MANNKIND CORP
Form 10-Q
August 11, 2008

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

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

For the quarterly period ended June 30, 2008

or

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

For the transition period from to .

Commission file number: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

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

(661) 775-5300

(*Registrant s telephone number, including area code)*

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

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

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

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

As of August 1, 2008, there were 101,598,408 shares of the registrant s common stock, $.01 par value per share, outstanding.

MANNKIND CORPORATION
Form 10-Q
For the Quarterly Period Ended June 30, 2008
TABLE OF CONTENTS

PART I: FINANCIAL INFORMATION
Item 1. Financial Statements (unaudited)
Condensed Consolidated Balance Sheets: June 30, 2008 and December 31, 2007
Condensed Statements of Operations: Three and six months ended June 30, 2008 and 2007 and the period from inception (February 14, 1991) to June 30, 2008
Condensed Statements of Cash Flows: Six months ended June 30, 2008 and 2007 and the period from inception (February 14, 1991) to June 30, 2008
Notes to Condensed Financial Statements
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations
Item 3. Quantitative and Qualitative Disclosures About Market Risk
Item 4. Controls and Procedures
PART II: OTHER INFORMATION
Item 1. Legal Proceedings
Item 1A. Risk Factors
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds
Item 3. Defaults Upon Senior Securities
Item 4. Submission of Matters to a Vote of Security Holders
Item 5. Other Information
Item 6. Exhibits
SIGNATURES
EXHIBIT 31.1
EXHIBIT 31.2
EXHIBIT 32
EXHIBIT 31.1
EXHIBIT 31.2
EXHIBIT 32

Table of Contents

PART 1: FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
MANNKIND CORPORATION
(A Development Stage Company)
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands except share data)

	June 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 180,454	$ 368,285
State research and development credit exchange		831
Prepaid expenses and other current assets	7,253	9,596
Total current assets	187,707	378,712
Property and equipment net	208,742	162,683
State research and development credit exchange receivable net of current portion	2,250	1,500
Other assets	549	548
Total	$ 399,248	$ 543,443
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 30,084	$ 35,463
Accrued expenses and other current liabilities	31,874	32,095
Total current liabilities	61,958	67,558
Senior convertible notes	112,004	111,761
Other liabilities		24
Total liabilities	173,962	179,343
Commitments and contingencies		
Stockholders equity:		
Undesignated preferred stock, $0.01 par value 10,000,000 shares authorized; no shares issued or outstanding at June 30, 2008 and December 31, 2007		
Common stock, $0.01 par value 150,000,000 shares authorized; 101,594,745 and 101,380,823 shares issued and outstanding at June 30, 2008 and December 31, 2007, respectively	1,016	1,014
Additional paid-in capital	1,456,556	1,444,125
Deficit accumulated during the development stage	(1,232,286)	(1,081,039)
Total stockholders equity	225,286	364,100

Total	$	399,248	$	543,443

See notes to condensed financial statements

Table of Contents

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

	Three months ended June 30, 2008	Three months ended June 30, 2007	Six months ended June 30, 2008	Six months ended June 30, 2007	Cumulative period from February 14, 1991 (date of inception) to June 30, 2008
Revenue	$	$	$ 20	$ 10	$ 2,988
Operating expenses:					
Research and development	67,574	61,480	126,019	125,268	873,059
General and administrative	13,290	13,913	28,930	27,463	219,429
In-process research and development costs					19,726
Goodwill impairment					151,428
Total operating expenses	80,864	75,393	154,949	152,731	1,263,642
Loss from operations	(80,864)	(75,393)	(154,929)	(152,721)	(1,260,654)
Other income (expense)	(60)	44		96	(1,881)
Interest expense on note payable to principal stockholder					(1,511)
Interest expense on senior convertible notes	(124)	(901)	(461)	(2,046)	(4,091)
Interest income	1,222	4,261	4,143	9,541	35,875
Loss before provision for income taxes	(79,826)	(71,989)	(151,247)	(145,130)	(1,232,262)
Income taxes					(24)
Net loss	(79,826)	(71,989)	(151,247)	(145,130)	(1,232,286)
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	$ (79,826)	$ (71,989)	$ (151,247)	$ (145,130)	$ (1,255,498)
	$ (0.79)	$ (0.98)	$ (1.49)	$ (1.98)	

