets provide us with better opportunities.

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Our targeted asset classes and the principal investments we expect to make in each class are as follows:

Asset Class	Principal Investments			
Residential Mortgage Loans	Newly originated mortgage loans			
	Seasoned performing, sub-performing and non-performing residential mortgage loans			
RMBS	Non-U.S. government agency RMBS, including investment-grade and non-investment			
	grade classes, including the BB-rated, B-rated and non-rated classes			
	U.S. government agency RMBS			
Other assets and other MBS	Condominium development and other commercial real estate-secured loans			
	Mortgage servicing rights			
	Commercial mortgage-backed securities ("CMBS")			
	Mortgage-related derivatives, including, but not limited to, credit default swaps, options,			
	futures and derivatives on MBS			
	Policies, instruments and agreements related to mortgage insurance or reinsurance risk			
	Hedging instruments that include U.S. Treasury securities, options and futures.			

Our Portfolio

During the period from August 4, 2009 (commencement of operations) to December 31, 2009, we purchased \$93.0 million of MBS and \$26.0 million of mortgage loans. At December 31, 2009, we had committed to purchase an additional \$56.3 million of mortgage loans. During the period from December 31, 2009 through the date of this Report, PCM has committed to purchases of loans at a price of approximately \$143 million. The portion of the purchases that we will be allocated has not been fully determined but will be at least \$39 million.

These acquisitions notwithstanding, PCM has encountered a low volume of available performing mortgage transactions, which we believe offer greater opportunity for value enhancement, and less attractive trading levels for the pools that have been marketed. These acquisitions have been effected after PCM has reviewed and evaluated whole loan pools with unpaid principal balances totaling over \$11.8 billion and placed bids on \$6.3 billion of those loans for investment by us and the PennyMac funds during the six months ended December 31, 2009. To address the limited availability of attractive whole loan pools, PCM has worked to expand sources of assets for us, including:

developing a mortgage conduit whereby we will acquire newly originated loans from small mortgage lenders, pool those loans into MBS, and sell the resulting securities into the MBS markets;

pursuing opportunities to acquire distressed mortgage assets that result from distressed condominium development projects. We anticipate these acquisitions would involve acquisition by us of the construction loan underlying the condominium development while PCM and PLS would work together to design and deliver complete condominium financing solutions, creating

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the opportunity to effectively repackage distressed developer loans into high quality residential loans on our behalf; and

pursuing investments in mortgage servicing rights from liquidating and other entities. Mortgage servicing rights reflect the value of the future stream of expected cash flows from the contractual rights to service a given pool of mortgage loans. We believe investments in mortgage servicing rights would allow us to capture attractive current returns by utilizing the capabilities and efficiencies of PLS.

During the period from August 4, 2009 (commencement of operations) to December 31, 2009, most of our investments were held in a liquidity management (or money market) fund managed by an affiliate. This investment was made pending identification and acquisition of higher yielding investments in our targeted asset classes.

While our primary investment during the period from August 4, 2009 (commencement of operations) to December 31, 2009 was in money market deposits, our primary source of net investment income was interest earned on MBS, owing to the low yields on money market deposits. During the period from August 4, 2009 (commencement of operations) to December 31, 2009, we recorded net investment income from MBS totaling \$2.3 million, comprised of interest and net appreciation in fair value. Our investments in MBS earned an annualized yield of approximately 7.33% for the period, along with net appreciation in value of approximately \$152,000. Our portfolio of MBS securities is backed by non-agency Alt-A, subprime and prime jumbo loans and consists of currently cash flowing senior priority securities with an average remaining life of approximately 1.2 years. We acquired these securities to provide an enhanced yield pending reinvestment in suitable pools of mortgage loans or mortgage-related assets.

As noted above, PCM continues to source and bid on pools of mortgage loans and MBS for investment. We expect to make continued progress in the deployment of our assets into our targeted asset classes in the first quarter of 2010.

Our Financing and Hedging Strategy

As we deploy our capital, we may leverage our investment capacity by financing our investments with borrowings, the level of which may vary based upon the particular characteristics of our portfolio and on market conditions. We are not required to maintain any specific debt-to-equity ratio, and we believe the appropriate leverage for the particular assets we may finance depends on, among other things, the credit quality and risk of such assets. Our declaration of trust and bylaws do not limit the amount of indebtedness we can incur, and our board of trustees has discretion to deviate from or change our financing strategy at any time.

In light of current market conditions, we anticipate initially utilizing limited borrowings on our portfolio as part of our financing strategy. With regard to mortgage loans, we anticipate that leverage may be available to us in connection with our acquisitions, if any, of mortgage assets from the FDIC as receiver for failed depository institutions. Although the amount of any borrowings for this type of acquisition would be determined on a case-by-case basis, we anticipate that borrowings may be available which would provide for a debt-to-equity ratio for acquisitions in the range of 2:1 to 3:1, and would likely not exceed 6:1.

Direct acquisitions of mortgage loans from financial institutions may include seller financing, although the amount of potential borrowings available, if any, would vary depending upon the seller. Our financing sources may include borrowings in the form of bank credit facilities (including term loans and revolving facilities), repurchase agreements, warehouse facilities, structured financing arrangements, public and private equity and debt issuances and derivative instruments, in addition to transaction or asset specific funding arrangements.

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We expect to attempt to manage interest rate risk on any outstanding debt and to minimize exposure to interest rate fluctuations thereon through the use of match funded financing structures, when appropriate, whereby we seek (i) to match the maturities of our debt with the maturities of the assets that we finance and (ii) to match the interest rates on our leveraged investments with like-kind debt (*i.e.*, floating rate assets are financed with floating rate debt and fixed-rate assets are financed with fixed-rate debt), directly or through the use of interest rate swaps, caps or other financial instruments, or through a combination of these strategies. Subject to maintaining our qualification as a REIT and exclusion from the Investment Company Act, we intend to utilize derivative financial instruments as hedging instruments, in an effort to hedge the interest rate risk associated with the financing of our portfolio and not for speculative purposes.

We expect this approach will allow us to minimize the risk that we have to refinance our liabilities before the maturities of our assets and to reduce the impact of changing interest rates on our earnings.

In utilizing borrowings and interest rate hedges, our objectives will be to improve risk-adjusted returns and, where possible, to lock in, on a long-term basis, a spread between the yield on our assets and the cost of our financing. We will use borrowings to finance our portfolio and not to speculate on changes in interest rates.

Investment Policies

Our board of trustees has adopted the policies set forth below for our investments and borrowings. PCM will review our compliance with the investment policies regularly and will report periodically to our board of trustees regarding such compliance.

No investment shall be made that would cause us to fail to qualify as a REIT for U.S. federal income tax purposes;

No investment shall be made that would cause us to be regulated as an investment company under the Investment Company Act; and

With the exception of real estate and housing, no single industry shall represent greater than 20% of the investments or aggregate risk exposure in our portfolio.

These investment policies may be changed by a majority of our board of trustees without the approval of, or prior notice to, our shareholders.

Investment Allocation Policy

Investment opportunities in pools of mortgage loans that are consistent with our investment objective, on the one hand, and the investment objectives of the PennyMac funds and other future entities or accounts managed by PCM, on the other hand, will be allocated among us and the PennyMac funds and the other entities or accounts generally *pro rata* based upon relative amounts of investment capital (including undrawn capital commitments) available for new investments by us, the PennyMac funds and any other relevant entities or accounts or by assigning opportunities among the relevant entities such that investments assigned among us, such funds, entities or accounts are fair and equitable over time; *provided* that PCM, in its sole discretion, may allocate investment opportunities in any other manner that it deems to be fair and equitable.

In the case of the assignment of investment opportunities, PCM will consider a number of factors. These factors include:

investment objectives or strategies for particular entities or accounts

tax considerations of an entity or account

risk or investment concentration parameters for an entity or account

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supply or demand for an investment at a given price level
size of available investment
cash availability and liquidity requirements for an entity or account
minimum investment size of an entity or account
relative size or "buying power" of an entity or account
regulatory considerations, including the impact on an entity's status under the Investment Company Act, and, in our case, our REIT status
such other factors as may be relevant to a particular transaction.
In the case of <i>pro rata</i> purchases of pools of loans where the pool is allocated among us and other entities or accounts, PCM will, at the time of purchase, seek to allocate the hundreds, or potentially thousands, of individual mortgage loans in the pools among us and the other entities or accounts such that the overall allocation of acquired mortgage loans in the pools will target reasonable symmetry with reference to, among other factors, the following:
unpaid principal balances
default status
discounts from purchase price
lien position
expected cash flows
geography
such other factors as may be relevant to a particular transaction.

As the investment programs of the various entities and accounts managed by PCM change and develop over time, additional issues and considerations may affect PCM's and our allocation policy and PCM's and our expectations with respect to the allocation of investment opportunities among the various entities and accounts managed by PCM. Despite PCM's intention to effect fair and equitable allocations of investment opportunities, it is likely that our performance will differ from the performance of the PennyMac funds and any other PennyMac-managed entity or account for many reasons, including differences in the legal or regulatory characteristics, or tax classification, of the entities or accounts or due to differing fee structures or the idiosyncratic differences in the outcome of individual mortgage loans.

We have not adopted any policy that would allow us to, or prohibit us from, buying or otherwise obtaining assets from the PennyMac funds or selling or transferring any assets to the PennyMac funds.

Before the investment of the offering proceeds into our targeted asset classes, we have made and may make investments in senior priority, currently cash flowing short-term securities and BlackRock-sponsored money market funds.

We have not adopted a policy that expressly prohibits our trustees, officers, shareholders or affiliates from having a direct or indirect financial interest in any investment to be acquired or disposed of by us or in any transaction to which we are a party or have an interest. Nor do we have a policy that expressly prohibits any such persons from engaging for their own account in business activities of the types conducted by us. However, our code of business conduct and ethics contains a conflicts of interest policy that prohibits our trustees, officers and employees, as well as employees of PCM who provide services to us, from engaging in any transaction that involves an actual or apparent conflict of interest

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with us without the appropriate approval. We also have written policies and procedures for the review and approval of related party transactions.

Operating and Regulatory Structure

REIT Qualification

We intend to elect to be treated as a REIT under Sections 856 through 859 of the Internal Revenue Code of 1986 (the "Internal Revenue Code") commencing with our taxable year ended December 31, 2009. Our qualification as a REIT depends upon our ability to meet on a continuing basis, through actual investment and operating results, various complex requirements under the Internal Revenue Code relating to, among other things, the sources of our gross income, the composition and values of our assets, our distribution levels and the diversity of ownership of our shares. We believe that we are organized in conformity with the requirements for qualification and taxation as a REIT under the Internal Revenue Code, and that our intended manner of operation will enable us to meet the requirements for qualification and taxation as a REIT.

As a REIT, we generally are not subject to U.S. federal income tax on our REIT taxable income we distribute currently to our shareholders. If we fail to qualify as a REIT in any taxable year and do not qualify for certain statutory relief provisions, we will be subject to U.S. federal income tax at regular corporate rates and may be precluded from qualifying as a REIT for the subsequent four taxable years following the year during which we lost our REIT qualification. Accordingly, our failure to qualify as a REIT could have a material adverse impact on our results of operations and amounts available for distribution to our shareholders.

Even if we qualify for taxation as a REIT, we may be subject to some U.S. federal, state and local taxes on our income or property. We expect a significant portion of our business to be conducted through, and a significant portion of our income may be earned in, one or more taxable REIT subsidiaries ("TRSs") that are subject to corporate income taxation. In general, a TRS of ours may hold assets and engage in activities that we cannot hold or engage in directly and generally may engage in any real estate or non-real estate related business. A TRS is subject to U.S. federal, state and local corporate income taxes. To maintain our REIT election, no more than 25% of the value of a REIT's assets may consist of stock or securities of one or more TRSs (at the end of each quarter).

While our TRSs will generate net income, our TRSs can declare dividends to us, which will be included in our taxable income and necessitate a distribution to our shareholders. Conversely, if we retain earnings at the TRS level, no distribution is required and we can increase book equity of the consolidated entity. As discussed in Section 1A of this Report entitled *Risk Factors*, the combination of the requirement to maintain no more than 25% of our assets in the TRS coupled with the effect of TRS dividends on our allowable income tests creates compliance complexities for us in the maintenance of our qualified REIT status.

The dividends paid deduction of a REIT for qualifying dividends to its shareholders is computed using our taxable income as opposed to net income reported on our financial statements. Taxable income, generally, differs from net income reported on our financial statements because the determination of taxable income is based on tax laws and regulations and not financial accounting principles.

Licensing

We and PLS are required to be licensed to conduct business in certain jurisdictions. We and PLS are currently evaluating the need for various licenses in order to conduct our most important business activities directly and the timing of the pursuit of these licenses. PLS is licensed, or is taking steps to become licensed, in those jurisdictions, and for those activities, where it believes it is cost effective and

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appropriate to become licensed. Through our wholly owned taxable REIT subsidiary, PennyMac Corp., we are also licensed, or are taking steps to become licensed, in those jurisdictions, and for those activities, where we believe it is cost effective and appropriate to become licensed. In jurisdictions in which neither we nor PLS is licensed, PLS retains sub-servicers and other vendors. For example, PLS has entered into sub-servicing arrangements with regard to 10% of the unpaid principal balance of its servicing portfolio, which includes loans purchased pending transfer of servicing responsibilities to PLS (approximately 2% of the unpaid principal balance of its loan servicing portfolio). Our failure or the failure by PLS to obtain any necessary licenses promptly or our failure to satisfy the various requirements or to maintain them over time will restrict our direct business activities.

Competition

We intend to achieve our investment objective largely by investing in mortgage loans, a substantial portion of which may be distressed and acquired at discounts to their unpaid principal balances. We seek to maximize the value of the mortgage loans that we acquire through both proprietary and government sponsored loan modification programs, special servicing and other initiatives designed to keep borrowers in their homes.

In acquiring mortgage assets, we compete with other mortgage REITs, specialty finance companies, private funds, savings and loan associations, banks, mortgage bankers, insurance companies, mutual funds, institutional investors, investment banking firms, depository institutions, governmental bodies and other entities. A number of these competitors may also be focused on acquiring distressed mortgage loans, and therefore may increase competition for the available supply of mortgage assets suitable for purchase. Many of our competitors are significantly larger than we are and have stronger balance sheets and access to greater capital and other resources than we have and may have other advantages over us. Such advantages include the ability to obtain lower-cost financing, such as deposits and operational efficiencies arising from their larger size. In addition, some of our competitors may have higher risk tolerances or different risk assessments and may not be subject to the operating restraints associated with REIT tax compliance or maintenance of an exclusion from the Investment Company Act, which could allow them to consider a wider variety of investments and establish more relationships than we can.

Current market conditions will likely attract more competitors, which would increase the competition for assets and sources of financing. Increased competition for assets may result in our paying higher prices for acquisitions of residential mortgage loans and other assets or adversely influence our ability to "win" our bids for such assets. An increase in the competition for sources of funding could adversely affect the availability and terms of financing, and thereby adversely affect the market price of our common shares.

In the face of this competition, we have access to PCM's professionals and their industry expertise, which may provide us with a competitive advantage and help us assess investment risks and determine appropriate pricing for certain potential investments. We expect these relationships to enable us to compete more effectively for attractive investment opportunities. Furthermore, we believe that our access to PLS's special servicing expertise helps us to maximize the value of our residential mortgage loans and provides us with a competitive advantage over other companies with a similar focus. We believe that current market conditions may have adversely affected the financial condition and liquidity of certain competitors. Thus, not having a legacy portfolio may also enable us to compete more effectively for attractive investment opportunities. However, we cannot assure you that we will be able to achieve our business goals or expectations due to the competitive and other risks that we face.

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Staffing

We are managed by PCM pursuant to our management agreement with PCM. PLS provides servicing and special servicing for our portfolio of residential mortgage loans pursuant to our loan servicing agreement with PLS. All of our officers are employees of PCM or its affiliates. We have no employees. As of December 31, 2009, PennyMac had 137 employees. See *Our Manager and its Operating Platform*.

Item 1A. Risk Factors

Risks Associated with Our Management and Relationship with Our Manager and Its Affiliates

We are dependent upon PCM, PLS and their resources and may not find suitable replacements if our management agreement with PCM is terminated and/or our loan servicing agreement with PLS is terminated.

In accordance with our management agreement, we are externally advised and managed by PCM. We have no employees, and all of our officers are also employees of PCM or its affiliates. Among other matters, PCM supplies us with our senior management team, makes all or substantially all of our investment, financing and risk management decisions, and has significant discretion as to the implementation of our operating policies and strategies. As a result, we are completely reliant upon, and our success depends exclusively on, PCM's investment decisions, the advice of PCM's employees, the use of PCM's vendors and other resources, and the manner and extent to which PCM selects its vendors and allocates those resources to manage our business. No assurance can be given that PCM's strategies will be successful, that it will conduct complete and accurate due diligence or provide sound advice, or that it will act in our best interests with respect to the allocation of its resources to our business. Its failure to do any of the above would materially and adversely affect our ability to execute our business plan. In addition, the initial term of our management agreement only extends until August 4, 2012 (subject to annual automatic renewals for one-year terms), and it may be terminated earlier under certain circumstances. If our management agreement is terminated and a suitable replacement is not secured in a timely manner, it would materially and adversely affect our ability to execute our business plan.

Under our loan servicing agreement with PLS, PLS provides primary servicing and special servicing for our portfolio of residential mortgage loans for an initial term through August 4, 2012. We rely on PLS to provide these services for our portfolio and have no in-house capability to handle these services independently of PLS. The costs of these services increase our operating costs and may adversely affect our net income. The term of our loan servicing agreement is identical to the term of our management, and is subject to early termination in the event our management agreement is terminated for any reason. If our loan servicing agreement is terminated, we will have to obtain the loan servicing from another servicer. We may not be able to replace these services in a timely manner or on favorable terms, or at all.

PNMAC, the parent company of PCM and PLS, has a limited operating history and its success will be largely determinative of our own success. PennyMac is undergoing significant growth and its development and integration of new operations may not be effective.

PNMAC, the parent company of PCM, our manager, and PLS, our loan servicer, was organized in January 2008 and has only a limited operating history. PennyMac's success, which will be largely determinative of our own success, depends on many factors, including the availability of attractive risk-adjusted investment opportunities that satisfy its targeted investment strategies and its identification and consummation of them on favorable terms, the level and volatility of interest rates, the level of competition for attractive investment opportunities, and conditions in the financial markets, real estate market and the economy, as to which no assurance can be given.

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In addition, PennyMac's significant growth since it commenced operations has caused significant demands on its operational, accounting and legal infrastructure, and increased expenses. The ability of PCM and PLS to provide us with the services we require to be successful depends, among other things, on the ability of PennyMac, including PCM and PLS, to maintain an operating platform and management system sufficient to address its growth. This may require PennyMac to incur significant additional expenses and to commit additional senior management and operational resources. There can be no assurance that PennyMac will be able to effectively integrate its expanding operations or that PennyMac will continue to grow successfully. PennyMac's failure to do so could adversely affect the ability of PCM and PLS to manage us and service our mortgage loan portfolio, respectively, which would materially and adversely affect us.

Our management agreement and our loan servicing agreement were not negotiated on an arm's length basis and the terms may not be as favorable to us as they would be if those agreements were negotiated with unaffiliated third parties.

Our management agreement and our loan servicing agreement were each negotiated between related parties, and we did not have the benefit of arm's length negotiations of the type normally conducted with an unaffiliated third party and the terms, including the fees payable to PCM and PLS, as the case may be, may not be as favorable to us as they would be if those agreements were negotiated with unaffiliated third parties. We may also choose not to enforce, or to enforce less vigorously, certain of our rights under our management agreement or our loan servicing agreement in an effort to maintain our ongoing relationship with PCM or PLS, as the case may be.

The management fee structure could cause disincentive and/or create greater investment risk.

Pursuant to our management agreement, PCM is entitled to receive a base management fee that is based on our shareholders' equity (as defined in our management agreement) at the end of each quarter. As a result, significant base management fees may be payable to PCM for a given quarter despite the fact that we experience a net loss during that quarter. In fact, PCM received its base management fees for each of our first two operating periods even though we reported a net loss for each of those periods. PCM's right to non-performance-based compensation may not provide sufficient incentive to PCM to devote its time and effort to source and maximize risk-adjusted returns on our investment portfolio, which could, in turn, adversely affect our ability to make distributions to our shareholders and the market price of our common shares.

Conversely, PCM is also entitled to receive incentive compensation under our management agreement based on our performance in each quarter. In evaluating investments and other management strategies, the opportunity to earn incentive compensation based on our core earnings (as defined in our management agreement) may lead PCM to place undue emphasis on the maximization of short-term net income at the expense of other criteria, such as preservation of capital, maintaining sufficient liquidity and/or management of market risk, in order to achieve higher incentive compensation. Investments with higher yield potential are generally riskier and more speculative. PCM may also have a conflict of interest in deciding upon whether to sell any investment at a gain, thereby recognizing additional incentive compensation, or to hold such investment based on its long-term value. This could result in increased risk to the value and long-term performance of our portfolio.

The servicing fee structure could create a conflict of interest.

For its services under our loan servicing agreement, PLS is entitled to base servicing fees that are competitive with those charged by specialty servicers and are calculated as a percentage of the unpaid principal balance of the mortgage loans in our portfolio. Because the base servicing fees are calculated on this basis, PLS's interests may not be aligned with ours with regard to loan modifications that would reduce the unpaid principal balances of our mortgage loans. PLS is also entitled to certain customary

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market-based fees and charges, including boarding and deboarding fees, liquidation and disposition fees, assumption, modification and origination fees and late charges, as well as interest on funds on deposit in custodial or escrow accounts. In addition, to the extent we participate in the HAMP (or other similar mortgage loan modification programs), PLS will be entitled to retain any incentive payments made to it in connection with our participation therein.

On our behalf, PLS also refinances sub-performing and non-performing loans and originates new loans to facilitate the disposition of real estate that we acquire through foreclosure. In order to provide PLS with an incentive to produce such loans, we have agreed to pay PLS customary market-based origination fees of 1.0% of the unpaid principal balance of the loan plus \$750. The amount of the origination fee is intended to reflect market rates and will be subject to review by our board of trustees from time to time. This may provide PLS with an incentive to refinance a greater proportion of our loans than it otherwise would and/or to refinance loans on our behalf instead of arranging the refinancings with a third party lender. It may also provide PLS with an incentive to provide financing to facilitate sales to third parties with regard to the disposition of real estate that we acquire in settlement of loans.

Termination of our management agreement would be difficult and costly.

It is difficult and costly to terminate, without cause, our management agreement. Following the initial term ending August 4, 2012, our management agreement provides that it may be terminated annually by us without cause under limited circumstances and upon 180 days' prior written notice and the payment to PCM of a significant termination fee. The cost to us of terminating our management agreement may adversely affect our desire or ability to terminate our management agreement with PCM without cause.

PCM may terminate our management agreement if we become required to register as an investment company under the Investment Company Act, or decline to renew our management agreement by providing us with 180 days' prior written notice, in which case we would not be required to pay a termination fee to PCM. PCM may also terminate our management agreement upon at least 60 days' prior written notice if we default in the performance of any material term of our management agreement and the default continues for a period of 30 days after written notice to us, whereupon we would be required to pay to PCM a significant termination fee. If our management agreement is terminated, we will have to obtain investment and other management services from another investment manager. We may not be able to replace these services in a timely manner or on favorable terms, or at all.

PCM and PLS both have limited liability and indemnity rights.

Our management agreement and our loan servicing agreement provide that PCM (in the case of our management agreement) and PLS (in the case of our loan servicing agreement) will not assume any responsibility other than to provide the services specified in such agreements. Our management agreement further provides that PCM will not be responsible for any action of our board of trustees in following or declining to follow its advice or recommendations. In addition, each of PCM (in the case of our management agreement) and PLS (in the case of our loan servicing agreement) and their respective affiliates, managers, officers, trustees, directors, employees and members will be held harmless from, and indemnified by us against, certain liabilities on customary terms.

Existing or future entities or accounts managed by PCM may compete with us for PCM's time and services, and they may compete with us for, or may participate in, investments, any of which could result in conflicts of interest. BlackRock and Highfields Capital, PennyMac's strategic investors, could compete with us or transact business with us.

Pursuant to our management agreement, PCM is obligated to supply us with our senior management team, and the members of that team are required to devote such time to us as is necessary and appropriate, commensurate with the level of our activity. The members of our senior management team may have conflicts in allocating their time and services between us and other entities or accounts managed by PCM now or in the future, including the PennyMac funds.

Although we and PCM have adopted an allocation policy to specifically address some of the conflicts relating to our investment opportunities, there is no assurance that this policy will be adequate to address all of the conflicts that may arise or will address such conflicts in a manner that is favorable to us. We are also limited in our ability to acquire assets that are not qualifying real estate assets and/or real estate related assets, whereas the PennyMac funds and other entities or accounts that PCM manages now or may manage in the future are not, or will not be, as applicable, so limited. In addition, PCM and/or the PennyMac funds and the other entities or accounts managed by PCM now or in the future may participate in some of our investments, which may not be the result of arm's length negotiations and may involve or later result in potential conflicts between our interests in the investments and those of PCM or such other entities.

In addition, PNMAC's strategic investors, BlackRock and Highfields Capital, each own 37% of PNMAC. Affiliates of each of BlackRock and Highfields Capital currently manage investment vehicles and separate accounts that may compete directly or indirectly with us. BlackRock and Highfields Capital are under no obligation to provide us with any financial or operational assistance, or to present opportunities to us for matters in which they may become involved. We may enter into transactions with BlackRock or Highfields Capital or with market participants with which BlackRock or Highfields Capital has business relationships, and such transactions and/or relationships could influence the decisions made by PCM with respect to the purchase or sale of assets and the terms of such purchase or sale. Such activities could have an adverse effect on the value of the positions held by us, or may result in BlackRock and/or Highfields Capital having interests adverse to ours.

If ownership interests held by PennyMac's strategic investors were transferred to a third party, this could result in a change in our objectives and cause us material harm.

If either or both of BlackRock and Highfields Capital were to sell their ownership interests in PNMAC to a third party, that party might, subject to certain limitations, attempt to cause us to materially amend our investment policies, attempt to cause a sale or disposition of PCM and/or PLS or change in the composition of PCM's professionals. A change in ownership could also cause a termination of our management agreement with PCM. If any of the foregoing were to occur, we could experience difficulty in making new investments and the value of our existing investments, our business, our results of operations and our financial condition could suffer materially. Additionally, we cannot predict the effect that any transfer in the ownership of PNMAC would have on the trading price of our common shares or our ability to raise capital or make investments in the future because such matters would depend to a large extent on the identity of the new owner and the new owner's intentions with regard to our business and affairs. As a result, the future of our company would be uncertain and the value of our investments, our results of operations and our financial condition could suffer.

Negative publicity and media attention involving Countrywide Financial Corporation and certain of its former officers could have an adverse impact on PennyMac and us.

There are several lawsuits pending against Countrywide Financial Corporation ("Countrywide") and certain of its former officers. Certain of our and PennyMac's officers who are former employees of Countrywide, including Stanford L. Kurland, our chairman and chief executive officer, have been named as defendants in lawsuits involving Countrywide and certain of its employees and former employees. Neither we nor PennyMac nor any of our officers in their capacity as officers of PennyMac or us are party to, nor do any such parties expect to become party in such capacities to, aines MAGE-A3, delivered as a purified recombinant protein, with certain immunostimulating compounds that are intended to increase the anti-tumor immune response. This investigational product is being evaluated in Phase 3 clinical trials for the treatment of non-small cell lung cancer and melanoma. CDX-110 is an immunotherapy being developed by Celldex, Inc. in collaboration with Pfizer. CDX-110 targets a mutated form of epidermal growth factor receptor that is present in multiple cancer types and is currently being evaluated for the treatment of glioblastoma multiforme in a Phase 2/3 clinical trial.

GOVERNMENT REGULATION AND PRODUCT APPROVAL

The FDA and comparable regulatory agencies in state, local and foreign jurisdictions impose substantial requirements upon the clinical development, manufacture and marketing of medical devices and new drug and biologic products. These agencies, through regulations that implement the Federal Food, Drug, and Cosmetic Act, as amended, or FDCA, and other regulations, regulate research and development activities and the development, testing, manufacture, labeling, storage, shipping, approval, recordkeeping, advertising, promotion, sale and distribution of such products. In addition, if our products are marketed abroad, they also are subject to export requirements and to regulation by foreign governments. The regulatory approval process is generally lengthy, expensive and uncertain. Failure to comply with applicable FDA and other regulatory requirements can result in sanctions being imposed on us or the manufacturers of our products, including hold letters on clinical research, civil or criminal fines or other penalties, product recalls, or seizures, or total or partial suspension of production or injunctions, refusals to permit products to be imported into or exported out of the United States, refusals of the FDA to grant approval of drugs or to allow us to enter into government supply contracts, withdrawals of previously approved marketing applications and criminal prosecutions.

The steps typically required before an unapproved new drug or biologic product for use in humans may be marketed in the United States include:

Preclinical studies that include laboratory evaluation of product chemistry and formulation, as well as animal studies to assess the potential safety and efficacy of the product. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, or requiring such studies to be repeated. In some cases, long-term preclinical studies are conducted while clinical studies are ongoing.

Submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may commence. The results of the preclinical studies are submitted to the FDA as part of the IND. Unless the FDA objects, the IND becomes effective 30 days following receipt by the FDA.

Approval of clinical protocols by independent institutional review boards, or IRBs, at each of the participating clinical centers conducting a study. The IRBs consider, among other things, ethical factors, the potential risks to individuals participating in the trials and the potential liability of the institution. The IRB also approves the consent form signed by the trial participants.

Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product. Clinical trials involve the administration of the drug to healthy volunteers or to patients under the supervision of a qualified medical investigator according to an approved protocol. The clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor participant safety and efficacy or other criteria to be evaluated. Each protocol is submitted to the FDA as part

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of the IND. Human clinical trials are typically conducted in the following four sequential phases that may overlap or be combined:

In Phase 1, the drug is initially introduced into a small number of individuals and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase 1 clinical trials are often conducted in healthy human volunteers and such cases do not provide evidence of efficacy. In the case of severe or life-threatening diseases, the initial human testing is often conducted in patients rather than healthy volunteers. Because these patients already have the target disease, these studies may provide initial evidence of efficacy that would traditionally be obtained in Phase 2 clinical trials. Consequently, these types of trials are frequently referred to as Phase 1/2 clinical trials. The FDA receives reports on the progress of each phase of clinical testing and it may require the modification, suspension or termination of clinical trials if it concludes that an unwarranted risk is presented to patients or healthy volunteers.

Phase 2 involves clinical trials in a limited patient population to further identify any possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3 clinical trials are undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded patient population at geographically dispersed clinical study sites. Phase 3 clinical trials usually include a broader patient population so that safety and efficacy can be substantially established. Phase 3 clinical trials cannot begin until Phase 2 evaluation demonstrates that a dosage range of the product may be effective and has an acceptable safety profile.

Phase 4 clinical trials are performed if the FDA requires, or a company pursues, additional clinical trials after a product is approved. These clinical trials may be made a condition to be satisfied after a drug receives approval. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information to augment the FDA s voluntary adverse drug reaction reporting system.

Concurrent with clinical trials and preclinical studies, companies also must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with drug cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and the manufacturer must develop methods for testing the quality, purity, and potency of the final products. Additionally, appropriate packaging must be selected and tested and chemistry stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

Submission to the FDA of an NDA, or Biologics License Application, or BLA, based on the clinical trials. The results of product development, preclinical studies, and clinical trials are submitted to the FDA in the form of an NDA or BLA for approval of the marketing and commercial shipment of the product. Under the Pediatric Research Equity Act of 2003, NDAs are required to include an assessment, generally based on clinical study data, of the safety and efficacy of drugs for all relevant pediatric populations. The statute provides for waivers or deferrals in certain situations but we can make no assurances that such situations will apply to us or our product candidates.

Medical products containing a combination of new drugs, biological products, or medical devices are regulated as combination products in the United States. A combination product generally is defined as a product comprised of components from two or more regulatory categories (*e.g.*, drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic, or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product. The determination whether a product is a combination product or two separate products is made by the FDA on a case-by-case basis. The FDA considers AFREZZA to be a drug-device combination product, so the

review of our NDA for AFREZZA involves reviews within the Division of Metabolism and Endocrinology Products and the Division of Pulmonary and Allergy Products, both within the Center for Drug Evaluation and Research, as well as review within the Center for Devices and Radiological Health, the Center within the FDA that reviews Medical Devices. The Division of Metabolic and Endocrine Products is the lead group and obtains consulting reviews from the other two FDA groups.

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The testing and approval process requires substantial time, effort and financial resources. Data that we submit are subject to varying interpretations, and the FDA and comparable regulatory authorities in foreign jurisdictions may not agree that our product candidates have been shown to be safe and effective. We cannot be certain that any approval of our products will be granted on a timely basis, if at all. If any of our products are approved for marketing by the FDA, we will be subject to continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the product, submitting other periodic reports, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, and complying with certain electronic records and signature requirements. Prior to and following approval, if granted, all manufacturing sites are subject to inspection by the FDA and other national regulatory bodies and must comply with cGMP, QSR and other requirements enforced by the FDA and other national regulatory bodies through their facilities inspection program. Foreign manufacturing establishments must comply with similar regulations. In addition, our drug-manufacturing facilities located in Danbury and the facilities of our insulin supplier, the supplier(s) of our Technosphere material and the supplier(s) of our inhaler and cartridges are subject to federal registration and listing requirements and, if applicable, to state licensing requirements. Failure, including those of our suppliers, to obtain and maintain applicable federal registrations or state licenses, or to meet the inspection criteria of the FDA or the other national regulatory bodies, would disrupt our manufacturing processes and would harm our business. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full compliance. Currently, we believe we are operating under all of the necessary guidelines and permits.

As a drug-device combination, we currently expect that our inhaler will be approved, if at all, as part of the NDA for AFREZZA. However, numerous device regulatory requirements still apply to the device part of the drug-device combination. These include:

product labeling regulations;

general prohibition against promoting products for unapproved or off-label uses;

corrections and removals (e.g., recalls);

establishment registration and device listing;

general prohibitions against the manufacture and distribution of adulterated and misbranded devices; and

the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

Further, the company we contract with to manufacture our inhaler and cartridges will be subject to the QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process of medical devices, among other requirements.

Failure to adhere to regulatory requirements at any stage of development, including the preclinical and clinical testing process, the review process, or at any time afterward, including after approval, may result in various adverse consequences. These consequences include action by the FDA or another national regulatory body that has the effect of delaying approval or refusing to approve a product; suspending or withdrawing an approved product from the market; seizing or recalling a product; or imposing criminal penalties against the manufacturer. In addition, later discovery of previously unknown problems may result in restrictions on a product, its manufacturer, or the NDA holder, or market restrictions through labeling changes or product withdrawal. Also, new government requirements may be established or current government requirements may be changed at any time, which could delay or prevent regulatory approval of our products under development. For example, healthcare reform legislation currently being considered in Congress could provide the FDA and other federal agencies with greater authority to consider the comparative effectiveness of products and to control costs of public spending on prescription drugs and biologics. We

cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

In addition, the FDA imposes a number of complex regulations on entities that advertise and promote drugs, which include, among other requirements, standards for and regulations of direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has very broad enforcement authority under the FDCA, and failure to comply with these regulations can

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result in penalties, including the issuance of a warning letter directing us to correct deviations from FDA standards, including corrective advertising to healthcare providers, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

Products manufactured in the United States and marketed outside the United States are subject to certain FDA regulations, as well as regulation by the country in which the products are to be sold. We also would be subject to foreign regulatory requirements governing clinical trials and drug product sales if products are studied or marketed abroad. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries usually must be obtained prior to the marketing of the product in those countries. The approval process varies from jurisdiction to jurisdiction and the time required may be longer or shorter than that required for FDA approval.

Product development and approval within this regulatory framework take a number of years, involve the expenditure of substantial resources and are uncertain. Many drug products ultimately do not reach the market because they are not found to be safe or effective or cannot meet the FDA s other regulatory requirements. In addition, there can be no assurance that the current regulatory framework will not change or that additional regulation will not arise at any stage of our product development that may affect approval, delay the submission or review of an application or require additional expenditures by us. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals on a timely basis, if at all, for any of our product candidates under development, and delays in receipt or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business and results of operations.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this latter procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the application and assessment report, each member state must decide whether to recognize approval. We plan to choose the appropriate route of European regulatory filing in an attempt to accomplish the most rapid regulatory approvals. However, the chosen regulatory strategy may not secure regulatory approvals or approvals of the chosen product indications. In addition, these approvals, if obtained, may take longer than anticipated.

In addition to the foregoing, we are subject to numerous federal, state and local laws relating to such matters as laboratory practices, the experimental use of animals, the use and disposal of hazardous or potentially hazardous substances, controlled drug substances, privacy of individually identifiable healthcare information, safe working conditions, manufacturing practices, environmental protection and fire hazard control. We may incur significant costs to comply with those laws and regulations now or in the future.

Patent Restoration and Marketing Exclusivity

The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, permits the FDA to approve abbreviated new drug applications, or ANDAs, for generic versions of innovator drugs and also provides certain patent restoration and market exclusivity protections to innovator drug manufacturers. The ANDA process permits competitor companies to obtain marketing approval for a new drug with the same active ingredient for the same uses, dosage form and strength as an innovator drug but does not require the conduct and submission of preclinical or clinical studies demonstrating safety and efficacy for that product. Instead of providing completely new safety and efficacy data, the ANDA applicant only needs to submit manufacturing information and clinical data demonstrating that the copy is bioequivalent to the innovator s product in order to gain marketing approval from the FDA.

Another type of marketing application allowed by the Hatch-Waxman Amendments, a Section 505(b)(2) application, may be permitted where a company does not own or have a right to reference all the data required for approval. Section 505(b)(2) applications are often submitted for drug products that contain the same active ingredient as those in first approved drug products and where additional studies are required for approval, such as for changes in routes of administration or dosage forms.

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Once an NDA is approved, the product covered thereby becomes a listed drug which can, in turn, be cited by potential competitors in support of approval of an ANDA or a 505(b)(2) application.

The Hatch-Waxman Amendments provide for a period of three years exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage, dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor. During this period of exclusivity, the FDA cannot grant effective approval of an ANDA or a 505(b)(2) application based on that listed drug.

The Hatch-Waxman Amendments also provide a period of five years exclusivity following approval of a drug containing no previously approved active ingredients. During this period of exclusivity, ANDAs or 505(b)(2) applications based upon those drugs cannot be submitted unless the submission accompanies a challenge to a listed patent, in which case the submission may be made four years following the original product approval.

Additionally, in the event that the sponsor of the listed drug has informed the FDA of patents covering its listed drug and FDA lists those patents in the Orange Book, applicants submitting an ANDA or a 505(b)(2) application referencing that drug are required to certify whether they intend to market their generic products prior to expiration of those patents. If an ANDA applicant certifies that it believes one or more listed patents is invalid or not infringed, it is required to provide notice of its filing to the NDA sponsor and the patent holder. If either party then initiates a suit for patent infringement against the ANDA sponsor within 45 days of receipt of the notice, the FDA cannot grant effective approval of the ANDA until either 30 months has passed or there has been a court decision holding that the patent in question is invalid or not infringed. If the ANDA applicant certifies that it does not intend to market its generic product before some or all listed patents on the listed drug expire, then the FDA cannot grant effective approval of the ANDA until those patents expire. The first ANDA applicant submitting substantially complete applications certifying that listed patents for a particular product are invalid or not infringed may qualify for a period of 180 days after a court decision of invalidity or non-infringement or after it begins marketing its product, whichever occurs first. During this 180 day period, subsequently submitted ANDAs cannot be granted effective approval.

Pediatric exclusivity, if granted, provides an additional six months of market exclusivity in the United States for new or currently marketed drugs if certain pediatric studies requested by the FDA are completed by the applicant and the applicant has other existing patent or exclusivity protection for the drug. To obtain this additional six months of exclusivity, it would be necessary for us to first receive a written request from the FDA to conduct pediatric studies and then to conduct the requested studies according to a previously agreed timeframe and submit the report of the study. There can be no assurances that we would receive a written request from the FDA and if so that we would complete the studies in accordance with the requirements for this six-month exclusivity. The current pediatric exclusivity provision is scheduled to end on October 1, 2012, and there can be no assurances that it will be reauthorized.

EMPLOYEES

As of December 31, 2009, we had 443 full-time employees. 49 of these employees were engaged in research and development, 157 in manufacturing, 134 in clinical, regulatory affairs and quality assurance and 103 in administration, finance, management, information systems, marketing, corporate development and human resources. 58 of these employees have a Ph.D. degree and/or M.D. degree and are engaged in activities relating to research and development, manufacturing, quality assurance and business development. None of our employees is subject to a collective bargaining agreement. We believe relations with our employees are good.

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SCIENTIFIC ADVISORS

We seek advice from a number of leading scientists and physicians on scientific, technical and medical matters. These advisors are leading scientists in the areas of pharmacology, chemistry, immunology and biology. Our scientific advisors are consulted regularly to assess, among other things:

our research and development programs;

the design and implementation of our clinical programs;

our patent and publication strategies;

market opportunities from a clinical perspective;

new technologies relevant to our research and development programs; and

specific scientific and technical issues relevant to our business.

Our diabetes program is supported by the following scientific advisors (and their primary affiliations):

Primary Affiliation

King s College London School of Medicine Stephanie Amiel, MD, FRCP Richard Bergenstal, MD International Diabetes Center, Park Nicollet Institute

Geremia Bolli University of Perugia

Vanderbilt University Medical Center Alan D. Cherrington, PhD

David D Alessio, MD University of Cincinnati

University of California, San Diego Steven Edelman, MD

Alexander Fleming, MD Kinexum Box LLC Brian Frier, MD, FECP, BS Edinburgh Royal Infirmary

University of Washington Medical Center Irl B. Hirsch, MD

Sansum Medical Research Institute Lois Jovanovic, MD

State University of New York, Brooklyn Harold E Lebovitz, MD, FACE

Daniel Lorber, MD

Diabetes Care & Information Center of New York

Hvidovre University Hospital, Copenhagen Sten Madsbad

Laboratorium voor Experimentele Geneeskunde en Chantal Mathieu, MD, PhD

Endocrinologie Loyola College Center Mark Peyrot, MD

Daniel Porte, MD University of California, San Diego

University of Texas Philip Raskin, MD, FACE, FACP

Julio Rosenstock, MD Dallas Diabetes and Endocrinology Center Jesse Roth, MD, FACP North Shore-Long Island Jewish Health System

Johns Hopkins University School of Medicine Richard Rubin, PhD, CDE Robert Sherwin, MD Yale University School of Medicine

University of Miami, Diabetes Research Institute Jay Skyler, MD, MACP

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Our cancer program is supported by the following scientific advisors (and their primary affiliations):

Name Primary Affiliation

Kenneth Anderson, M.D.

Philippe Bey, Ph.D.

Jeffrey Bluestone, Ph.D.

W. Martin Kast, Ph.D.

Dana Farber Cancer Institute, Boston
Pharmaceutical consultant
University of California, San Francisco
University of Southern California

Antoni Ribas, M.D.

University of California, Los Angeles

EXECUTIVE OFFICERS

The following table sets forth our current executive officers and their ages as of December 31, 2009:

<u>Name</u>	<u>Age</u>	Position(s)
Alfred E. Mann	84	Chairman of the Board of Directors and Chief Executive
		Officer
Hakan S. Edstrom	59	President, Chief Operating Officer and Director
Matthew J. Pfeffer	52	Corporate Vice President and Chief Financial Officer
Juergen A. Martens, Ph.D.	54	Corporate Vice President, Technical Operations and Chief
		Technical Officer
Diane M. Palumbo	56	Corporate Vice President, Human Resources
Dr. Peter C. Richardson	50	Corporate Vice President and Chief Scientific Officer
David Thomson, Ph.D., J.D.	43	Corporate Vice President, General Counsel and Secretary

Alfred E. Mann has been one of our directors since April 1999, our Chairman of the Board since December 2001 and our Chief Executive Officer since October 2003. He founded and formerly served as Chairman and Chief Executive Officer of MiniMed, Inc., a publicly traded company focused on diabetes therapy and microinfusion drug delivery that was acquired by Medtronic, Inc. in August 2001. Mr. Mann also founded and, from 1972 through 1992, served as Chief Executive Officer of Pacesetter Systems, Inc. and its successor, Siemens Pacesetter, Inc., a manufacturer of cardiac pacemakers, now the Cardiac Rhythm Management Division of St. Jude Medical Corporation. Mr. Mann founded and since 1993, has served as Chairman and until January 2008, as Co-Chief Executive Officer of Advanced Bionics Corporation, a medical device manufacturer focused on neurostimulation to restore hearing to the deaf and to treat chronic pain and other neural deficits, that was acquired by Boston Scientific Corporation in June 2004. In January 2008, the former stockholders of Advanced Bionics Corporation repurchased certain segments from Boston Scientific Corporation and formed Advanced Bionics LLC for cochlear implants and Infusion Systems LLC for infusion pumps. Mr. Mann was non-executive Chairman of both entities. Advanced Bionics LLC was acquired by Sonova Holdings on December 30, 2009. Infusion Systems LLC was acquired by the Alfred E. Mann Foundation in February 2010. Mr. Mann has also founded and is non-executive Chairman of Second Sight Medical Products, Inc., which is developing a visual prosthesis for the blind; Bioness Inc., which is developing rehabilitation neurostimulation systems; Quallion LLC, which produces batteries for medical products and for the military and aerospace industries; and Stellar Microelectronics Inc., a supplier of electronic assemblies to the medical, military and aerospace industries. Mr. Mann also founded and is the managing member of PerQFlo, LLC, which is developing drug delivery systems. Mr. Mann is the managing member of the Alfred Mann Foundation and is also non-executive Chairman of Alfred Mann Institutes at the University of Southern California, AMI Purdue and AMI Technion, and the Alfred Mann Foundation for Biomedical Engineering, which is establishing additional institutes at other research universities. Mr. Mann is also non-executive Chairman of the Southern California Biomedical Council and a Director of the Nevada Cancer Institute. Mr. Mann holds a bachelor s and master s degree in Physics from the University of California at Los Angeles, honorary doctorates from Johns Hopkins University, the University of Southern California, Western University and the Technion-Israel Institute of Technology and is a member of the National Academy of Engineering.

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Hakan S. Edstrom has been our President and Chief Operating Officer since April 2001 and has served as one of our directors since December 2001. Mr. Edstrom was with Bausch & Lomb, Inc., a health care product company, from January 1998 to April 2001, advancing to the position of Senior Corporate Vice President and President of Bausch & Lomb, Inc. Americas Region. From 1981 to 1997, Mr. Edstrom was with Pharmacia Corporation, where he held various executive positions, including President and Chief Executive Officer of Pharmacia Ophthalmics Inc. Mr. Edstrom was educated in Sweden and holds a master s degree in Business Administration from the Stockholm School of Economics.

Matthew J. Pfeffer has been our Corporate Vice President and Chief Financial Officer since April 2008. Previously, Mr. Pfeffer served as Chief Financial Officer and Senior Vice President of Finance and Administration of VaxGen, Inc. from March 2006 until April 2008, with responsibility for finance, tax, treasury, human resources, IT, purchasing and facilities functions. Prior to VaxGen, Mr. Pfeffer served as CFO of Cell Genesys, Inc. During his nine year tenure at Cell Genesys, Mr. Pfeffer served as Director of Finance before being named CFO in 1998. Prior to that, Mr. Pfeffer served in a variety of financial management positions at other companies, including roles as Corporate Controller, Manager of Internal Audit and Manager of Financial Reporting. Mr. Pfeffer began his career at Price Waterhouse. Mr. Pfeffer serves on boards and advisory committees of the Biotechnology Industry Organization and the American Institute of Certified Public Accountants. Mr. Pfeffer has a bachelor s degree in Accounting from the University of California, Berkeley and is a Certified Public Accountant.

Juergen A. Martens, Ph.D. has been our Corporate Vice President of Operations and Chief Technology Officer since September 2005. From 2000 to August 2005, he was employed by Nektar Therapeutics, Inc., most recently as Vice President of Pharmaceutical Technology Development. Previously, he held technical management positions at Aerojet Fine Chemicals from 1998 to 2000 and at FMC Corporation from 1996 to 1998. From 1987 to 1996, Dr. Martens held a variety of management positions with increased responsibility in R&D, plant management, and business process development at Lonza, in Switzerland and in the United States. Dr. Martens holds a bachelor s degree in chemical engineering from the Technical College Mannheim/Germany, a bachelor s and master s degree in Chemistry and a doctorate in Physical Chemistry from the University of Marburg/Germany.

Diane M. Palumbo has been our Corporate Vice President of Human Resources since November 2004. From July 2003 to November 2004, she was President of her own human resources consulting company. From June 1991 to July 2003, Ms. Palumbo held various positions with Amgen, Inc., a California-based biopharmaceutical company, including Senior Director, Human Resources. In addition, Ms. Palumbo has held Human Resources positions with Unisys and Mitsui Bank Ltd. of Tokyo. She holds a master s degree in Business Administration from St. John s University, New York and a bachelor s degree, magna cum laude, also from St. John s University.

Dr. Peter C. Richardson has been our Corporate Vice President and Chief Scientific Officer since October 2005. From 1991 to October 2005, he was employed by Novartis Pharmaceuticals Corporation, which is the U.S. affiliate of Novartis AG, a world leader in healthcare, most recently as Senior Vice President, Global Head of Development Alliances. From 2003 until 2005, he was Senior Vice President and Head of Development of Novartis Pharmaceuticals KK Japan. He earlier practiced as an endocrinologist. Dr. Richardson holds a B.Med.Sci (Hons.) and a BM.BS (Hons.) from University of Nottingham Medical School; a MRCP (UK) from the Royal College of Physicians, UK; a Certificate in Pharmaceutical Medicine from Universities of Freibourg, Strasbourg and Basle; and a Diploma in Pharmaceutical Medicine from the Royal College of Physicians Faculty of Pharmaceutical Medicine.

David Thomson, Ph.D., J.D. has been our Corporate Vice President, General Counsel and Corporate Secretary since January 2002. Prior to joining us, he practiced corporate/commercial and securities law at the Toronto law firm of Davies Ward Phillips & Vineberg LLP. Earlier in his career, Dr. Thomson was a post-doctoral fellow at the Rockefeller University. Dr. Thomson obtained his bachelor s degree, master s degree and Ph.D. degree from Queens University and obtained his J.D. degree from the University of Toronto.

Executive officers serve at the discretion of our Board of Directors. There are no family relationships between any of our directors and executive officers.

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report 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 Annual Report. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. 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, AFREZZA, 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 AFREZZA 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. On March 12, 2010, we received a Complete Response letter from the FDA regarding the NDA for AFREZZA. A Complete Response letter is issued by the FDA s Center for Drug Evaluation and Research when the review of a submitted file is completed and questions remain that preclude the approval of the NDA in its current form. As recommended by the FDA, we will request an End-of-Review meeting with the agency to discuss our approach for resolving the remaining issues. There can be no assurance that we will be able to satisfy all of the FDA s requirements with currently available data or that the FDA will find our proposed approach acceptable. The FDA could also request that we conduct additional clinical trials to provide sufficient data for approval of the NDA. There can be no assurance that we will obtain approval of the NDA in a timely manner or at all.

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 AFREZZA.

We have expended significant time, money and effort in the development of our lead product candidate, AFREZZA, 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 AFREZZA 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 AFREZZA 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 AFREZZA, 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 AFREZZA, 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 AFREZZA 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

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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 AFREZZA 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 AFREZZA may be approved, or if it will be approved.

We have never been profitable and, as of December 31, 2009, we had an accumulated deficit of \$1.6 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 AFREZZA. 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 December 31, 2009, we had an accumulated deficit in stockholders equity of \$59.2 million. Our ability to achieve and sustain profitability depends upon obtaining regulatory approvals for and successfully commercializing AFREZZA, 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 AFREZZA 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 AFREZZA 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 into the first quarter of 2011. 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 AFREZZA 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 December 31, 2009, we had an accumulated deficit in stockholders equity of \$59.2 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 AFREZZA;

the emergence of competing technologies and products and other adverse market developments;

the timing and amount of payments we might receive from potential licensees;

the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others;

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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. We anticipate that we will seek approval by our stockholders of an amendment to our certificate of incorporation to increase the authorized number of shares of our common stock to facilitate any future capital-raising transactions. Such a proposal would require approval by the holders of a majority of the outstanding shares of our common stock. If we were unable to obtain the requisite approval, our ability to raise additional capital by selling our equity securities would be constrained. 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 AFREZZA 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;

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our ability to identify and enroll patients who meet clinical trial eligibility criteria;

our ability to access sufficient, reliable and affordable supplies of components used in the manufacture of our product candidates, including insulin and other materials for AFREZZA;

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 AFREZZA 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 AFREZZA. 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 AFREZZA 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 AFREZZA, 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 AFREZZA. To date we have not reached an agreement with any of these companies on a collaboration. 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

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activities at our own expense. Accordingly, we may have to substantially reduce our development efforts, which would delay or otherwise impede the commercialization of AFREZZA.

We will face similar challenges as we seek to develop our other product candidates. Our current strategy for developing, manufacturing and commercializing our other product candidates includes evaluating the potential for collaborating with pharmaceutical and biotechnology companies at some point in the drug development process and for these collaborators to undertake the advanced clinical development and commercialization of our product candidates. It may be difficult for us to find third parties that are willing to enter into collaborations on economic terms that are favorable to us, or at all. Failure to enter into a collaboration with respect to any other product candidate could substantially increase our requirements for capital and force us to substantially reduce our development effort. If we enter into collaborative agreements with respect to AFREZZA and if our third-party collaborators do not perform satisfactorily or if our collaborations fail, development or commercialization of AFREZZA may be delayed and our business could be harmed.

We may enter into license agreements, partnerships or other collaborative arrangements to support the financing, development and marketing of AFREZZA. 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 AFREZZA 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 AFREZZA or our other product candidate may not yield successful results, and even if it does, we may still be unable to commercialize our product candidate.

Our research and development programs are designed to test the safety and efficacy of AFREZZA 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 AFREZZA 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 AFREZZA, over terms longer than the clinical trials or in much larger populations may not be consistent with the clinical results. If use of AFREZZA results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our ability to market and sell AFREZZA, 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.

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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 AFREZZA at any time. Any suspension or termination of our clinical trials or marketing activities may harm our business and results of operations and the market price of our common stock may decline.

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

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

align our management structure to accommodate the increasing complexity of our operations;

develop comprehensive and detailed commercialization, clinical development and regulatory plans; and

implement standard operating procedures.

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

If our suppliers fail to deliver materials and services needed for the production of AFREZZA 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 AFREZZA to be commercially viable, we need access to sufficient, reliable and affordable supplies of insulin, our AFREZZA inhaler, the related cartridges and other materials. We have a long-term agreement with N.V. Organon for the supply of insulin. In June 2009, we purchased from Pfizer, 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 AFREZZA, 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 our contract manufacturers have the capacity to supply our current clinical and future commercial requirements. We have obtained our AFREZZA 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 cGMP for drug products, and the production of AFREZZA inhaler and related cartridges in accordance with 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 AFREZZA may be delayed. Any such events could delay market introduction and subsequent sales of AFREZZA 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 AFREZZA or any other product candidates 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 facility to formulate AFREZZA, fill plastic cartridges with AFREZZA and blister package the cartridges for our clinical trials. This facility has been fully qualified and undergone regulatory inspection that is 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. 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 are required by the FDA to establish that the results obtained from the clinical trials may reasonably be extrapolated to such commercial material. We have submitted documentation to the FDA to show correlation to the clinical-scale production materials with no assurance that approval would be obtained.

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 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.

During the construction of our expanded manufacturing facility, we completed the final stages of the soil cleanup plan in the third quarter of 2008, at a cost of approximately \$2.25 million. We are in discussions with the party responsible for remediation regarding their contribution to past clean-up costs and their obligation to pay for or indemnify us for any future costs and expenses directly related to the final closure of the environmental remediation. If we are unable to collect these future costs and expenses, if any, from the responsible party, 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.

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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 AFREZZA 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 AFREZZA, 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 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 succeed in entering into acceptable collaborations, 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.

AFREZZA 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 AFREZZA and our other product candidates will depend on many factors, including the:

claims for which FDA approval can be obtained, including superiority claims;

perceived advantages and disadvantages of competitive products;

willingness and ability of patients and the healthcare community to adopt new technologies;

ability to manufacture the product in sufficient quantities with acceptable quality and at an acceptable cost;

perception of patients and the healthcare community, including third-party payers, regarding the safety, efficacy and benefits of the product compared to those of competing products or therapies;

convenience and ease of administration of the product relative to existing treatment methods;

pricing and reimbursement of the product relative to other treatment therapeutics and methods; and

marketing and distribution support for the product.

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

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

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

In the United States and elsewhere, sales of prescription pharmaceuticals still depend in large part on the availability of reimbursement to the consumer from third-party payers, such as governmental and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. In addition, because each third-party payer individually approves reimbursement, obtaining these approvals is a time-consuming and costly process. We would be required to provide scientific and clinical support for the use of any product to each third-party payer separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing one or more products to market, we cannot be certain that any such products would be considered cost-effective or that reimbursement to the consumer would be available, in which case our business and results of operations would be harmed and the market price of our common stock could decline. If product liability claims are brought against us, we may incur significant liabilities and suffer damage to our reputation.

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

In order to commercialize our product candidates successfully, we will be required to expand our work force, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development, and sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel. We face intense competition for qualified employees among companies in the biotechnology and biopharmaceutical industries. Our success depends upon our ability to attract, retain and motivate highly skilled employees. We may be unable to attract and retain these individuals on acceptable terms, if at all.

The loss of the services of any principal member of our management and scientific staff could significantly delay or prevent the achievement of our scientific and business objectives. All of our employees are at will and we currently do not have employment agreements with any of the principal members of our management or scientific staff, and we do not have key person life insurance to cover the loss of any of these individuals. Replacing key employees may be

difficult and time-consuming because of the limited number of individuals in our industry with 32

the skills and experience required to develop, gain regulatory approval of and commercialize our product candidates successfully.

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

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

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

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

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

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

RISKS RELATED TO REGULATORY APPROVALS

Our product candidates must undergo rigorous nonclinical and clinical testing and we must obtain regulatory approvals, which could be costly and time-consuming and subject us to unanticipated delays or prevent us from marketing any products.

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

product design, development, manufacture and testing;

product labeling;
product storage and shipping;
pre-market clearance or approval;
advertising and promotion; and

product sales and distribution.

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

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

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. We are not aware of any precedent for the successful commercialization of products based on our technology. On January 26, 2006, the FDA approved the first pulmonary insulin product, Exubera. This approval has had an impact on and, notwithstanding the voluntary withdrawal of the product from the market by its manufacturer, could still impact the development and registration of AFREZZA in different ways. For example, Exubera may be used as a reference for safety and efficacy evaluations of AFREZZA, and the approval standards set for Exubera may be applied to other products that follow, including AFREZZA.

On March 16, 2009, we submitted an NDA for AFREZZA, which the FDA accepted for review on May 16, 2009. The FDA has advised us that it will regulate AFREZZA as a combination product because of the complex nature of the system that includes the combination of a new drug (AFREZZA) and a new medical device (the AFREZZA inhaler used to administer the insulin). The FDA indicated that the review of our drug marketing application for

AFREZZA will involve several separate review groups of the FDA including: (1) the Metabolic and Endocrine Drug Products Division; (2) the Pulmonary Drug Products Division; and (3) the Center for Devices and Radiological Health, which reviews medical devices. The Metabolic and Endocrine Drug Products Division is the lead group and obtains consulting reviews from the other two FDA groups. We can make no

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assurances at this time about what impact FDA review by multiple groups will have on the approvability of our product.

On March 12, 2010, we received a Complete Response letter from the FDA regarding the NDA for AFREZZA. A Complete Response letter is issued by the FDA s Center for Drug Evaluation and Research when the review of a submitted file is completed and questions remain that preclude the approval of the NDA in its current form. As recommended by the FDA, we will request an End-of-Review meeting with the agency to discuss our approach for resolving the remaining issues. There can be no assurance that we will be able to satisfy all of the FDA s requirements with currently available data or that the FDA will find our proposed approach acceptable. The FDA could also request that we conduct additional clinical trials to provide sufficient data for approval of the NDA. There can be no assurance that we will obtain approval of the NDA in a timely manner or at all.

Also, questions that have been raised about the safety of marketed drugs generally, including pertaining to the lack of adequate labeling, may result in increased cautiousness by the FDA in reviewing new drugs based on safety, efficacy, or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Such regulatory considerations may also result in the imposition of more restrictive drug labeling or marketing requirements as conditions of approval, which may significantly affect the marketability of our drug products. FDA review of AFREZZA as a combination product may lengthen the product development and regulatory approval process, increase our development costs and delay or prevent the commercialization of AFREZZA.

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

We also must obtain final approval from the FDA for the trade name of our product. The FDA had informed us that the name previously proposed for our product may be too similar to other drugs on the market and that we had to propose another trade name for our product. In September 2009, we proposed AFREZZA as a trade name, which the FDA found conditionally acceptable in December 2009.

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

We will not be able to commercialize AFREZZA or any other product candidates until we have obtained regulatory approval. Until we prepared and submitted our NDA for AFREZZA, we had no experience as a company in late-stage regulatory filings, such as preparing and submitting NDAs, which may place us at risk of delays, overspending and human resources inefficiencies. Any delay in obtaining, or inability to obtain, regulatory approval could harm our business. We are currently reviewing the Complete Review letter issued by the FDA regarding the NDA for AFREZZA and working with the FDA to provide the requested information and data as quickly as possible. As recommended by the FDA, we will request an End-of-Review meeting with the agency to discuss our approach for resolving the remaining issues. There can be no assurance that we will be able to satisfy all of the FDA is requirements with currently available data or that the FDA will find our proposed approach acceptable. The FDA could also request that we conduct additional clinical trials to provide sufficient data for approval of the NDA. There can be no assurance that we will obtain approval of the NDA in a timely manner or at all.

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

Even if we comply with regulatory requirements, we may not be able to obtain the labeling claims necessary or desirable for product promotion. We may also be required to undertake post-marketing trials. In addition, if we or other parties identify adverse effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and a reformulation of our products, additional clinical trials, changes in labeling of, or indications of use for, our products and/or additional marketing applications may be required. If we

encounter any of the foregoing problems, our business and results of operations will be harmed and the market price of our common stock may decline.

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

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Even if regulatory authorities approve any of our product candidates, they could approve less than the full scope of uses or labeling that we seek or otherwise require special warnings or other restrictions on use or marketing or could require potentially costly post-marketing follow-up clinical trials. Regulatory authorities may limit the segments of the diabetes population to which we or others may market AFREZZA or limit the target population for our other product candidates. Based on currently available clinical studies, we believe that AFREZZA may have certain advantages over currently approved insulin products including its approximation of the natural early insulin secretion normally seen in healthy individuals following the beginning of a meal. Nonetheless, there are no assurances that these or any other advantages of AFREZZA will be agreed to by the FDA or otherwise included in product labeling or advertising and, as a result, AFREZZA may not have our expected competitive advantages when compared to other insulin products.

The manufacture, marketing and sale of any of our product candidates will be subject to stringent and ongoing government regulation. The FDA may also withdraw product approvals if problems concerning safety or efficacy of a product occurs following approval. We cannot be sure that FDA and United States Congressional initiatives pertaining to ensuring the safety of marketed drugs or other developments pertaining to the pharmaceutical industry will not adversely affect our operations.

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

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

Our insulin supplier for purposes of the AFREZZA NDA sells its product outside of the United States. However, we can make no assurances that our insulin supplier will be acceptable to the FDA. If we were required to find a new or additional supplier of insulin, we would be required to evaluate the new supplier is ability to provide insulin that meets our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and future commercialization of AFREZZA. We also depend on suppliers for other materials that comprise AFREZZA, including our AFREZZA inhaler and cartridges. All of our device suppliers must comply with relevant regulatory requirements including QSR. The FDA is currently in the process of conducting a preapproval inspection of our suppliers. There can be no assurance, in the conduct of a preapproval inspection of our suppliers, that the agency would find that the supplier substantially comply with the QSR or cGMP requirements, where applicable. If we or any potential third-party manufacturer or supplier fails to comply with these requirements or comparable requirements in foreign countries, regulatory authorities may subject us to regulatory action, including criminal prosecutions, fines and suspension of the manufacture of our products.

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

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

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

RISKS RELATED TO INTELLECTUAL PROPERTY

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

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

Moreover, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be afforded by our patents. A third party may challenge the validity or enforceability of a patent after its issuance by various proceedings such as oppositions in foreign jurisdictions or re-examinations in the United States. If we attempt to enforce our patents, they may be challenged in court where they could be held invalid, unenforceable, or have their breadth narrowed to an extent that would destroy their value.

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

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

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

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

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

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

Over the past three decades the number of patents issued to biotechnology companies has expanded dramatically. As a result it is not always clear to industry participants, including us, which patents cover the multitude of biotechnology product types. Ultimately, the courts must determine the scope of coverage afforded by a patent and the courts do not always arrive at uniform conclusions.

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

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

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

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

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any of these patent rights, we would have to establish with the court that these patents were invalid or unenforceable in order to avoid legal liability for infringement of these patents. However, proving patent invalidity or unenforceability can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in an infringement or invalidity action we will have to either acquire the third-party patents outright or seek a royalty-bearing license. Royalty-bearing licenses effectively increase production costs and therefore may materially affect product profitability. Furthermore, should the patent holder refuse to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and/or design around the patents, if possible. In either event, our business would be harmed and our profitability could be materially adversely impacted.

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

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

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

We have not selected trade names for some of our products and product candidates; therefore, we have not filed trademark registrations for our potential trade names for our products in all jurisdictions, nor can we assure that we will be granted registration of those potential trade names for which we have filed. Although we intend to defend any opposition to our trademark registrations, no assurance can be given that any of our trademarks will be registered in the United States or elsewhere or that the use of any of our trademarks will confer a competitive advantage in the marketplace. Furthermore, even if we are successful in our trademark registrations, the FDA has its own process for drug nomenclature and its own views concerning appropriate proprietary names. It also has the power, even after granting market approval, to request a company to reconsider the name for a product because of evidence of confusion in the marketplace. We cannot assure you that the FDA or any other regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks at some time in the future.

RISKS RELATED TO OUR COMMON STOCK

Our stock price is volatile.

The current turbulence in the U.S. and global financial markets could adversely affect our stock price and our ability to raise additional capital through the sale of equity and/or debt securities. The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks, and this trend may continue. The volatility of pharmaceutical and biotechnology stocks often does not relate to the operating performance of the companies represented by the stock. Our business and the market price of our common stock may be influenced by a large variety of factors, including:

the progress and results of our clinical trials;

general economic, political or stock market conditions;

announcements by us or our competitors concerning clinical trial results, acquisitions, strategic alliances, technological innovations, newly approved commercial products, product discontinuations, or other developments;

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the availability of critical materials used in developing and manufacturing AFREZZA or other product candidates:

developments or disputes concerning our patents or proprietary rights;

the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;

announcements by us concerning our financial condition or operating performance;

changes in securities analysts estimates of our financial condition or operating performance;

general market conditions and fluctuations for emerging growth and pharmaceutical market sectors;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders; and

discussion of AFREZZA, our other product candidates, competitors products, or our stock price by the financial and scientific press, the healthcare community and online investor communities such as chat rooms.

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

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

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

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

Our Chief Executive Officer and principal stockholder can individually control our direction and policies, and his interests may be adverse to the interests of our other stockholders. After his death, his stock will be left to his funding foundations for distribution to various charities, and we cannot assure you of the manner in which those entities will manage their holdings.

At February 19, 2010, Mr. Mann beneficially owned approximately 42.3% of our outstanding shares of capital stock. We believe members of Mr. Mann s family beneficially owned approximately an additional 1% of our outstanding shares of common stock, although Mr. Mann does not have voting or investment power with respect to these shares. By virtue of his holdings, Mr. Mann can and will continue to be able to effectively control the election of the members of our board of directors, our management and our affairs and prevent corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders or cause a transaction that we or our other stockholders may view as unfavorable.

Subject to compliance with United States federal and state securities laws, Mr. Mann is free to sell the shares of our stock he holds at any time. Upon his death, we have been advised by Mr. Mann that his shares of our capital stock will be left to the Alfred E. Mann Medical Research Organization, or AEMMRO, and AEM Foundation for Biomedical Engineering, or AEMFBE, not-for-profit medical research foundations that serve as funding

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organizations for Mr. Mann s various charities, including the Alfred Mann Foundation, or AMF, and the Alfred Mann Institute at the University of Southern California, the Technion-Israel Institute of Technology, and at Purdue University, and that may serve as funding organizations for any other charities that he may establish. The AEMMRO is a membership foundation consisting of six members, including Mr. Mann, his wife, three of his children and Dr. Joseph Schulman, the chief scientist of the AEMFBE. The AEMFBE is a membership foundation consisting of five members, including Mr. Mann, his wife, and the same three of his children. Although we understand that the members of AEMMRO and AEMFBE have been advised of Mr. Mann s objectives for these foundations, once Mr. Mann s shares of our capital stock become the property of the foundations, we cannot assure you as to how those shares will be distributed or how they will be voted.

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

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

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

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

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

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

We have paid no cash dividends on any of our capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, the success of your investment in our common stock will likely depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value after the offering or even maintain the price at which you purchased your shares, and you may not realize a return on your investment in our common stock.

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Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

In 2001, we acquired a facility in Danbury, Connecticut that included two buildings comprising approximately 190,000 square feet encompassing 17.5 acres. In September 2008, we completed the construction of approximately 140,000 square feet of new manufacturing space providing us with two buildings totaling approximately 328,000 square feet, housing our research and development, administrative and manufacturing functions, primarily for AFREZZA, filling and packaging. We believe the Danbury facility will have sufficient space to satisfy potential commercial demand for the launch of AFREZZA and, with the expansion completed, the first few years thereafter for AFREZZA and other AFREZZA-related products.

We own and occupy approximately 147,000 square feet of laboratory, office and manufacturing space in Valencia, California. The facility contains our principal executive offices and houses our research and development laboratories for our cancer and other programs. We also use this facility to provide support for the development of our AFREZZA programs.

We lease approximately 59,000 square feet of office space in Paramus, New Jersey pursuant to a lease that ends in May 2010, with an option to extend the lease through May 2012.

Item 3. Legal Proceedings

None.

Item 4. (Removed and Reserved)

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PART II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Common Stock Market Price

Our common stock has been traded on the Nasdaq Global Market under the symbol MNKD since July 28, 2004. The following table sets forth for the quarterly periods indicated, the high and low sales prices for our common stock as reported by the Nasdaq Global Market.

	High	Low
Year ended December 31, 2008		
First quarter	\$ 8.62	\$4.25
Second quarter	\$ 6.44	\$1.86
Third quarter	\$ 5.25	\$2.39
Fourth quarter	\$ 4.30	\$2.61
Year ended December 31, 2009		
First quarter	\$ 4.09	\$2.00
Second quarter	\$ 9.25	\$3.35
Third quarter	\$12.30	\$6.62
Fourth quarter	\$ 9.94	\$5.02

The closing sales price of our common stock on the Nasdaq Global Market was \$10.10 on February 19, 2010 and there were 188 registered holders of record as of that date.

Performance Measurement Comparison

The material in this section is not soliciting material, is not deemed filed with the SEC and shall not be incorporated by reference by any general statement incorporating by reference this Annual Report on Form 10-K into any of our filings under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act of 1934, as amended, or the Exchange Act, except to the extent we specifically incorporate this section by reference.

Performance Measurement Comparison

The following graph illustrates a comparison of the cumulative total stockholder return (change in stock price plus reinvested dividends) of our common stock with (i) the Nasdaq Composite Index and (ii) the Nasdaq Biotechnology Index. The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.

Assumes a \$100 investment, on December 31, 2004, in (i) our common stock, (ii) the securities comprising the Nasdaq Composite Index and (iii) the securities comprising the Nasdaq Biotechnology Index.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business. Accordingly, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors.

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

None.

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Item 6. Selected Financial Data

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and notes thereto and with Management s Discussion and Analysis of Financial Condition and Results of Operations, which are included elsewhere in this Annual Report on Form 10-K.

Statement of Operations Data:	2005	2006	Ended Decembe	2008	2009
Revenue	\$	\$ 100	s, except per sha \$ 10	\$ 20	\$
Operating expenses: Research and development General and administrative	95,347 22,775	191,796 42,001	256,844 50,523	250,442 55,343	156,331 53,447
Total operating expenses	118,122	233,797	307,367	305,785	209,778
Loss from operations Other income (expense) Interest expense on note payable to	(118,122) 78	(233,697) 208	(307,357) (197)	(305,765) (62)	(209,778) 51
principal stockholder Interest expense on senior convertible		(1,511)		(12)	(5,679)
notes Interest income	3,707	(222) 4,679	(3,408) 17,775	(2,327) 5,129	(4,768) 70
Loss before provision for income taxes Income taxes	(114,337) (1)	(230,543) (5)	(293,187) (3)	(303,037) (2)	(220,104)
Net loss Deemed dividends related to beneficial conversion feature of convertible preferred stock Accretion on redeemable preferred stock	(114,338)	(230,548)	(293,190)	(303,039)	(220,104)
Net loss applicable to common stockholders	\$ (114,338)	\$ (230,548)	\$ (293,190)	\$ (303,039)	\$ (220,104)
Basic and diluted net loss per share	\$ (2.87)	\$ (4.52)	\$ (3.66)	\$ (2.98)	\$ (2.07)
Shares used to compute basic and diluted net loss per share	39,871	50,970	80,038	101,561	106,534
Balance Sheet Data:	2005	2006	f December 31, 2007 n thousands)	2008	2009
Cash, cash equivalents and marketable securities \$ Working capital Total assets	145,634 \$ 128,507 228,371	436,479 \$ 404,588 539,737	368,285 \$ 311,154 543,443	46,492 503 282,459	\$ 32,494 8,813 247,397

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Deferred compensation and other					
liabilities	29	24	24		
Senior convertible notes		111,267	111,761	112,253	112,765
Note payable to related party				30,000	165,000
Deficit accumulated during the					
development stage	(557,301)	(787,849)	(1,081,039)	(1,384,078)	(1,604,182)
Total stockholders equity (deficit)	206,977	383,487	364,100	86,734	(59,221)
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Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and notes thereto included in this Annual Report on Form 10-K.

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, AFREZZA, is an ultra rapid-acting insulin. In March 2009, we submitted an NDA to the FDA requesting approval of AFREZZA 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. On March 12, 2010, we received a Complete Response letter from the FDA regarding the NDA for AFREZZA. A Complete Response letter is issued by the FDA s Center for Drug Evaluation and Research when the review of a submitted file is completed and questions remain that preclude the approval of the NDA in its current form. As recommended by the FDA, we will request an End-of-Review meeting with the agency to discuss our approach for resolving the remaining issues. There can be no assurances that we will be able to satisfy all of the FDA could also request that we conduct additional clinical trials to provide sufficient data for approval of the NDA. No assurances can be made that we will obtain approval of the NDA in a timely manner or at all.

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of December 31, 2009, we have incurred a cumulative net loss of \$1.6 billion and accumulated deficit in stockholders equity of \$59.2 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 AFREZZA. 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 AFREZZA. 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 AFREZZA and new inhalation systems for the treatment of diabetes;

seek regulatory approval to sell AFREZZA in the United States and other markets;

increase our manufacturing capacity for AFREZZA to meet our currently anticipated commercial production needs;

expand our cancer research, discovery and development programs;

expand our proprietary Technosphere platform technology and develop additional applications for the pulmonary delivery of other drugs; and

enter into sales and marketing collaborations with other companies, if available on commercially reasonable terms, or develop these capabilities ourselves.

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

RESEARCH AND DEVELOPMENT EXPENSES

Our research and development expenses consist mainly of costs associated with the clinical trials of our product candidates that have not yet received regulatory approval for marketing and for which no alternative future use has been identified. This includes the salaries, benefits and stock-based compensation of research and development personnel, raw materials, such as insulin purchases, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees, and depreciation of 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 year ended December 31, 2009 were purchases of insulin totaling \$12.1 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 the majority of 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 AFREZZA through regulatory filings. Based on the results of preclinical studies, we plan to develop additional applications of our Technosphere technology. Additionally, we anticipate that we will continue to determine which research and development projects to pursue, and how much funding to direct to each project, on an ongoing basis, in response to the scientific and clinical success of each product candidate. We cannot be certain when any revenues from the commercialization of our products will commence.

At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product candidates other than AFREZZA, 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 AFREZZA will be largely dependent on the cost and efficiency of our manufacturing process and discussions with the FDA regarding its requirements.

GENERAL AND ADMINISTRATIVE EXPENSES

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

CRITICAL ACCOUNTING POLICIES

We have based our discussion and analysis of our financial condition and results of operations on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making estimates of expenses such as stock option expenses and judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. The significant accounting policies that are critical to the judgments and estimates used in the preparation of our financial statements are described in more detail below.

Impairment of long-lived assets

Assessing long-lived assets for impairment requires us to make assumptions and judgments regarding the carrying value of these assets. We evaluate long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. The assets are considered to be impaired if we determine that the carrying value may not be recoverable based upon our assessment of the following events or changes in circumstances:

significant changes in our strategic business objectives and utilization of the assets;

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a determination that the carrying value of such assets cannot be recovered through undiscounted cash flows;

loss of legal ownership or title to the assets; or

the impact of significant negative industry or economic trends.

If we believe our assets to be impaired, the impairment we recognize is the amount by which the carrying value of the assets exceeds the fair value of the assets. Any write-downs would be treated as permanent reductions in the carrying amount of the asset and an operating loss would be recognized. In addition, we base the useful lives and related amortization or depreciation expense on our estimate of the useful lives of the assets. If a change were to occur in any of the above-mentioned factors or estimates, our reported results could materially change.

To date, we have had recurring operating losses, and the recoverability of our long-lived assets is contingent upon executing our business plan. If we are unable to execute our business plan, we may be required to write down the value of our long-lived assets in future periods.

Clinical trial expenses

Our clinical trial accrual process seeks to account for expenses resulting from our obligations under contract with vendors, consultants, and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate trial expenses in our financial statements by matching period expenses with period services and efforts expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through discussions with internal clinical personnel and outside service providers as to the progress or state of completion of trials, or the services completed. Service provider status is then compared to the contractual obligated fee to be paid for such services. During the course of a clinical trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. In the event that we do not identify certain costs that have begun to be incurred or we underestimate or overestimate the level of services performed or the costs of such services, our reported expenses for a period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of the services are often judgmental. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Stock-based compensation

We account for stock-based compensation in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 718 (ASC 718) *Compensation-Stock Compensation*, previously FASB Statement No. 123R, *Accounting for Stock-Based Compensation*. ASC 718 requires all share-based payments to employees, including grants of stock options and the compensatory elements of employee stock purchase plans, to be recognized in the income statement based upon the fair value of the awards at the grant date. We use the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options and the compensatory elements of employee stock purchase plans.

Accounting for income taxes

We must make management judgments when determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. At December 31, 2009, we have established a valuation allowance of \$575.7 million against all of our net deferred tax asset balance, due to uncertainties related to our deferred tax assets as a result of our history of operating losses. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to change the valuation allowance, which could materially impact our financial position and results of operations.

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RESULTS OF OPERATIONS

Years ended December 31, 2009 and 2008

Revenues

During the year ended December 31, 2009 we recognized no revenue, and during the year ended December 31, 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 AFREZZA.

Research and Development Expenses

The following table provides a comparison of the research and development expense categories for the years ended December 31, 2009 and 2008 (dollars in thousands):

Year Ended December 31,

				%
	2009	2008	\$ Change	Change
Clinical	\$ 44,163	\$114,922	\$ (70,759)	(62)%
Manufacturing	82,116	92,935	(10,819)	(12)%
Research	19,259	30,081	(10,822)	(36)%
Research and development tax credit	(1,322)	(1,846)	524	(28)%
Stock-based compensation expense	12,115	14,350	(2,235)	(16)%
Research and development expenses	\$ 156,331	\$ 250,442	\$ (94,111)	(38)%

The decrease in research and development expenses for the year ended December 31, 2009, as compared to the year ended December 31, 2008, was primarily due to decreased costs associated with the clinical development of AFREZZA as we completed our pivotal AFREZZA trials during 2008, including decreased raw material purchases and clinical supplies costs, offset by a loss on disposal of approximately \$12.8 million in manufacturing expense related to the abandonment of MedTone specific assets, which would no longer be used as we pursue the commercialization of the next-generation device. 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 increase in 2010 as a result of our obligation to purchase an increased amount of insulin as well as increased costs associated with the development of our commercial inhaler.

The research and development tax credit recognized for the years ended December 31, 2009 and 2008 partially offsets our research and development expenses. The State of Connecticut provides an opportunity to exchange certain research and development income tax credit carryforwards for cash in exchange for forgoing the carryforward of the research and development credits. Estimated amounts receivable under the program are recorded as a reduction of research and development expenses. During the years ended December 31, 2009 and 2008, research and development expenses were offset by \$1.3 million and \$1.8 million, respectively, in connection with the program.

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the years ended December 31, 2009 and 2008 (dollars in thousands):

Year End	led
December	31,

				%
	2009	2008	\$ Change	Change
Salaries, employee related and other general expenses	\$45,343	\$44,900	\$ 443	1%
Stock-based compensation expense	8,104	10,443	(2,339)	(22)%
General and administrative expenses	\$ 53,447	\$ 55,343	\$ (1,896)	(3)%

The decrease in general and administrative expenses for the year ended December 31, 2009, as compared to the year ended December 31, 2008, was primarily due to decreased stock compensation expense and 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 of 2009 and partnership efforts during the third quarter of 2009. We expect general and administrative expenses to remain effectively the same in 2010.

Interest Income and Expense

Interest income for the year ended December 31, 2009 decreased \$5.1 million as compared to the year ended December 31, 2008 primarily due to lower cash and cash equivalent balances as we used cash to fund operating and capital expenditures. Interest expense for the year ended December 31, 2008 was related to the convertible notes issued in December 2006 and amortization of the debt issuance costs, partially offset by capitalized interest related to construction in progress. Interest expense for the year ended December 31, 2009 also included interest related to amounts borrowed under the loan agreement with our principal stockholder in December 2008.

Years ended December 31, 2008 and 2007

Revenues

During the year ended December 31, 2008 and 2007, we recognized \$20,000 and \$10,000, respectively, in revenue under a license agreement.

Research and Development Expenses

The following table provides a comparison of the research and development expense categories for the years ended December 31, 2008 and 2007 (dollars in thousands):

	Year l Decem			
		•	\$	%
	2008	2007	Change	Change
Clinical	\$114,922	\$ 124,655	\$ (9,733)	(8)%
Manufacturing	92,935	86,473	6,462	7%
Research	30,081	36,720	(6,639)	(18)%
Research and development tax credit	(1,846)	(753)	(1,093)	145%
Stock-based compensation expense	14,350	9,749	4,601	47%
Research and development expenses	\$ 250,442	\$ 256,844	\$ (6,402)	(2)%

The decrease in research and development expenses for the year ended December 31, 2008, as compared to the year ended December 31, 2007, was primarily due to decreased costs associated with the clinical development of AFREZZA as we completed our pivotal AFREZZA trials during 2008, offset by increases in manufacturing costs associated with preparations for commercial scale manufacturing of AFREZZA, including the expansion, qualification and validation of our commercial manufacturing processes and facilities.

During the years ended December 31, 2008 and 2007, research and development expenses were offset by \$1.8 million and \$0.8 million, respectively, in connection with the Connecticut program to exchange certain research and development income tax credit carryforwards for cash.

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the years ended December 31, 2008 and 2007 (dollars in thousands):

Vear Ended

	1 car	Liiucu		
	Decem	ber 31,		
			\$	%
	2008	2007	Change	Change
Salaries, employee related and other general expenses	\$44,900	\$ 42,627	\$ 2,273	5%
Stock-based compensation expense	10,443	7,896	2,547	32%

General and administrative expenses

\$ 55,343

\$50,523

\$ 4,820

10%

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The increase in general and administrative expenses for the year ended December 31, 2008, as compared to the year ended December 31, 2007, was primarily due to increased salary-related expenses and consulting fees.

Interest Income and Expense

Interest income for the year ended December 31, 2008 decreased \$12.6 million as compared to the year ended December 31, 2007 primarily due to lower cash balances as we used cash to fund operating and capital expenditures. Interest expense for the year ended December 31, 2007 was related to the convertible notes issued in December 2006 and amortization of the debt issuance costs, partially offset by capitalized interest related to construction in progress. Interest expense for the year ended December 31, 2008 also included interest related to amounts borrowed under the loan agreement with our principal stockholder in December 2008.

LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations primarily through the sale of equity securities and convertible debt securities and borrowings under our related party loan.

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. The principal stockholder has agreed not to exercise his prepayment right if such prepayment would require the use of existing working capital resources to repay the loan. 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 December 31, 2009, the amount borrowed and outstanding under the arrangement was \$165.0 million.

During the year ended December 31, 2009, we used \$184.1 million of cash for our operations compared to using \$271.3 million for our operations in the year ended December 31, 2008. We had a net loss of \$220.1 million for the year ended December 31, 2009, of which \$38.9 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 AFREZZA.

We used \$3.1 million of cash in investing activities during the year ended December 31, 2009, compared to \$99.9 million for the years ended December 31, 2008. For the years ended December 31, 2009 and 2008, \$18.9 million and \$82.5 million, respectively, were used to purchase machinery and equipment to expand our manufacturing operations and our quality systems that support clinical trials for AFREZZA.

Our financing activities generated \$189.5 million of cash for the year ended December 31, 2009, compared to \$30.6 million for the same period in 2008. For the year ended December 31, 2009, cash from financing activities was primarily from the common stock offering completed in August 2009 and related party borrowings as well as the exercise of stock options.

As of December 31, 2009, we had \$32.5 million in cash, cash equivalents and marketable securities (including a \$2.0 million certificate of deposit held as collateral for foreign exchange hedging instruments). Although we believe our existing cash resources, including the \$185.0 million remaining available under our loan arrangement with an entity controlled by our principal stockholder, will be sufficient to fund our anticipated cash requirements into the first quarter of 2011, 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 51

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

We have held extensive discussions with a number of pharmaceutical companies concerning a potential strategic business collaboration for AFREZZA. 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 capital through equity or debt financing or entering a business collaboration, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, including AFREZZA 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 December 31, 2009, we did not have any off-balance sheet arrangements.

COMMITMENTS AND CONTINGENCIES

Our contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payments. Accordingly, the table below excludes contractual obligations relating to milestone and royalty payments due to third parties, all of which are contingent upon certain future events. The expected timing of payment of the obligations presented below is estimated based on current information. Future payments relate to operating lease obligations (including facility leases executed in March 2005 and November 2005), the senior convertible notes, and open purchase order and supply commitments consisted of the following at December 31, 2009 (in thousands):

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]	Payments Due i				
	Less			More			
	Than		Than				
	One						
Contractual Obligations	Year	1-3 Years	3-5 Years	5 Years	Total		
Open purchase order and supply							
commitments(1)	\$ 34,904	\$ 90,164	\$	\$	\$ 125,068		
Senior Convertible Note Obligations(2)	4,372	8,757	119,372		132,501		
Note Payable to Principal Stockholder(3)	7,975	172,976			180,951		
Operating lease obligations	798	14	2		814		
Total contractual obligations	\$ 48,049	\$ 271,911	\$ 119,374	\$	\$ 439,334		

(1) The amounts included in open purchase order and supply commitments are subject to performance under the purchase order or contract by the supplier of the goods or services and do not become our obligation until such performance is rendered. The amount shown is principally for the purchase of materials for our clinical trials, the acquisition manufacturing equipment, and commitments related to the expansion of our manufacturing plant and the purchase of raw

materials under long-term supply agreements.

- (2) The senior convertible note obligation amounts include future interest payments at a fixed rate of 3.75% and payment of the notes in full upon maturity in 2013.
- (3) The obligation for the note payable to the principal stockholder includes future principal and interest payments related to the \$165.0 million of borrowings as of December 31, 2009. Interest is paid based on a fixed rate equal to the one-year LIBOR rate on the date of advance plus 3% and the principal payment is due on December 31,

2011.

RELATED PARTY TRANSACTIONS

For a description of our related party transactions see Note 15 Related Party Transactions in the notes to our financial statements.

RECENT ACCOUNTING PRONOUNCEMENTS

In October of 2009, the FASB ratified the Emerging Issues Task Force (EITF) consensus on EITF Issue No. 08-1 *Revenue Arrangements with Multiple Deliverables*, and issued Accounting Standards Update (ASU) 2009-13 which

amends the guidance in ASC 605-25 on multiple-element revenue arrangements. This guidance addresses the unit of accounting for arrangements involving multiple deliverables and how arrangement consideration should be allocated to the separate units of accounting, when applicable. The ASU is effective for fiscal year beginning on or after June 15, 2010. Early adoption is permitted. Adoptions of this guidance is expected to have a significant effect on how revenue arrangements entered into subsequent to January 1, 2011 are reflected in the financial statements.

Item 7A. 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 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 December 31, 2009 are comprised mainly of a certificate of deposit and a common stock investment. We have entered into a foreign exchange hedging transaction as part of our risk management program. We continue to utilize our \$350.0 million credit facility to fund operations. As of December 31, 2009, the amount borrowed and outstanding under the credit facility was \$165.0 million. The interest rate is fixed at the time of the draw. If interest rates were to increase from levels at December 31, 2009 we could experience a higher level of interest expense than assumed in our current operating plan.

Item 8. Financial Statements and Supplementary Data

The information required by this Item is included in Items 15(a)(1) and (2) of Part IV of this Annual Report on Form 10-K.

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Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure None

Item 9A. 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 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 Rule 13a-15(e) and 15d-15(e) of the Exchange Act) as of December 31, 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.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework set forth in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework set forth in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2009. Deloitte & Touche LLP, the independent registered public accounting firm that audited the financial statements included in this 2009 Form 10-K, has issued an attestation report on our internal control over financial reporting as of December 31, 2009, which is included herein.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of MannKind Corporation Valencia, California

We have audited the internal control over financial reporting of MannKind Corporation (the Company) as of December 31, 2009, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements as of and for the year ended December 31, 2009 of the Company and our report dated March 16, 2010 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California March 16, 2010

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Item 9B. Other Information.

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we will file our Proxy Statement within 120 days after the end of our fiscal year pursuant to Regulations 14A for our 2010 Annual Meeting of Stockholders, and the information included in the Proxy Statement is incorporated herein by reference. **Item 10.** *Directors, Executive Officers and Corporate Governance.*

- (a) *Executive Officers* For information regarding the identification and business experience of our executive officers, see Executive Officers in Part I, Item 1 of this Annual Report on Form 10-K.
- (b) *Directors* The information required by this Item regarding the identification and business experience of our directors and corporate governance matters is contained in the section entitled Proposal 1- Election of Directors and Corporate Governance Principles and Board and Committee Matters in the Proxy Statement, and is incorporated herein by reference.

Additional information required by this Item is incorporated by reference to this section entitled Section 16(a) Beneficial Ownership Reporting Compliance in the Proxy Statement.

We have adopted a Code of Business Conduct and Ethics Policy that applies to our directors and employees (including our principal executive officer, principal financial officer, principal accounting officer and controller), and have posted the text of the policy on our website (*www.mannkindcorp.com*) in connection with Investors materials. In addition, we intend to promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver.

Item 11. Executive Compensation

The information under the caption Executive Compensation in the Proxy Statement is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information under the captions Security Ownership of Certain Beneficial Owners and Management and

Executive Compensation Securities Authorized for Issuance under Equity Compensation Plans in the Proxy

Statement is incorporated herein by this reference.

Item 13. Certain Relationships, Related Transactions and Director Independence

The information under the caption Certain Transactions and Corporate Governance Principles and Board and Committee Matters in the Proxy Statement is incorporated herein by reference. With the exception of the information specifically incorporated by reference from the Proxy Statement in this Annual Report on Form 10-K, the Proxy Statement shall not be deemed to be filed as part of this report. Without limiting the foregoing, the information under the captions Report of the Audit Committee of the Board of Directors and Report of the Compensation Committee of the Board of Directors in the Proxy Statement is not incorporated by reference.

Item 14. Principal Accounting Fees and Services

The information under the caption Principal Accounting Fees and Services in the Proxy Statement is incorporated herein by reference.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

- (a) The following documents are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K:
- (1)(2) Financial Statements and Financial Statement Schedules. The following Financial Statements of MannKind Corporation, Financial Statement Schedules and Report of Independent Registered Public Accounting Firm are included in a separate section of this report beginning on page F-2:

Report of Independent Registered Public Accounting Firm	62
Consolidated Balance Sheets	63
Consolidated Statements of Operations	64
Consolidated Statements of Stockholders Equity (Deficit)	65
Consolidated Statements of Cash Flows	70
Notes to Consolidated Financial Statements	72

All financial statement schedules have been omitted because the required information is not applicable or not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements or the notes thereto.

- (3) Exhibits. The exhibits listed under Item 15(b) hereof are filed with, or incorporated by reference into, this Annual Report on Form 10-K. Each management contract or compensatory plan or arrangement is identified separately in Item 15(b) hereof.
- (b) Exhibits. The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K:

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Exhibit Index

Exhibit	
Number	Description of Document
2.1**(14)	LIP Asset or Business Sale and Purchase Agreement, dated March 6, 2009, by and among Pfizer
	Manufacturing Frankfurt GmbH, Pfizer Inc., MannKind Deutschland GmbH and MannKind, as
	amended on April 3, 2009.
2.2**(14)	Insulin Sale and Purchase Agreement, dated March 6, 2009, by and among Pfizer Manufacturing
2.1(1)	Frankfurt GmbH, Pfizer Inc. and MannKind.
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(12)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.3(9) 4.1(10)	Amended and Restated Bylaws. Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated November 1, 2006.
4.1(10)	First Supplemental Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated
4.2(3)	December 12, 2006.
4.3(3)	Form of 3.75% Senior Convertible Note due 2013.
4.4(1)	Form of common stock certificate.
4.5(1)	Registration Rights Agreement, dated October 15, 1998 by and among CTL ImmunoTherapies Corp.,
	Medical Research Group, LLC, McLean Watson Advisory Inc. and Alfred E. Mann, as amended.
10.1(15)	Promissory Note made by MannKind in favor of The Mann Group LLC dated February 26, 2009.
10.2(12)	Agreement, dated September 13, 2006, between MannKind and Torcon, Inc.
10.3(2)	Securities Purchase Agreement, dated August 2, 2005 by and among MannKind and the purchasers
	listed on Exhibit A thereto.
10.4**(4)	Supply Agreement, dated December 31, 2004, between MannKind and Vaupell, Inc.
10.5*(1)	Form of Indemnity Agreement entered into between MannKind and each of its directors and officers.
10.6*(8) 10.7*(5)	Description of Officers Incentive Program. Description of 2006 executive officer salaries.
10.7*(5)	Description of 2006 non-employee director compensation.
10.9*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Hakan Edstrom.
10.10*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and David Thomson.
10.11*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Peter Richardson.
10.12*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Juergen Martens.
10.13*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Diane Palumbo.
10.14*(11)	Executive Severance Agreement, dated April 21, 2008, between MannKind and Matthew J. Pfeffer.
10.15*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Hakan Edstrom.
10.16*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and David Thomson.
10.17*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Peter Richardson.
10.18*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Juergen Martens.
10.19*(11) 10.20*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Diane Palumbo. Change of Control Agreement, dated April 21, 2008, between MannKind and Matthew J. Pfeffer.
10.20*(11)	Agreement dated December 20, 2007, between MannKind and Richard L. Anderson.
10.21*(13)	2004 Equity Incentive Plan, as amended.
10.23*(1)	Form of Stock Option Agreement under the 2004 Equity Incentive Plan.
10.24*(6)	Form of Phantom Stock Award Agreement under the 2004 Equity Incentive Plan.
10.25*(8)	2004 Non-Employee Directors Stock Option Plan and form of stock option agreement there under.
10.26*(1)	2004 Employee Stock Purchase Plan and form of offering document there under.
10.27*(1)	Pharmaceutical Discovery Corporation 1991 Stock Option Plan.
10.28*(1)	Pharmaceutical Discovery Corporation 1999 Stock Plan and form of stock option plan there under.
10.29*(1)	AlleCure Corp. 2000 Stock Option and Stock Plan.

10.30*(1)	CTL Immunotherapies Corp. 2000 Stock Option and Stock Plan.
10.31*(1)	2001 Stock Awards Plan.
10.32**(16)	Supply Agreement, dated November 16, 2007, between MannKind and N.V. Organon.
10.33**(14)	Insulin Maintenance and Call-Option Agreement, dated June 19, 2009, by and among Pfizer
	Manufacturing Frankfurt GmbH, Pfizer Inc. and MannKind.
23.1	Consent of Independent Registered Public Accounting Firm
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Exhibit Number	Description of Document
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities
	Exchange Act of 1934, as amended.
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities
	Exchange Act of 1934, as amended.
32	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(b)
	and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of
	Title 18 of the United States Code (18 U.S.C. §1350)

- * Indicates management contract or compensatory plan.
- ** Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.
- (1) Incorporated by reference to MannKind s Registration Statement on Form S-1 (File No. 333-115020) filed with the SEC on April 30, 2004, as amended.
- (2) Incorporated by reference to MannKind s Current Report on Form 8-K filed with the SEC on August 5, 2005.

- (3) Incorporated by reference to MannKind s Current Report on Form 8-K filed with the SEC on December 12, 2006.
- (4) Incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865) filed with the SEC on February 23, 2005.
- (5) Incorporated by reference to MannKind s Current Report on Form 8-K filed with the SEC on February 22, 2006.
- (6) Incorporated by reference to MannKind s Current Report on Form 8-K filed with the SEC on December 14, 2005.
- (7) Incorporated by reference to MannKind s Current Report on Form 8-K filed with the SEC on June 9, 2009.

- (8) Incorporated by reference to MannKind s Annual Report on Form 10-K filed with the SEC on March 16, 2006.
- (9) Incorporated by reference to MannKind s Current Report on Form 8-K filed with the SEC on November 19, 2007.
- (10) Incorporated by reference to MannKind s Registration Statement on Form S-3 (File No. 333-138373) filed with the SEC on November 2, 2006.
- (11) Incorporated by reference to MannKind s Current Report on Form 8-K, as amended, filed with the SEC on October 16, 2007.
- (12) Incorporated by reference to MannKind s Quarterly Report on Form 10-Q filed with the SEC on August 9, 2007.
- (13) Incorporated by reference to MannKind s

Quarterly Report on Form 10-Q filed with the SEC on December 20, 2007.

- (14) Incorporated by reference to MannKind s Quarterly Report on Form 10-Q filed with the SEC on May 4, 2009.
- (15) Incorporated by reference to MannKind s Annual Report on Form 10-K filed with the SEC on February 27, 2009.
- (16) Incorporated by reference to MannKind s Annual Report on Form 10-K filed with the SEC on March 14, 2008.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Mannkind Corporation

By: /s/ Alfred E. Mann Alfred E. Mann Chief Executive Officer

Dated: March 16, 2010

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Hakan S. Edstrom, Matthew Pfeffer and David Thomson, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Report, and any other documents in connection therewith, and to file the same, with all exhibits thereto, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their or his substitute or substituted, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ Alfred E. Mann	Chief Executive Officer and Chairman of the Board of Directors	March 16, 2010
Alfred E. Mann /s/ Hakan S. Edstrom	(Principal Executive Officer) President, Chief Operating Officer and Director	March 16, 2010
Hakan S. Edstrom	Director	
/s/ Matthew J. Pfeffer	Corporate Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2010
Matthew J. Pfeffer	Director	March 16, 2010
A. E. Cohen		
/s/ Ronald J. Consiglio Ronald J. Consiglio	Director	March 16, 2010
/s/ Michael Friedman, M.D.	Director	March 16, 2010
Michael Friedman, M.D. /s/ Kent Kresa Kent Kresa	Director	March 16, 2010
/s/ David H. MacCallum David H. MacCallum	Director	March 16, 2010
Henry L. Nordhoff	Director	March 16, 2010
/s/ James S. Shannon	Director	March 16, 2010

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company) INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	62
Consolidated Balance Sheets	63
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Consolidated Statements of Stockholders Equity (Deficit)	65
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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of MannKind Corporation Valencia, California

We have audited the accompanying consolidated balance sheets of MannKind Corporation (a development stage company) (the Company) as of December 31, 2008 and 2009 and the related consolidated statements of operations, stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2009 and for the period from February 14, 1991 (date of inception) to December 31, 2009. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of MannKind Corporation as of December 31, 2008 and 2009, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009 and for the period from February 14, 1991 (date of inception) to December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company s internal control over financial reporting as of December 31, 2009, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2010 expressed an unqualified opinion on the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP Los Angeles, California March 16, 2010

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company) CONSOLIDATED BALANCE SHEETS

	December 31, 2008 20 (In thousands, exce share data)			2009 xcept
ASSETS				
Current assets: Cash and cash equivalents Marketable securities State research and development credit exchange receivable current Prepaid expenses and other current assets	\$	27,648 18,844 1,500 5,983	\$	30,019 2,475 1,500 3,672
Total current assets Property and equipment net State research and development credit exchange receivable net of current portion Other assets		53,975 226,436 1,500 548		37,666 208,229 918 584
Total	\$	282,459	\$	247,397
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)				
Current liabilities: Accounts payable Accrued expenses and other current liabilities	\$	15,630 37,842	\$	6,519 22,334
Total current liabilities Senior convertible notes Note payable to related party		53,472 112,253 30,000		28,853 112,765 165,000
Total liabilities		195,725		306,618
Commitments and contingencies Stockholders equity (deficit): Undesignated preferred stock, \$0.01 par value 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2008 and 2009 Common stock, \$0.01 par value 150,000,000 shares authorized at December 31, 2008 and 2009; 102,008,096 and 113,025,291 shares issued and outstanding at				
December 31, 2008 and 2009, respectively Additional paid-in capital Accumulated other comprehensive income (loss)		1,020 1,469,497 295		1,130 1,544,112 (281)
Deficit accumulated during the development stage	(1,384,078)	(1,604,182)
Total stockholders equity (deficit)		86,734		(59,221)

Total \$ 282,459 \$ 247,397

See notes to consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company) CONSOLIDATED STATEMENTS OF OPERATIONS

Cumulative Period from February 14, 1991 (Date of Inception) to December 31, 2009

				Inception) to December
		Ended Decembe	·	31,
	2007	2008	2009	2009
_		In thousands, ex		
Revenue	\$ 10	\$ 20	\$	\$ 2,988
Operating expenses:				
Research and development	256,844	250,442	156,331	1,153,813
General and administrative	50,523	55,343	53,447	299,289
In-process research and development costs				19,726
Goodwill impairment				151,428
Total operating expenses	307,367	305,785	209,778	1,624,256
	,	,	,	, ,
Loss from operations	(307,357)	(305,765)	(209,778)	(1,621,268)
Other income (expense)	(197)	(62)	51	(1,892)
Interest expense on note payable to principal				
stockholder		(12)	(5,679)	(7,202)
Interest expense on senior convertible notes	(3,408)	(2,327)	(4,768)	(10,725)
Interest income	17,775	5,129	70	36,931
Loss before provision for income taxes	(293,187)	(303,037)	(220,104)	(1,604,156)
Income taxes	(2)3,107) (3)	(303,037) (2)	(220,104)	(26)
meome wices	(3)	(2)		(20)
Net loss	(293,190)	(303,039)	(220,104)	(1,604,182)
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	\$ (293,190)	\$ (303,039)	\$ (220,104)	\$ (1,627,394)
The loss applicable to common stockholders	φ (255,156)	Ψ (202,027)	ψ (22 0,10 1)	ψ (1,027,331)
Net loss per share applicable to common				
stockholders basic and diluted	\$ (3.66)	\$ (2.98)	\$ (2.07)	
Shares used to compute basic and diluted net loss				
per share applicable to common stockholders	80,038	101,561	106,534	
_				

See notes to consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company) CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

Series

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eries

	Series Convertible Series Series]	Deficit	
	В			Ptiblæ rre	d				Notes	Not	es		umulated During	i
•	Convertion Preferre			err St bck	Comr		Ad	ldition&	eceiv a t	d e eiv	a Oltd n		the	
9	Stock Sha Acs not	Stock	SSo	ndkscripti Rlebeivab	onsSto	ck					_		i vk opmen Stage	t Total
Issuance of common stock for cash Net loss		\$	\$	\$		\$ 10		-		\$	\$	\$	(911)	\$ 900
BALANCE, FEBRUARY 29, 1992 Issuance of common	n				998	10		890					(911)	(11)
stock for cash and services Capital contribution Net loss	ı				73	1		887 20					(1,175)	888 20 (1,175)
BALANCE, FEBRUARY 28, 1993 Issuance of common	n				1,071	11		1,797					(2,086)	(278)
stock for cash Issuance of stock for					11			526						526
notes receivable Net loss					8			400	(400))			(1,156)	(1,156)
BALANCE, FEBRUARY 28, 1994 Issuance of common	n				1,090	11		2,723	(400))			(3,242)	(908)
stock for cash and services					36			1,805						1,805
Collection of stock subscription Net loss									400				(2,004)	400 (2,004)

BALANCE, DECEMBER 31, 1994 Issuance of common stock for services Exercise of stock options Stock compensation Net loss	1,126	11	4,528 8 22 384	(5,246) (2,815)	(707) 8 22 384 (2,815)
BALANCE, DECEMBER 31, 1995 Issuance of common stock for cash and	1,127	11	4,942	(8,061)	(3,108)
services	1		59		59
Exercise of stock options Stock compensation Net loss	3		12 126	(2,570)	12 126 (2,570)
BALANCE, DECEMBER 31, 1996 Issuance of common	1,131	11	5,139	(10,631)	(5,481)
stock for cash and services Stock compensation Exercise of stock	548	6	190 2		196 2
options	27		135		135
Conversion of notes payable Net loss	12		60	(2,280)	60 (2,280)
BALANCE, DECEMBER 31, 1997 Issuance of common	1,718	17	5,526	(12,911)	(7,368)
stock for cash and services Stock compensation Exercise of stock	2,253	23	12,703 150		12,726 150
options	68	1	24		25
Conversion of notes payable Net loss	215	2	1,200	(3,331)	1,202 (3,331)

BALANCE,					
DECEMBER 31,					
1998	4,254	43	19,603	(16,242)	3,404
Issuance of common					
stock	162	2	532		534
Conversion of notes					
payable	80	1	994		995
Net loss				(5,679)	(5,679)
BALANCE,					
DECEMBER 31,					
1999	4,496	46	21,129	(21,921)	(746)
Conversion of notes					
payable	63	1	1,073		1,074
	ϵ	55			

MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

Series

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Series

Convertible Deficit

Series

Series B Convertible Red Notes Notes Accumulated

During

Convertible

Preferred Preferred Common

Stock StockStubscriptions Stock Paid-In from Comprehibasislopment
Shares Amount Capital Stock hold of fidewome Stage T.

S	hares	Amoun§ha \re	s ő snika bbi v a	ab Sc ares A	mount	CapitalSto	ockhol deffiderc	ome Stage	Total
Issuance of									
Series B									
preferred stock									
for cash	193	15,000							15,000
Issuance of									
common stock									
for cash,									
services and									
notes				4,690	46	33,945	(2,358)		31,633
Discount on									
notes below									
market rate							241		241
Accrued									
interest on									
notes							(117)		(117)
Purchase of									
Series A									
redeemable									
convertible									
preferred stock						(993)			(993)
Amount in									
excess of									
redemption									
obligation						999			999
Accretion to									
redemption									
value on									
Series A									
redeemable									
convertible						(1.40)			(1.40)
preferred stock						(149)			(149)
Stock-based						0.600			0.600
compensation						9,609		(0.1.661)	9,609
Net loss								(24,661)	(24,661)

BALANCE, DECEMBER	102	15 000	0.240	02	<i>45 4</i> 1 2	(2.224)	(46,582)	21 200
31, 2000 Issuance of	193	15,000	9,249	93	65,613	(2,234)	(46,382)	31,890
common stock for cash Cash received for common			3,052	30	78,000			78,030
stock to be issued Issuance of					3,900			3,900
common stock for services			3		60			60
Exercise of stock options Accrued			1		13			13
interest on notes Payments on						(189)		(189)
notes receivable Accretion to redemption value on						28		28
Series A redeemable convertible								
preferred stock Stock-based					(239)			(239)
compensation Issuance of put					1,565			1,565
option by stockholder					(2,949)			(2,949)
Record merger of entities Net loss					171,154		(48,245)	171,154 (48,245)
BALANCE, DECEMBER 31, 2001	193	15,000	12,305	123	317,117	(2,395)	(94,827)	235,018
Issuance of common stock for cash Issuance of common stock for cash			3,922	40	58,775			58,815
already received			234	2	(2)			

Issuance of			
stock award to			
employee	3	84	84
Cash received			
for common			
stock issuable		98	98
Accrued			
interest on			
notes		(229)	(229)
Payments on			
notes			
receivable		1,314	1,314
Beneficial			
conversion			
feature of			
Series B			
convertible			
preferred stock		1,421	1,421
Deemed			
dividend			
related to			
beneficial			
conversion			
feature of			
Series B			
convertible			
preferred stock		(1,421)	(1,421)
Accretion to			
redemption			
value on			
Series A			
redeemable			
convertible			
preferred stock		(251)	(251)
Stock-based		260	260
compensation		268	268
Put option			
redemption by		1 001	1.001
stockholder		1,921	1,921
Net loss			(206,265) (206,265)
	66		

LANCE, CEMBER 2002

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company) CONSOLIDATED STATEMENTS OF STOCKHOLDERS FOURTY (DEFICIT) (Continued)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

	Series B	Series C	Series C C Convertible	Series C Convertible Preferred				Notes	Notes	Deficit Accumulated During	
	Convertible Preferred	Preferred	Preferred		Comm	on	Additiona	eceiva B	e ceiva 61 t	_	
	Stock Shares Amour	Stock nt Shares Amoun		bscriptions Receivable \$			Paid-In t CapitaBto	from ockholde		e Dansik apment ome Stage	Tota
	193 15,00	00			16,464	165	378,010	(1,310)		(301,092)	90,7
ed			50,000	(50,000)							
				31,847							31,8
k					3,494	35	49,965				50,0
1											
n											
k							70				
					17						
r											

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s eficial version										(102)	(3)		(1
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vertible erred k									(1,017)				(1,0
retion to mption e on es A emable rertible													
erred k k-based									(253)				(2
pensation shares to									4,501				4,5
ority kholder loss									623			(65,879)	(65,8
LANCE, CEMBER 2003 ance of es C vertible	193	15,000			50,000	(18,153)	19,975	200	433,141	(1,412)	(228)	(366,971)	111,5
rertible erred k for cash ance of es C rertible erred k for cash ady			356 624	18,153 31,847	(18,153) (31,847)								18,

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ivable by kholder											
ed to											
ers							(225)		228		
ayment of							(225)		220		
k note											
ivable					(90)	(1)	(1,518)	1,519			
version of					` '			•			
es A											
vertible											
erred											
k to											
mon stock					891	9	5,239			5	5,2
version of											
es B											
rertible											
erred											
k to man staals	(102)	(15,000)			011	O	14.002				
mon stock version of	(193)	(15,000)			811	8	14,992				
es C											
es C vertible											
erred											
k to											
mon stock			(980)	(50,000)	4,464	45	49,955				
ance of			(),	(50,000)	1,		12,22-				
mon											
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loyee											
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hase Plan					36		430				4
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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company) CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

Series

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Series

		Series					m .	
		Converti	ible				Deficit	
	Series	Series	•			N I		
	В	CConvertifier				NoteNotes	Accumulated	
(benver i i befer Stock			Addition	ece nedele able	er During the	
	Preferrel			C4 1	D '11	c <i>a</i> c		
		Stock Stubkeript				_	he Driwe lopment	7 75 ()
	Shakenob	h aAca oksada b deiva	bl b hares A	Amount	Capitalto	ckh Odectms o	me Stage	Total
Accretion to								
redemption								
value on								
Series A								
redeemable								
convertible	1				(60)			(60)
preferred stoc	CK				(60))		(60)
Stock-based					(010			(010
compensation	1				6,810		(75,000)	6,810
Net loss							(75,992)	(75,992)
DALANCE								
BALANCE, DECEMBER								
	-		32,756	227	502.000		(442.062)	150 262
31, 2004 Issuance of			32,730	327	592,999		(442,963)	150,363
common								
shares in								
exchange for								
warrants			24		245			245
Issuance of			27		2-13			213
common								
shares under								
Employee								
Stock Purchas	se							
Plan			58	1	494			495
Exercise of								
stock options			304	3	1,948			1,951
Issuance of								
stock awards								
to consultants	3		40	1	(146))		(145)
Issuance of								
stock and								
warrants for								
cash			17,132	171	170,063			170,234

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Stock-based compensation Net loss			(1,828)	(114,338)	(1,828) (114,338)
BALANCE, DECEMBER 31, 2005 Exercise of warrants Issuance of common shares under	50,314 339	503	763,775 2,691	(557,301)	206,977 2,694
Employee Stock Purchase Plan Exercise of stock options Cancellation of	86 263	1	980 2,309		981 2,312
common shares for stock notes receivable Issuance of stock for cash	(844) 23,000	(8) 230	8 384,440		384,670
Issuance of common shares from the release of restricted stock units	102	1	(341)		(340)
Issuance of common shares pursuant to research	102	1	(341)		(340)
agreement Stock-based compensation Net loss	100	1	2,073 14,667	(230,548)	2,074 14,667 (230,548)
BALANCE, DECEMBER 31, 2006 Issuance of common shares under	73,360	734	1,170,602	(787,849)	383,487
Employee Stock Purchase Plan	124	1	1,064		1,065

Section Sect	Exercise of				
Sasuance of stock awards to consultants 30 123		607	6	4 917	4 923
stock awards 123 123 to consultants 30 123 123 Issuance of stock for cash 27,014 270 249,480 249,750 Issuance of common shares from the release of restricted stock crestricted stock	_	307	O	1,517	1,223
Issuance of stock for cash 27,014 270 249,480 249,750 Issuance of common shares from the release of restricted stock units 146 2 (526) (524) Issuance of common shares 146 2 (526) (524) Issuance of common shares 5 5 5 pursuant to research agreement greement					
stock for cash 27,014 270 249,480 249,750 Issuance of common shares from the release of restricted stock units 146 2 (526) (524) Issuance of common shares pursuant to research agreement 100 1 943 944 Stock-based compensation 17,522 17,522 17,522 Net loss 2093,190 (293,190) (293,190) (293,190) BALANCE, DECEMBER 31, 2007 101,381 1,014 1,444,125 (1,081,039) 364,100 Issuance of common shares under Employee Stock Purchase Plan 349 4 896 900 Issuance of stock awards to consultants 30 (18) (18) (18) Issuance of stock awards to consultants 30 (18) (18) (18) Issuance of common shares from the release of restricted stock units 248 2 (317) (315)		30		123	123
Issuance of common shares from the release of restricted stock units 146 2 (526) (524) Issuance of common shares pursuant to research agreement 100 1 943 944 Stock-based compensation 17,522 17,522 17,522 Net loss 101,381 1,014 1,444,125 (1,081,039) 364,100 BALANCE, DECEMBER 31, 2007 101,381 1,014 1,444,125 (1,081,039) 364,100 Issuance of common shares under Employee Stock Purchase Plan 349 4 896 900 Stock Purchase Of stock awards to consultants 30 (18) (18) Issuance of common shares from the release of restricted stock units 248 2 (317) (315) Stock-based compensation 24,811 24,811 24,811	Issuance of				
common shares from the release of restricted stock units 146 2 (526) (526) (524) Issuance of common shares pursuant to research agreement 100 1 943 944 Stock-based compensation 17,522 17,522 17,522 Net loss 101,381 1,014 1,444,125 (1,081,039) 364,100 Issuance of common shares under Employee Stock Purchase Plan 349 4 896 900 Issuance of stock awards to consultants 30 (18) (18) (18) Issuance of common shares rfrom the release of restricted stock units 248 12 (317) (315) Stock-based compensation 1815 1815 1816 1815 1816 1816 1816 1816	stock for cash	27,014	270	249,480	249,750
shares from the release of release of restricted stock units 146 2 (526) (524) Issuance of common shares spursuant to research agreement 100 1 943 944 Stock-based compensation 101,381 1,014 1,444,125 (1,081,039) 364,100 Issuance of common shares spursuant to research agreement 101,381 1,014 1,444,125 (1,081,039) 364,100 Issuance of common shares under Employee Stock Purchase Plan 349 4 8896 900 Issuance of stock awards to consultants 30 (18) (18) (18) (18) (18) Issuance of common shares rom the release of restricted stock units 248 2 (317) (315) Stock-based compensation 124,811	Issuance of				
relase of restricted stock units 146 2 (526) (527) Issuance of common shares pursuant to research agreement 100 1 943 944 Compensation 17,522 17,522 Net loss 17					
restricted stock units 146 2 (526) (526) (524) Issuance of common shares pursuant to research agreement 100 1 943 944 Stock-based compensation 17,522 17,522 Net loss 17,522					
units 146 2 (526) (524) Issuance of common shares (524) (524) (524) pursuant to research (524) (526) (524) (526) (524) agreement 100 1 943 944 944 945 (525) (526) 17,522 (526) 17,522 (526) 17,522 (526) 1900 (527) (527) (527) (527) (527) (527) (528)					
Issuance of common shares pursuant to research agreement 100 1 943 944 Stock-based compensation 17,522 17,522 17,522 Net loss 17,522 17,522 Net loss 1		146	2	(526)	(524)
common share's pursuant to research agreement 100 1 943 944 944 Stock-based compensation PECEMBER 31, 2007 101,381 1,014 1,444,125 (1,081,039) 364,100 Issuance of common shares under Employee Stock Purchase Plan 349 4 896 900 Issuance of stock awards to consultants 30 (18) (18) Issuance of common shares from the release of restricted stock units 248 2 (317) (315) Stock-based compensation (316) 324,811		146	2	(526)	(524)
shares pursuant to research agreement 100 1 943 944 Stock-based compensation 17,522 Net loss 17,522 17,522 Net loss (293,190) (293,190) BALANCE, DECEMBER 31, 2007 101,381 1,014 1,444,125 (1,081,039) 364,100 Issuance of common shares under Employee Stock Purchase Plan 349 4 896 900 Issuance of stock awards to consultants 30 (18) 900 Issuance of common shares from the release of restricted stock units 248 2 (317) (315) Stock-based compensation 24,811					
pursuant to research agreement 100 1 943 944 Stock-based compensation 17,522 17,522 17,522 Net loss 17,522 (293,190) (293,190) BALANCE, DECEMBER 31, 2007 101,381 1,014 1,444,125 (1,081,039) 364,100 Issuance of common shares under Employee 5000 Personal Stock Purchase 896 900 Plan 349 4 896 900 Issuance of stock awards to consultants 30 (18) (18) Issuance of common shares from the release of restricted stock units 248 2 (317) (315) Stock-based compensation 24,811 24,811 24,811					
research agreement					
agreement 100 1 943 944 Stock-based compensation 17,522 17,522 17,522 Net loss 17,522 (293,190) (293,190) BALANCE, DECEMBER 31, 2007 101,381 1,014 1,444,125 (1,081,039) 364,100 Issuance of common shares under 5000	•				
Stock-based compensation Net loss 17,522 17,5		100	1	943	944
Net loss (293,190) (293,190) BALANCE, DECEMBER 31, 2007 101,381 1,014 1,444,125 (1,081,039) 364,100 Issuance of common shares under Employee Stock Purchase 8 8 8 900 Issuance of stock Purchase Plan 349 4 896 900 Issuance of stock awards to consultants 30 (18) (18) Issuance of common shares from the release of restricted stock units 248 2 (317) (315) Stock-based compensation 24,811 24,811 24,811	-				
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DECEMBER 31, 2007 101,381 1,014 1,444,125 (1,081,039) 364,100 Issuance of common shares under Employee Stock Purchase Plan 349 4 896 900 Issuance of stock awards to consultants 30 (18) (18) Issuance of common shares from the release of restricted stock units 248 2 (317) (315) Stock-based compensation 564,100 164,10	Net loss				(293,190) (293,190)
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Issuance of common shares under Employee Stock Purchase Plan 349 4 896 900 Issuance of stock awards (18) (18) to consultants 30 (18) (18) Issuance of common (18) (18) shares from the release of restricted stock (18) (18) units 248 2 (317) (315) Stock-based compensation 24,811 24,811 24,811		101,381	1,014	1,444,125	(1,081,039) 364,100
shares under Employee Stock Purchase Plan 349 4 896 900 Issuance of stock awards 5 5 5 to consultants 30 (18) (18) (18) Issuance of 6 6 6 6 6 6 6 6 6 6 6 7 6 7 18) 18		*	•	, ,	
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Stock Purchase Plan 349 4 896 900 Issuance of stock awards 30 (18) (18) Issuance of common shares from the release of restricted stock units 248 2 (317) (315) Stock-based compensation 24,811 24,811 24,811	shares under				
Plan 349 4 896 900 Issuance of stock awards 30 (18) (18) Issuance of common shares from the release of restricted stock 5 5 units 248 2 (317) (315) Stock-based compensation 24,811 24,811					
Issuance of stock awards 30 (18) (18) Issuance of common shares from the release of restricted stock 30 (18) (18) Issuance of common shares from the release of restricted stock (18) (18) (18) Issuance of common shares from the release of restricted stock (18) (18) (18) Issuance of common shares from the release of restricted stock (18) (18) (18) Issuance of common shares from the release of restricted stock (18) (18) (18) Issuance of common shares from the release of restricted stock (18) (18) (18) Issuance of common shares from the release of restricted stock (18) (18) (18) Issuance of common shares from the release of restricted stock (18) (18) (18) Issuance of common shares from the release of restricted stock (18) (18) (18) Issuance of common shares from the release of restricted stock (18) (18) (18) Issuance of common shares from the release of restricted stock (18) (18) (18) Issuance of common shares from the release of restricted stock (18) (18) (18) (18)					
stock awards 30 (18) (18) Issuance of common 10 </td <td></td> <td>349</td> <td>4</td> <td>896</td> <td>900</td>		349	4	896	900
to consultants 30 (18) Issuance of common shares from the release of restricted stock units 248 2 (317) (315) Stock-based compensation 24,811 24,811					
Issuance of common shares from the release of restricted stock units 248 2 (317) (315) Stock-based compensation 24,811 24,811		20		(10)	(10)
common shares from the release of restricted stock units 248 2 (317) (315) Stock-based compensation 24,811 24,811		30		(18)	(18)
shares from the release of restricted stock units 248 2 (317) (315) Stock-based compensation 24,811 24,811					
release of restricted stock units 248 2 (317) (315) Stock-based compensation 24,811 24,811					
restricted stock units 248 2 (317) (315) Stock-based compensation 24,811 24,811					
units 248 2 (317) (315) Stock-based compensation 24,811 24,811					
Stock-based 24,811 24,811		248	2	(317)	(315)
				. ,	· ,
68	compensation			24,811	24,811
			68		

MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company) CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

Series

 \mathbf{C}

Series

Convertible Deficit

	Series	Series						
	В	Con Rudfele	ed		N	otesotes	Accumulated	
	Conver G l	oleve PtibleStod k			AdditionRece	Reabile al Ot her	During the	
	Preferr	deferred						
	Stock	Stockripti	Go mmor	ı Stock	Paid-In fi	ron icom prehen	Dec elopment	
	SharrasoSi	marestastatedeli vat	S hares	Amount	Capit St ock	th Oldineta come	Stage	Total
Comprehensive								
loss:								
Net loss							(303,039)	(303,039)
Unrealized gain								
(loss) on								
available-for-sa	le							
securities						295		295
Comprehensive								
loss								(302,744)
D. 17. 1316D								
BALANCE,								
DECEMBER 3	l,		102 000	1.020	1 460 405	205	(1.204.050)	06.724
2008			102,008	1,020	1,469,497	295	(1,384,078)	86,734
Issuance of								
common shares								
under Employee Stock Purchase	•							
Plan			323	3	1 207			1 400
Issuance of stoc	1,		323	3	1,397			1,400
for cash	K		8,360	84	59,640			59,724
Issuance of			8,300	04	39,040			39,724
common shares								
from the release								
of restricted sto								
units	J.K.		2,240	22	(7,023)			(7,001)
Exercise of stoc	k		2,240	22	(7,023)			(7,001)
options	K		94	1	382			383
Stock-based				-	202			202
compensation					20,219			20,219
Comprehensive					-,			- ,—
loss:								
Net loss							(220,104)	(220,104)
						(501)	. , ,	(501)

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(581)

(581)

Unrealized gain (loss) on available-for-sale securities

Unrealized gain

(loss) on foreign

currency

translation 5 5

Comprehensive

loss (220,680)

BALANCE, DECEMBER 31,

2009 \$ \$ 113,025 \$1,130 \$1,544,112 \$ \$ \$(281) \$(1,604,182) \$ (59,221)

See notes to consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company) CONSOLIDATED STATEMENTS OF CASH FLOWS

Cumulative

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				Period from February 14, 1991 (Date of Inception) to December	
	Years	Ended Decemb	er 31,	31,	
	2007	2008	2009	2009	
		(In the	ousands)		
CASH FLOWS FROM OPERATING					
ACTIVITIES:					
Net loss	\$ (293,190)	\$ (303,039)	\$ (220,104)	\$ (1,604,182)	
Adjustments to reconcile net loss to net cash used					
in operating activities:					
Depreciation and amortization	8,973	12,287	18,725	79,139	
Stock-based compensation expense	17,645	24,793	20,219	99,842	
Stock expense for shares issued pursuant to					
research agreement	944			3,018	
Loss on sale, abandonment/disposal or					
impairment of property and equipment	7,047	213	12,869	23,575	
Accrued interest on investments, net of		(227)	(10)	(101)	
amortization of premiums (discounts)		(237)	(12)	(191)	
In-process research and development				19,726	
Goodwill impairment				151,428	
Loss on available-for-sale securities			F	229	
Other, net			5	1,110	
Changes in assets and liabilities: State research and development credit exchange					
receivable	1,587	(669)	582	(2,418)	
Prepaid expenses and other current assets	2,654	3,613	2,311	(2,972)	
Other assets	(186)	3,013	(36)	(584)	
Accounts payable	16,265	(14,620)	(6,371)	5,989	
Accrued expenses and other current liabilities	(6,885)	6,395	(12,271)	21,483	
Other liabilities	(0,003)	(24)	(12,271)	(2)	
Other hadrings		(21)		(2)	
Net cash used in operating activities	(245,146)	(271,288)	(184,083)	(1,203,910)	
CASH FLOWS FROM INVESTING ACTIVITIES:					
Purchase of marketable securities	(169,801)	(63,651)	(2,000)	(792,601)	
Sales of marketable securities	286,725	46,100	17,800	790,565	
Purchase of property and equipment	(78,262)	(82,453)	(18,852)	(310,709)	
Proceeds from sale of property and equipment	(70,202)	(82,433)	(10,032)	(310,709)	
1 rocces from saic of property and equipment		70		204	
Net cash (used in) provided by investing activities	38,662	(99,934)	(3,052)	(312,461)	

CASH FLOWS FROM FINANCING

ACTIVITIES:				
Issuance of common stock and warrants	255,738	902	61,507	1,202,055
Collection of Series C convertible preferred stock				
subscriptions receivable				50,000
	70			

MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company) CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

	Vears	Ended Decemb	.er 31	Cumulative Period from February 14, 1991 (Date of Inception) to December 31,
	2007	2008	2009	2009
	2007			2009
I		(In the	ousands)	
Issuance of Series B convertible preferred stock for				15,000
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 from principal				
stockholder		30,000	135,000	235,000
Principal payments on notes payable to principal				
stockholder				(70,000)
Borrowings on notes payable				3,460
Principal payments on notes payable				(1,667)
Payable to stockholder				
Proceeds from senior convertible notes				111,267
Payment of employment taxes related to vested				•
restricted stock units	(524)	(317)	(7,001)	(8,182)
	(= -)	(=)	(,,,,,,	(=,-=)
Net cash provided by financing activities	255,214	30,585	189,506	1,546,390
The cash provided by immoning activities	200,21	20,202	105,000	1,6 .0,6 > 0
NET (DECREASE) INCREASE IN CASH AND				
CASH EQUIVALENTS	\$ 48,730	\$ (340,637)	\$ 2,371	\$ 30,019
CASH AND CASH EQUIVALENTS,	\$ 40,750	\$ (340,037)	φ 2,3/1	\$ 50,019
	210 555	260 205	27.649	
BEGINNING OF PERIOD	319,555	368,285	27,648	
CAGUAND CAGUEOUN/ALENTO END OF				
CASH AND CASH EQUIVALENTS, END OF	φ 2 60 2 0 5	Φ 27 640	Φ 20.010	Φ 20.010
PERIOD	\$ 368,285	\$ 27,648	\$ 30,019	\$ 30,019
SUPPLEMENTAL CASH FLOWS				
DISCLOSURES:				
Cash paid for income taxes	\$ 3	\$ 2	\$	\$ 26
Interest paid in cash	4,348	4,313	8,131	18,487
Accretion on redeemable convertible preferred				
stock				(952)
				3,331

Issuance of common stock upon conversion of notes payable

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	13,219	6,597	620	620
Non-cash transfer from property and equipment to				
other current assets	1,600			

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 consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

1. Description of business and basis of presentation

Business MannKind Corporation (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, AFREZZA, 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 AFREZZA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. In March 2010, the FDA provided a complete response letter regarding this NDA, requesting additional information. Currently, AFREZZA remains under regulatory review. AFREZZA 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 AFREZZA 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 December 31, 2009 the Company has reported accumulated net losses of \$1.6 billion, which include a goodwill impairment charge of \$151.4 million (see Note 2), 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 December 31, 2009 the Company s capital resources consisted of cash, cash equivalents, and marketable securities of \$32.5 million (including a \$2.0 million certificate of deposit held as collateral for foreign exchange hedging instruments) and \$185.0 million of available borrowings under the loan agreement with an entity controlled by the Company s principal stockholder (see Note 7). Based upon the Company s current expectations, management believes the Company s existing capital resources will enable it to continue planned operations into the first quarter of 2011. However, the Company cannot provide assurances that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. Accordingly, the Company expects that it will need to raise additional capital, either through the sale of equity and/or debt securities, a strategic business collaboration with a pharmaceutical company or the establishment of other funding facilities, in order to continue the development and commercialization of AFREZZA and other product candidates and to support its other ongoing activities.

On December 12, 2001, the stockholders of AlleCure Corp. (AlleCure) and CTL ImmunoTherapies Corp. (CTL) voted to exchange their shares for shares of Pharmaceutical Discovery Corporation (PDC). Upon approval of the merger, PDC then changed its name to MannKind Corporation. PDC was incorporated in the State of Delaware on February 14, 1991. The stockholders of PDC did not vote on the merger. At the date of the merger, Mr. Alfred Mann owned 76% of PDC, 59% of AlleCure and 69% of CTL. Accordingly, only the minority interest of AlleCure and CTL was stepped up to fair value using the purchase method of accounting. As a result of this purchase accounting, in-process research and development of \$19.7 million and goodwill of \$151.4 million were recorded at the entity level. The historical basis of PDC and the historical basis relating to the ownership interests of Mr. Mann in AlleCure and CTL have been reflected in the financial statements. For periods prior to December 12, 2001, the results of operations have been presented on a combined basis. All references in the accompanying financial statements and notes to the financial statements to number of shares, sales price and per share amounts of the Company s capital stock have been retroactively restated to reflect the share exchange ratios for each of the entities that participated in the merger.

For periods subsequent to December 12, 2001, the accompanying financial statements have been presented on a consolidated basis and include the wholly-owned subsidiaries, AlleCure and CTL. On December 31, 2002, AlleCure and CTL merged with and into MannKind and ceased to be separate entities.

Segment Information In accordance with Accounting Standards Codification (ASC) 280-10-50 Segment Reporting, Overall, Disclosure, previously Financial Accounting Standards Board (FASB) Statement No. 131, Disclosures about Segments of an Enterprise and Related Information, operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the

chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as one segment operating entirely in the United States of America.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. Summary of significant accounting policies

Financial Statement Estimates The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Cash and Cash Equivalents The Company considers all highly liquid investments with a purchased maturity date of three months or less to be cash equivalents.

Concentration of Credit Risk Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and marketable securities. Cash and cash equivalents consist primarily of interest-bearing accounts and are regularly monitored by management and held in high credit quality institutions. Marketable securities consist of a \$2.0 million certificate of deposit held as collateral for foreign exchange hedging instruments, and a common stock investment.

Marketable Securities The Company accounts for marketable securities as available for sale, in accordance with ASC 320-10 Investments- Debt and Equity Securities, Overall, previously FASB Statement No. 115, Accounting for Certain Debt and Equity Securities. Unrealized holding gains and losses for available-for-sale securities are reported as a separate component of stockholders equity until realized. The Company reviews the portfolio for other than temporary impairment in accordance with ASC 320-10-35 Investment- Debt and Equity Securities Overall Subsequent Measurement, previously Emerging Issues Task Force (EITF) Issue No. 03-01, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments and FASB Staff Position No. 115-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments.

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 foregoing the carryforward of the research and development 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.

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 related party 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 \$112.3 and \$112.8 million and an estimated fair value of \$53.9 and \$80.3 million as of December 31, 2008 and 2009, respectively, which is calculated based on quoted prices in an active market (Level 1 in the fair value hierarchy).

Goodwill and Identifiable Intangibles As a result of the merger with AlleCure and CTL on December 12, 2001, as described in Note 1, goodwill of \$151.4 million was recorded at the entity level in 2001. Upon adoption of FASB Statement No. 142, Goodwill and Other Intangible Assets, or ASC 350-10 Intangibles- Goodwill and Other Overall, the Company adopted a policy of testing goodwill and intangible assets with indefinite lives for impairment at least annually, as of December 31, with any related impairment losses being recognized in earnings when identified. In December 2002 the Company concluded that the major AlleCure product development program should be terminated and that the clinical trials of the CTL product should be halted and returned to the research stage. As a result of this determination, the Company closed the CTL facility and reduced headcount for AlleCure and CTL by approximately 50%. In connection with the annual test for impairment of goodwill as of December 31, 2002, the Company determined that on the basis of the internal study, the goodwill recorded for the AlleCure and CTL units was potentially impaired. The Company performed the second step of the annual impairment test as of December 31, 2002 for each of the potentially impaired reporting units and estimated the fair value of the AlleCure and CTL programs using the expected present value of future cash flows which were expected to be negligible. Accordingly, the goodwill

balance of \$151.4 million was determined to be fully impaired and an impairment loss

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

was recorded in 2002. Subsequent to December 31, 2002, the Company had no goodwill or intangibles with indefinite lives included on its balance sheet.

Property and Equipment Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the term of the lease or the service lives of the improvements, whichever is shorter. Assets under construction are not depreciated until placed into service.

Impairment of Long-Lived Assets The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable in accordance with ASC 360-10-35 Property Plant and Equipment Overall Subsequent Measurement, previously FASB Statement No. 144, Accounting for the Impairment or Disposal of Long Lived-Assets. Assets are considered to be impaired if the carrying value may not be recoverable based upon management s assessment of the following events or changes in circumstances:

significant changes in the Company s strategic business objectives and utilization of the assets;

a determination that the carrying value of such assets can not be recovered through undiscounted cash flows;

loss of legal ownership or title to the assets; or

the impact of significant negative industry or economic trends.

If the Company believes an asset to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets. Any write-downs would be treated as permanent reductions in the carrying amount of the asset and an operating loss would be recognized. No asset impairment was recognized during the year ended December 31, 2009. During the years ended December 31, 2007 and 2008, asset impairments of approximately \$6.6 million and \$0.5 million, respectively, were recognized as described in Note 5 Property and Equipment.

Accounts Payable and Accrued Expenses All liabilities, including accounts payable and accrued expenses, are recorded consistent with the definition of liabilities and accrual accounting.

Income Taxes Deferred income tax assets and liabilities are recorded for the expected future tax consequences of temporary differences between the financial statement carrying amounts and the income tax basis of assets and liabilities. A valuation allowance is recorded to reduce net deferred income tax assets to amounts that are more likely than not to be realized (see Note 14).

Income tax positions are considered for uncertainty in accordance with ASC 740-10-25 *Income Taxes Overall Recognition*, previously FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* (FIN 48). 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.

Significant management judgment is involved in determining the provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets. Due to uncertainties related to deferred tax assets as a result of the history of operating losses, a valuation allowance has been established against the gross deferred tax asset balance. The valuation allowance is based on management sestimates of taxable income by jurisdiction in which the Company operates and the period over which deferred tax assets will be recoverable. In the event that actual results differ from these estimates or the Company adjusts these estimates in future periods, a change in the valuation allowance may be needed, which could materially impact the Company s financial position and results of operations.

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Contingencies Contingencies are recorded in accordance with ASC 450 Contingencies, previously FASB Statement No. 5, Accounting for Contingencies. Accordingly, the Company records a loss contingency for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

Stock-Based Compensation As of December 31, 2009, the Company had three active stock-based compensation plans, which are described more fully in Note 10. The Company accounts for all share-based payments to employees, including grants of stock awards and the compensatory elements of the employee stock purchase plan in accordance with ASC 718 Compensation- Stock Compensation (ASC 718), previously FASB Statement No. 123R Share-based Payment. ASC 718 requires all share-based payments to employees, including grants of stock options and the compensatory elements of employee stock purchase plans, to be recognized in the income statement based upon the fair value of the awards at the grant date. The Company uses the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options and the compensatory elements of employee stock purchase plans.

Warrants The Company has issued warrants to purchase shares of its common stock. Warrants have been accounted for as equity in accordance with the provisions of ASC 815-40 Derivatives and Hedging, Contracts in an Entity s Own Stock, previously EITF Issue No. 00-19: Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock.

Comprehensive Income (Loss) Other Comprehensive Income (loss) (OCI) is recorded in accordance with ASC 220-10-45 Comprehensive Income, Overall, Other Presentation, previously FASB Statement No. 130, Reporting Comprehensive Income, which requires that all components of comprehensive income (loss) be reported in the financial statements in the period in which they are recognized. OCI includes certain changes in stockholders equity that are excluded from net income. Specifically, the Company includes in OCI unrealized gains and losses on its available-for-sale securities and cumulative translation gains and losses.

Research and Development Expenses Research and development expenses consist primarily of costs associated with the clinical trials of the Company's product candidates, manufacturing supplies and other development materials, including raw material purchases of insulin, compensation and other expenses for research and development personnel, costs for consultants and related contract research, facility costs, and depreciation. Research and development costs, which are net of any tax credit exchange recognized for the Connecticut state research and development credit exchange program, are expensed as incurred consistent with ASC 730-10 Research and Development, Overall, previously FASB Statement No. 2, Accounting for Research and Development Costs.

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

Interest Expense Interest costs are expensed as incurred, except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest expense, net, for the years ended December 31, 2007, 2008 and 2009 was \$3.4 million, \$2.3 million and \$10.4 million, respectively. Interest costs capitalized for the years ended December 31, 2008 and 2009 were \$2.5 million and \$0.1 million, respectively.

MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Net Loss Per Share of Common Stock 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.

Potentially dilutive securities outstanding are summarized as follows:

	December 31,			
	2007	2008	2009	
Exercise of common stock options	6,886,657	5,591,101	6,403,498	
Conversion of senior convertible notes into common				
stock	5,117,523	5,117,523	5,117,523	
Exercise of common stock warrants	2,882,873	2,882,873	2,882,873	
Vesting of restricted stock units	1,359,662	5,947,408	3,419,533	

Exit or Disposal Activities The obligations related to exit or disposal obligations, including reductions in force, are accounted for in accordance with ASC 420-10-30 Exit or Disposal Cost Obligations, Initial Measurement (ASC 420-10-30), previously FASB Statement No. 146, Accounting for Costs Associated with Exit or Disposal Activities and EITF Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Costs to Exit and Disposal Activity (Including Certain Costs Incurred in a Restructuring). In accordance with ASC 420-10-30, a liability for costs associated with an exit or disposal activity is recognized when the liability is incurred and establishes that fair value is the objective for initial measurements of the liability.

Recently Issued Accounting Standards In October of 2009, the FASB ratified the EITF consensus on EITF Issue No. 08-1 Revenue Arrangements with Multiple Deliverables, and issued Accounting Standards Update (ASU) 2009-13 which amends the guidance in ASC 605-25 on multiple-element revenue arrangements. This guidance addresses the unit of accounting for arrangements involving multiple deliverables and how arrangement consideration should be allocated to the separate units of accounting, when applicable. The ASU is effective for fiscal year beginning on or after June 15, 2010. Early adoption is permitted. Adoptions of this guidance is expected to have a significant effect on how revenue arrangements entered into subsequent to January 1, 2011 are reflected in the financial statements.

3. Investment in securities

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

	December 31,			December 31,		
		2008			2009	
		Gross			Gross	
		Unrealized		Cost	Unrealized	Fair
	Cost Basis	Gain	Fair Value	Basis	Loss	Value
Available-for-sale						
securities	\$18,549	\$ 295	\$18,844	\$2,761	\$(286)	\$2,475

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 available-for-sale securities at December 31, 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. The certificate of deposit is stated at fair value based on quoted prices for similar instruments in an active market (Level 2 in the fair value hierarchy) and the common stock investment is stated at fair

value based on quoted prices in an active market (Level 1 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 \$286.7 million, \$46.1 million and \$17.8 million for the years ended December 31, 2007, 2008 and 2009, respectively. Gross realized gains and losses for available-for-sale securities were insignificant for the years ended December 31, 2007, 2008 and 2009. Gross realized gains and losses

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

for available-for-sale securities are recorded as other income (expense). The cost of securities sold is based on the specific identification method. Unrealized gains and losses for available-for-sale securities were a gain of \$295,000 for the year ended December 31, 2008 and a loss of \$581,000 for the year ended December 31, 2009. Unrealized gains and losses are included in other comprehensive income (loss).

4. 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. During the years ended December 31, 2007, 2008 and 2009, research and development expenses were offset by \$0.8 million, \$1.8 million and \$1.3 million, respectively, in connection with the program.

5. Property and equipment

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

	Estimated Useful			
	Life	Decem	December 31,	
	(Years)	2008	2009	
Land		\$ 5,273	\$ 5,273	
Buildings	39-40	53,786	54,966	
Building improvements	5-40	111,346	113,188	
Machinery and equipment	3-15	70,633	72,958	
Furniture, fixtures and office equipment	5-10	6,622	5,312	
Computer equipment and software	3	14,818	15,840	
Leasehold improvements		184	172	
Construction in progress		15,165	6,261	
		277,827	273,970	
Less accumulated depreciation and amortization		(51,391)	(65,741)	
Property and equipment net		\$ 226,436	\$ 208,229	

Leasehold improvements are amortized over four years which is 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 years ended December 31, 2007, 2008 and 2009, and the cumulative period from February 14, 1991 (date of inception) to December 31, 2009 was \$8.5 million, \$11.8 million, \$18.2 million and \$77.6 million, respectively. Capitalized interest during the years ended December 31, 2007, 2008 and 2009 was \$1.4 million, \$2.5 million and \$0.1 million, respectively.

In December 2007, the Company determined that machinery being built for commercial manufacturing use would no longer be used for this purpose and had no other further alternative use other than for research related to AFREZZA. Accordingly, the Company expensed to research and development the \$5.0 million carrying value of the machinery previously included in construction in progress. Additionally, in November 2007, the Company initiated a plan to sell certain manufacturing machines. A charge in the amount of \$1.6 million is reflected in the research and development expenses in the accompanying statement of operations for the year ended December 31, 2007 to write down the machines being held for sale to their estimated fair value of \$1.6 million. In December 2008, the Company

determined that software previously purchased would no longer be utilized, resulting in an impairment charge of \$459,000.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In December of 2009, the Company recognized a loss on disposal of approximately \$12.8 million in research and development expense related to the abandonment of first-generation inhaler specific assets which would no longer be used as the Company pursued the commercialization of the next-generation device.

6. Accrued expenses and other current liabilities

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

	Decem	ber 31,
	2008	2009
Salary and related expenses	\$ 12,452	\$ 13,362
Research and clinical trial costs	13,438	3,169
Accrued interest	204	2,065
Construction in progress	3,327	203
Other	8,421	3,535
Accrued expenses and other current liabilities	\$ 37,842	\$ 22,334

7. 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 principal stockholder can require the Company to prepay up to \$200.0 million in advances that have been outstanding for at least 12 months. If the principal stockholder exercises this right, the Company will have until the earlier of 180 days after the principal stockholder provides written notice or December 31, 2011 to prepay such advances. The principal stockholder has agreed not to exercise his prepayment right if such prepayment would require the use of existing working capital resources to repay the loan. In the event of a default, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at the principal stockholder 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 \$30.0 million and \$165.0 million at December 31, 2008 and 2009, respectively. As of December 31, 2009, the Company had accrued interest of \$1.9 million related to the amount outstanding.

8. Senior convertible notes

On December 12, 2006, the Company completed an offering of \$115.0 million aggregate principal amount of 3.75% Senior Convertible Notes due 2013 (the Notes), including \$15.0 million aggregate principal amount of the Notes sold pursuant to the underwriters over-allotment option that was exercised in full. The Notes are governed by the terms of an indenture dated as of November 1, 2006 and a First Supplemental Indenture, dated as of December 12, 2006. The Notes bear interest at the rate of 3.75% per year on the principal amount of the Notes, payable in cash semi-annually in arrears on June 15 and December 15 of each year, beginning June 15, 2007. The Company had accrued interest of \$192,000 and \$192,000 related to the Notes for the years ended December 31, 2008 and 2009, respectively. 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. The maturity date of the Notes is December 15,

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2013 and payment is due in full on that date for unconverted securities. Holders may convert, at any time prior to the close of business on the business day immediately preceding the stated maturity date, any outstanding Notes into shares of the Company s common stock at an initial conversion rate of 44.5002 shares per \$1,000 principal amount of Notes, which is equal to a conversion price of approximately \$22.47 per share, subject to adjustment. Except in certain circumstances, if the Company undergoes a fundamental change: (1) the Company will pay a make-whole premium on the Notes converted in connection with a fundamental change by increasing the conversion rate on such Notes, which amount, if any, will be based on the Company s common stock price and the effective date of the fundamental 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 debt issuance costs which are recorded as an offset to the debt in the accompanying balance sheet. These costs are being amortized to interest expense using the effective interest method over the term of the Notes.

9. Common and preferred stock

Private Placements On August 5, 2005, the Company closed a \$175.0 million private placement of common stock and the concurrent issuance of warrants for the purchase of additional shares of common stock to accredited investors including the Company s principal stockholder who purchased \$87.3 million of the private placement. The Company sold 17,132,000 shares of common stock in the private placement, together with warrants to purchase up to 3,426,000 shares of common stock at an exercise price of \$12.228 per share which became exercisable on February 1, 2006 and expire on August 5, 2010. In connection with this private placement, the Company paid \$4.5 million in commissions to the placement agents and incurred \$300,000 in other offering expenses which resulted in net proceeds of approximately \$170.2 million.

On October 2, 2007, the Company sold 15,940,489 shares of the Company s common stock to its principal stockholder at a price per share of \$9.41 and 11,074,197 shares of common stock to other investors at a price per share of \$9.03. The sale of common stock resulted in aggregate net proceeds to the Company of approximately \$249.8 million after deducting offering expenses.

Public Equity Offering On December 12, 2006, the Company closed the sale of 20,000,000 shares of its common stock at a public offering price of \$17.42 per share and on December 19, 2006, closed the sale of an additional 3,000,000 shares of its common stock at a public offering price of \$17.42 per share pursuant to an over-allotment option granted to the underwriters of the offering. Approximately 5.8 million shares were sold to certain of the Company s officers and directors, including 5.75 million shares sold to the principal stockholder. In connection with this offering, the Company paid approximately \$15.0 million in underwriting fees and incurred approximately \$1.1 million in other offering expenses which resulted in net proceeds of approximately \$384.7 million.

On August 5, 2009, the Company closed the sale of 8,360,000 shares of its common stock, including 960,000 shares sold pursuant to the full exercise of an over-allotment option previously granted to the underwriters of the offering, at a public offering price of \$7.35 per share. The Company s principal stockholder purchased 1,000,000 of these shares from the underwriters at a price per share of \$8.11. The sale of common stock resulted in aggregate net proceeds to the Company of approximately \$59.7 million after deducting offering expenses.

Common Stock In May 2007, the Company's stockholders approved an increase in the Company's authorized shares of common stock from 90,000,000 to 150,000,000. As of December 31, 2009, 113,025,291 shares of common stock are issued and outstanding.

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company had reserved shares of common stock for issuance as follows:

	December 31,	December 31,
	2008	2009
Exercise of common stock options	5,591,101	6,403,498
Conversion of senior convertible notes into common stock	5,117,523	5,117,523
Exercise of common stock warrants	2,882,873	2,882,873
Vesting of restricted stock units	5,947,408	3,419,533
	19,538,905	17,823,427

Preferred Stock The Company is authorized to issue 10,000,000 shares of preferred stock. As of December 31, 2009, no shares of preferred stock are issued and outstanding.

Registration rights In August 2007, the registration rights of the holders of 17,132,000 shares of common stock together with warrants to purchase up to 2,882,873 shares of common stock, all of which were issued in the August 2005 private placement, expired. All of the warrants remained outstanding as of December 31, 2009.

10. Stock award plans

As of December 31, 2009, the Company has three active stock-based compensation plans—the 2004 Equity Incentive Plan (the Plan), the 2004 Non-Employee Directors—Stock Option Plan (the NED Plan), and the 2004 Employee Stock Purchase Plan (the ESPP). The Plan provides for the granting of stock awards including stock options and restricted stock units, to employees, directors and consultants. The NED Plan provides for the automatic, non-discretionary grant of options to the Company—s non-employee directors. Awards also remain outstanding at December 31, 2009 under the following inactive plans: the CTL Plan and the AlleCure Plan. There are also options outstanding to the Company—s principal stockholder at December 31, 2009 that were not granted under any plan; these options were granted during the year ended December 31, 2002, vested over four years, and have an exercise price of \$25.23 per share. The following table summarizes information about the Company—s stock-based award plans as of December 31, 2009:

	Outstanding	Outstanding Restricted	Shares Available for Future
	Options	Stock Units	Issuance
2004 Equity Incentive Plan	5,602,292	3,419,533	6,105,566
2004 Non-Employee Directors Stock Option Plan	537,500		294,500
CTL and AlleCure Plans	22,735		
Options outside of any plan granted to principal			
stockholder	240,971		
Total	6,403,498	3,419,533	6,400,066

The Company s board of directors determines eligibility, vesting schedules and exercise prices for stock awards granted under the Plan. The NED Plan provides for automatic, non-discretionary grant of options to the Company s non-employee directors. Options and other stock awards under the Plan and the NED Plan expire not more than ten years from the date of the grant and are exercisable upon vesting. Stock options generally vest over four years. Current stock option grants vest and become exercisable at the rate of 25% after one year and ratably on a monthly basis over

a period of 36 months thereafter. Restricted stock units generally vest at a rate of 25% per year over four years with consideration satisfied by service to the Company. Certain performance-based awards vest upon achieving three pre-determined performance milestones which are expected to occur over periods ranging from 27 months to 42 months from the date of grant. The Plan provides for full acceleration of vesting if an employee is terminated within thirteen months of a change in control, as defined.

On February 6, 2008, the Compensation Committee approved a management proposal designed to encourage employee retention. The proposal involved the issuance of restricted stock units to the majority of employees and executive officers of the Company. A total of 1,678,674 restricted stock units were granted under the Plan. These units fully vested on June 30, 2009. Stock compensation expense associated with these grants was recorded on a straight line basis from February 6, 2008 through June 30, 2009 and was approximately \$11.0 million.

On May 22, 2008, the Company s stockholders approved an amendment to the Plan to increase the number of shares of common stock available for issuance under the plan by 5,000,000 shares.

On July 9, 2008, the Company announced an Offer to Exchange Outstanding Options to Purchase Common Stock (the Offer) under which the Company offered eligible employees the opportunity to exchange up to an aggregate of 5,417,840 shares underlying their out-of-the money stock options, on a grant by grant basis, for a reduced number

MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

of restricted stock units. The Offer expired on August 6, 2008. Pursuant to the Offer, the Company accepted for exchange options to purchase an aggregate of 4,493,509 shares of the Company s common stock and issued restricted stock units covering an aggregate of 2,246,781 shares of the Company s common stock. For the restricted stock units issued pursuant to the offer, both the remaining estimated unamortized stock compensation expense related to the exchanged options of approximately \$13.9 million and the estimated incremental stock compensation expense resulting from the exchange of approximately \$3.7 million is being amortized over the vesting periods of the restricted stock units.

In March 2004, the Company s board of directors approved the ESPP, which became effective upon the closing of the Company s initial public offering. Initially, the aggregate number of shares that could be sold under the plan was 2,000,000 shares of common stock. On January 1 of each year, for a period of ten years beginning January 1, 2005, the share reserve automatically increases by the lesser of: 700,000 shares, 1% of the total number of shares of common stock outstanding on that date, or an amount as may be determined by the board of directors. However, under no event can the annual increase cause the total number of shares reserved under the ESPP to exceed 10% of the total number of shares of capital stock outstanding on December 31 of the prior year. On January 1, 2007, 2008 and 2009 the ESPP share reserve was increased by 700,000, 700,000 and 700,000 shares, respectively. In November 2006, the Company s board of directors approved a decrease of 2.6 million shares to the reserve in order to make additional shares available for the Company s December 2006 offerings (see Note 1 Description of Business and Basis of Presentation Public Offerings). As of December 31, 2009, 1,354,970 shares were available for issuance under the ESPP. For the years ended December 31, 2007, 2008 and 2009 the Company sold 124,011, 349,317 and 322,518 shares, respectively, of its common stock to employees participating in the ESPP.

In accordance with ASC 718, share-based payment transactions are recognized as compensation cost based on the fair value of the instrument on the date of grant. The Company accounts for non-employee stock-based compensation expense based on the estimated fair value of the options, determined using the Black-Scholes option valuation model and amortizes such expense on a straight-line basis. In November 2004, pursuant to assignment agreements with two consultants, the Company issued 200 shares of its common stock under the Plan. The Company agreed to issue 99,800 additional shares upon the achievement of certain milestones specified in consulting agreements and for the year ended December 31, 2004, the Company recorded approximately \$1.1 million in stock-based compensation expense related to these agreements. In November 2005, 39,800 of the 99,800 shares were issued to the consultants and the Company decreased stock-based compensation expense by approximately \$146,000 based on the fair market value of the shares when issued. In September 2007, the next milestone was considered probable and the Company decreased stock compensation expense by approximately \$115,000 based on the fair market value of the shares. In October 2007, the second milestone was met and 30,000 shares were issued. In December 2007, the third milestone was considered probable of achievement and the Company recognized stock compensation expense of approximately \$238,000. In January 2008, the final milestone was met and 30,000 shares were issued. As of December 31, 2009, there were 313,191 options outstanding to consultants.

During the years ended December 31, 2007, 2008 and 2009 the Company recorded stock-based compensation expense related to its stock award plans and the ESPP of \$17.6 million, \$24.8 million and \$20.2 million respectively. Total stock-based compensation expense/(benefit) recognized in the accompanying statements of operations is as

follows (in thousands):

	Year Ended December 31,			
	2007	2008	2009	
Employee-related	\$ 17,513	\$ 24,716	\$ 19,653	
Consultant-related	132	77	566	
Total	\$ 17,645	\$ 24,793	\$ 20,219	

Total stock-based compensation expense/(benefit) recognized in the accompanying statements of operations is included in the following categories (in thousands):

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company) NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Year Ended December 31,		
	2007	2008	2009
Research and development	\$ 9,749	\$ 14,350	\$ 12,115
General and administrative	7,896	10,443	8,104
Total	\$ 17,645	\$ 24,793	\$ 20,219

Included in stock compensation expense is approximately \$165,100 in expense related to the modification of stock awards for two individuals during the year ended December 31, 2009. Under the terms of the modification of stock awards, these individuals options that were granted during their association with the Company will continue to vest over their respective modification periods.

The Company uses the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options. The expected life of the option is estimated using the simplified method as provided in SEC Staff Accounting Bulletin No. 107 (SAB No. 107). Under this method, the expected life equals the arithmetic average of the vesting term and the original contractual term of the options. The Company estimates volatility using the historical volatility of its stock. The Company has selected risk-free interest rates based on U.S. Treasury Securities with an equivalent expected term in effect on the date the options were granted. Additionally, the Company uses historical data and management judgment to estimate stock option exercise behavior and employee turnover rates to estimate the number of stock option awards that will eventually vest. The Company calculated the fair value of employee stock options for the years ended December 31, 2008 and 2009 using the following assumptions:

	Year Ended Dec	ember 31,
	2008	2009
Risk-free interest rate	2.64% 3.69%	2.16% 3.07%
Expected lives	5.6 6.1 years	5.8 6.1 years
Volatility	55% 77%	78% 80%
Dividends		

The following table summarizes information about stock options outstanding:

	Number	Weighted Average Exercise	Weighted Average Grant Date Fair	Aggregate
	of	Price	Value	Intrinsic Value
	Shares	per Share	per Share	(\$000)
Outstanding at January 1, 2007	6,216,698	13.94		
Granted	1,639,845	10.48	\$5.86	
Exercised	(606,833)	8.11		\$ 1,252
Forfeit	(252,016)	14.11		
Expired	(111,036)	12.66		
Outstanding at December 31, 2007	6,886,658	13.64		
Granted	3,903,370	3.43	\$2.25	

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Exercised Forfeit Expired	(2,669,230) (2,529,697)	0.00 12.56 13.86		
Outstanding at December 31, 2008 Granted Exercised Forfeit	5,591,101 1,156,400 (94,413) (153,383)	6.97 7.41 4.06 3.67	\$5.15	\$ 1,292
Expired	(96,207)	10.43		
Outstanding at December 31, 2009	6,403,498	7.20		\$20,422
Vested or expected to vest at December 31,				
2009	6,089,899	7.32		\$19,201
Exercisable at December 31, 2009	2,938,321 82	9.86		\$ 6,931

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A summary of the status of the Company s nonvested stock options for the year ended December 31, 2009, is presented below:

		Av	eighted verage Frant
	Number	Date Fair Value	
	of Shares		r value Share
Nonvested at January 1, 2009	3,986,022	\$	2.64
Granted	1,156,400	\$	5.15
Vested	(1,523,862)	\$	3.05
Forfeited	(153,383)	\$	2.41
Nonvested at December 31, 2009	3,465,177	\$	3.32

Cash received from the exercise of options during the years ended December 31, 2007 and 2009 was approximately \$4.9 million and \$383,000, respectively. There were no stock options exercised during the year ended December 31, 2008. The weighted-average remaining contractual terms for options outstanding, vested or expected to vest, and exercisable at December 31, 2009 was 8.9 years, 7.4 years and 5.9 years, respectively.

A summary of restricted stock units activity for the years ended December 31, 2007, 2008 and 2009 is presented below:

		Weighted Average Grant
	Number	Date
	of	Fair Value
	Shares	per Share
Outstanding at January 1, 2007	776,653	16.26
Granted	876,575	9.81
Vested	(202,009)	15.63
Forfeited	(91,557)	13.54
Outstanding at December 31, 2007	1,359,662	12.36
Granted	5,135,000	6.63
Vested	(328,449)	12.94
Forfeited	(218,805)	8.43
Outstanding at December 31, 2008	5,947,408	7.51
Granted	1,095,900	7.46
Vested	(3,145,375)	7.56
Forfeited	(478,400)	5.33
Outstanding at December 31, 2009	3,419,533	7.50

The total fair value of restricted stock units vested during the years ended December 31, 2007, 2008 and 2009 was \$1.9 million, \$1.2 million and \$23.6 million, respectively. The weighted-average remaining contractual terms for restricted stock units outstanding at December 31, 2009 was 8.8 years. As of December 31, 2009, there were 49,988 restricted stock units outstanding to five consultants.

As of December 31, 2009, there was \$12.1 million and \$22.4 million of unrecognized compensation cost related to options and restricted stock units, respectively, which is expected to be recognized over the weighted average vesting period of 2.3 years.

11. Warrants

During 1995 and 1996, the Company issued warrants to purchase shares of common stock. The warrants contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event the Company declares any stock dividends or effects any stock split, reclassification or

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

consolidation of its common stock. The warrants also contain a provision that provides for an adjustment to the exercise price and the number of shares issuable in the event that the Company issues securities for a per share price less than a specified price. As of December 31, 2004, warrants to purchase 131,628 shares of common stock were outstanding. During the second quarter ended June 30, 2005, warrants to purchase 110,888 shares of common stock were exchanged for 24,210 shares of common stock resulting in stock-based compensation expense of \$245,000 based on a fair market value of the common stock of \$10.12 per share. Warrants to purchase 8,304 shares of common stock expired during 2005. The remaining warrants to purchase 12,459 shares of common stock at a weighted average exercise price of \$12.64 per share all expired unexercised on December 1, 2007.

In connection with the sale of common stock in the private placement which closed on August 5, 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. See also Note 9 Common and Preferred Stock Private Placement. These warrants became exercisable on February 1, 2006 and expire in August 2010. During the year ended December 31, 2006, approximately 543,000 warrants were exercised and net settled for approximately 339,000 shares. As of December 31, 2009, warrants to purchase 2,882,873 shares of common stock remained outstanding. As of December 31, 2009, all warrants were exercisable.

12. Commitments and contingencies

Operating Leases The Company leases certain facilities and equipment under various operating leases, which expire at various dates through 2013. Future minimum rental payments required under operating leases are as follows at December 31, 2009 (in thousands):

Year Ending December 31,

2010	\$ 798
2011	10
2012	4
After 2012	2

Total minimum lease payments

\$ 814

Rent expense under all operating leases for the years ended December 31, 2007, 2008 and 2009 was approximately \$1.5 million, \$1.7 million and \$2.1 million, respectively.

Capital Leases The Company s capital leases were not material for the years ended December 31, 2007, 2008 and 2009.

Supply Agreement In November 2007, the Company entered into a long-term supply agreement with Organon N.V. (Organon) pursuant to which Organon will manufacture and supply specified quantities of recombinant human insulin. The initial term of this supply agreement will end on December 31, 2012 and can be automatically extended for consecutive two-year terms under specified circumstances. As of December 31, 2009, the Company has annual purchase commitments through the remaining initial term aggregating to approximately \$100 million. These purchases are expected to be delivered from 2010 through 2012. If the Company terminates the supply agreement following failure to obtain or maintain regulatory approval of AFREZZA or either party terminates the agreement following the parties inability to agree after any regulatory authority mandated changes to product specifications that relate specifically to the use of insulin in AFREZZA, 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 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. No such losses have been recorded to date.

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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Litigation The Company is involved in various legal proceedings and other matters. In accordance with ASC 450 *Contingencies*, previously FASB Statement No. 5, *Accounting for Contingencies*, the Company would record a provision for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

Licensing Arrangement On October 12, 2006, the Company entered into an agreement with The Technion Research and Development Foundation Ltd. (TRDF), an Israeli corporation affiliated with the Technion-Israel Institute of Technology (the Technion) to license certain technology from TRDF and to collaborate with TRDF in the further research in and the development and commercialization of such technology. In exchange for the rights that the Company obtained under this agreement, the Company agreed to pay to TRDF aggregate license fees of \$3.0 million and to issue to TRDF a total of 300,000 shares of the Company s common stock. The license fees were to be paid and the shares issued in three equal installments. The first installment occurred on October 18, 2006. The second installment was paid on December 3, 2007. The third installment was scheduled to occur, subject to the accomplishment of certain milestones, on October 12, 2008. The Company had also agreed to pay royalties to TRDF with respect to sales of certain products that contain or use the licensed technology or are covered by patents included in the licensed technology or are discovered through the use of the licensed technology. The Company agreed to pay up to \$6.0 million of the royalties in advance upon the receipt of specified regulatory approvals. The Company agreed to pay to TRDF specified percentages of any lump-sum sub-license payments that the Company received if it decided to sub-license the technology. The Company had also agreed to pay a total of \$2.0 million to TRDF in three nearly equal installments to fund sponsored research to be conducted at TRDF by a team led by a faculty member at Technion. The initial sponsored research payment was made upon signing of the agreement. The second sponsored research payment occurred on December 3, 2007 and the third sponsored research payment was scheduled to occur, subject to the accomplishment of certain milestones, on October 12, 2008. The Company had also agreed to retain the services of the Technion faculty member as a consultant, for which the Company agreed to pay the consultant \$60,000 per year and granted the individual an option to purchase 60,000 shares of the Company s common stock. Under the terms of the agreement, the Company issued 100,000 shares of common stock to TRDF on October 12, 2006 and November 29, 2007, respectively. Additionally, \$1.6 million in license fees were paid on October 18, 2006 and December 3, 2007, respectively. In August of 2008, the Company ended its agreement with TRDF and made no further payments for licensing fees in 2008.

13. Employee benefit plans

The Company administers a 401(k) Savings Retirement Plan (the MannKind Retirement Plan) for its employees. For the years ended December 31, 2007, 2008 and 2009, the Company contributed \$821,000, \$914,000 and \$824,000 respectively, to the MannKind Retirement Plan.

14. Income taxes

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and income tax purposes. A valuation allowance is established when uncertainty exists as to whether all or a portion of the net deferred tax assets will be realized. Components of the net deferred tax asset as of December 31, 2008 and 2009 are approximately as follows (in thousands):

	December 31,	
	2008	2009
Deferred Tax Assets:		
Net operating loss carryforwards	\$ 424,497	\$ 462,913
Research and development credits	37,415	44,597
Accrued expenses	38,187	42,143
Non-qualified stock option expense	21,546	20,024
Depreciation	3,916	6,047

Total gross deferred tax assets Valuation allowance		525,561 (525,561)	575,724 (575,724)
Net deferred tax assets		\$	\$
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MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company s effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2007, 2008 and 2009:

	December 31,		
	2007	2008	2009
Federal tax benefit rate	35.0%	35.0%	35.0%
State tax benefit, net of federal benefit			
Permanent items			
Intercompany transfer of intellectual property			(18.0)
Other			
Valuation allowance	(35.0)	(35.0)	(17.0)
Effective income tax rate	0.0%	0.0%	0.0%

As required by ASC 740 *Income Taxes* (ASC 740), formerly FASB Statement No. 109, management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Management has concluded, in accordance with the applicable accounting standards, that it is more likely than not that the Company may not realize the benefit of its deferred tax assets. Accordingly, the net deferred tax assets have been fully reserved. Management reevaluates the positive and negative evidence on an annual basis. During the years ended December 31, 2007, 2008 and 2009, the change in the valuation allowance was \$135.4 million, \$138.1 million and \$50.2 million, respectively, for income taxes.

At December 31, 2009, the Company had federal and state net operating loss carryforwards of approximately \$1.2 billion and \$710.1 million available, respectively, to reduce future taxable income and which will expire at various dates beginning in 2010 and 2012, respectively. As a result of the Company s initial public offering, an ownership change within the meaning of Internal Revenue Code Section 382 occurred in August 2004. As a result, federal net operating loss and credit carry forwards of approximately \$216.0 million are subject to an annual use limitation of approximately \$13.0 million. The annual limitation is cumulative and therefore, if not fully utilized in a year can be utilized in future years in addition to the Section 382 limitation for those years. The federal net operating losses generated subsequent to the Company s initial public offering in August 2004 are currently not subject to any such limitation as there have been no ownership changes since August 2004 within the meaning of Internal Revenue Code Section 382. At December 31, 2009, the Company had research and development credits of \$53.5 million that expire at various dates through 2030.

The Company has evaluated the impact of ASC 740, previously FIN 48, on its financial statements, which was effective beginning January 1, 2007. The evaluation of a tax position in accordance with this guidance is a two-step process. The first step is recognition: The enterprise determines whether it is more-likely-than-not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, the enterprise should presume that the position will be examined by the appropriate taxing authority that would have full knowledge of all relevant information. The second step is measurement: A tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. Tax positions that previously failed to meet the more-likely-than-not recognition threshold should be recognized in the first subsequent financial reporting period in which that threshold is no longer met. 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. The cumulative effect, if any, of applying ASC 740 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 ASC 740. Tax years since 1993 remain subject to examination by the major tax jurisdictions in which the Company is subject to tax.

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MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. Related party transactions

The Company issued 8,550,446 shares of its common stock to its principal stockholder during the year ended December 31, 2005 for proceeds of approximately \$87.3 million. In connection with this issuance, the board of directors approved the issuance of warrants to purchase 1,710,091 shares of the Company s common stock at \$12.228 per share, which expire on August 2, 2010. The issuance of shares and warrants to the principal stockholder was on terms identical to the other purchasers in the private placement, as approved by the Company s board of directors.

During the year ended December 31, 2006 the principal stockholder purchased 5,750,000 shares of common stock at \$17.42 per share in the Company s December 2006 equity offering on terms identical to other purchasers resulting in proceeds of approximately \$100.1 million to the Company. In connection with the equity offering the Company paid \$280,000 in filing fees related to the principal stockholder s filings made pursuant to the Hart-Scott-Rodino Antitrust Improvement Act of 1976. During the year ended December 31, 2006, the Company borrowed \$70.0 million from its principal stockholder under the loan arrangement described in Note 7. On December 12, 2006, in connection with the completion of their equity and convertible debt offerings, the Company paid principal and interest of \$70.0 million and \$1.6 million, respectively, under the loan arrangement.

On October 2, 2007, the Company sold 15.9 million shares of the Company s common stock to its principal stockholder at a price per share of \$9.41 and 11.1 million shares of common stock to other investors at a price per share of \$9.03. The sales of common stock resulted in aggregate net proceeds to the Company of approximately \$249.8 million after deducting offering expenses. Also, on October 2, 2007, the Company entered into a loan arrangement with its principal stockholder to 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. As of December 31, 2009, the Company had borrowed \$165.0 million under this agreement and had accrued interest of \$1.9 million for the year ended December 31, 2009. See Note 7 Related-Party Loan Arrangement.

On August 5, 2009, the Company closed the sale of 8,360,000 shares of its common stock, including 960,000 shares sold pursuant to the full exercise of an over-allotment option previously granted to the underwriters of the offering, at a public offering price of \$7.35 per share. The Company s principal stockholder purchased 1,000,000 of these shares from the underwriters at a price per share of \$8.11. The sale of common stock resulted in aggregate net proceeds to the Company of approximately \$59.7 million after deducting offering expenses.

Alfred E. Mann, who is the Company s principal stockholder and chief executive officer, has established the Alfred Mann Institute for Biomedical Development at the Technion (AMI-Technion) to expedite the translation of intellectual property and technology of the Technion into commercial medical products for the public benefit. Over a period of several years, Mr. Mann will establish a \$100 million endowment for AMI-Technion. Mr. Mann does not directly or indirectly have any interest in TRDF (see Note 12 Commitments and Contingencies Licensing Arrangement).

In connection with certain meetings of the Company s board of directors and on other occasions when the Company s business necessitated air travel for the Company s principal stockholder and other Company employees, the Company utilized the principal stockholder s private aircraft, and the Company paid the charter company that manages the aircraft on behalf of the Company s majority stockholder approximately \$105,090, \$130,000 and \$136,800, respectively, for the years ended December 31, 2007, 2008 and 2009 on the basis of the corresponding cost of commercial airfare. These payments were approved by the audit committee of the board of directors.

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

MANNKIND CORPORATION AND SUBSIDIARIES (A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. Selected quarterly financial data (unaudited)

The following unaudited selected quarterly financial data has been prepared on the same basis as the audited information and includes all adjustments necessary to present fairly the information set forth in the Company s consolidated financial statements and notes herein. As a development stage enterprise, the Company has experienced fluctuations in its quarterly results related to the development of its lead product candidate, AFREZZA, and in its expansion of the product candidate portfolio. The Company expects these fluctuations to continue in the future. Due to these and other factors, the quarterly operating results are not indicative of the Company s future performance.

	March 31	June 30 In thousands, o	September 30 except per share d	December 31 ata)
2008 Net loss	\$ (71,421)	\$ (79,826)	\$ (68,496)	\$ (83,295)
Net loss applicable to common stockholders	\$ (71,421)	\$ (79,826)	\$ (68,496)	\$ (83,295)
Net loss per share applicable to common stockholders basic and diluted	\$ (0.70)	\$ (0.79)	\$ (0.67)	\$ (0.82)
Weighted average common shares used to compute basic and diluted net loss per share applicable to common stockholders	101,409	101,427	101,647	101,758
	March 31	June 30	September 30 except per share d	December 31
2009	(in mousanus, c	except per snare u	ata)
Net loss	\$ (59,412)	\$ (55,604)	\$ (45,555)	\$ (59,533)
Net loss applicable to common stockholders	\$ (59,412)	\$ (55,604)	\$ (45,555)	\$ (59,533)
Net loss per share applicable to common stockholders basic and diluted	\$ (0.58)	\$ (0.54)	\$ (0.42)	\$ (0.53)
Weighted average common shares used to compute basic and diluted net loss per share applicable to common stockholders	102,030	102,322	108,779	112,860
	102,030	102,322	100,777	,