Net loss per share applicable to common stockholders basic and diluted				
Shares used to compute basic and diluted net loss per share applicable to common stockholders	101,427	73,421	101,418	73,405

See notes to condensed financial statements

Table of Contents

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

	Six months ended June 30, 2008	Six months ended June 30, 2007	Cumulative Period from February 14, 1991 (Date of Inception) to June 30, 2008
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (151,247)	$ (145,130)	$ (1,232,286)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,804	4,165	51,931
Stock-based compensation expense	12,068	8,803	66,898
Stock expense for shares issued pursuant to research agreement			3,018
Loss on sale and abandonment/disposal of property and equipment	121		10,614
Accrued interest on investments, net of amortization of premiums			58
In-process research and development			19,726
Discount on stockholder notes below market rate			241
Non-cash compensation expense of officer resulting from stockholder contribution			70
Accrued interest expense on notes payable to stockholders			1,538
Non-cash interest expense			3
Accrued interest on notes receivable			(747)
Goodwill impairment			151,428
Loss on available-for-sale securities			229
Changes in assets and liabilities:			
State research and development credit exchange receivable	81	(750)	(2,250)
Prepaid expenses and other current assets	2,343	(14)	(5,653)
Other assets	(1)	(184)	(549)
Accounts payable	(5,982)	(5,062)	20,998
Accrued expenses and other current liabilities	(1,174)	10,722	26,185
Other liabilities	(24)		(2)
Net cash used in operating activities	(140,011)	(127,450)	(888,550)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities		(3,450)	(726,950)
Sales of marketable securities		52,775	726,665
Purchase of property and equipment	(48,255)	(26,120)	(257,659)

Proceeds from sale of property and equipment	70		284
Net cash (used in) provided by investing activities	(48,185)	23,205	(257,660)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock and warrants	424	1,178	1,140,070
Collection of Series C convertible preferred stock subscriptions receivable			50,000
Issuance of Series B convertible preferred stock for cash			15,000
Cash received for common stock to be issued			3,900
Repurchase of common stock			(1,028)
Put shares sold to majority stockholder			623
Borrowings under lines of credit			4,220
Proceeds from notes receivable			1,742
Borrowings on notes payable from principal stockholder			70,000
Principal payments on notes payable to principal stockholder			(70,000)
Borrowings on notes payable			3,460
Principal payments on notes payable			(1,667)
Proceeds from senior convertible notes			111,267
Payment of employment taxes related to vested restricted stock units	(59)	(59)	(923)
Net cash provided by financing activities	365	1,119	1,326,664

Table of Contents

	Six months ended June 30, 2008	Six months ended June 30, 2007	Cumulative Period from February 14, 1991 (Date of Inception) to June 30, 2008
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	$ (187,831)	$ (103,126)	$ 180,454
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	368,285	319,555	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 180,454	$ 216,429	$ 180,454
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$	$	$ 24
Interest paid in cash		2,192	6,043
Accretion on redeemable convertible preferred stock			(952)
Issuance of common stock upon conversion of notes payable			3,331
Increase in additional paid-in capital resulting from merger			171,154
Issuance of common stock for notes receivable			2,758
Issuance of put option by stockholder			(2,949)
Put option redemption by stockholder			1,921
Issuance of Series C convertible preferred stock subscriptions			50,000
Issuance of Series A redeemable convertible preferred stock			4,296
Conversion of Series A redeemable convertible preferred stock			(5,248)
Noncash construction in progress	14,775	7,792	14,775
Noncash transfer from fixed assets 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 condensed financial statements

Table of Contents

MANNKIND CORPORATION
(A Development Stage Company)
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

1. Description of business and basis of presentation

The accompanying unaudited condensed financial statements of MannKind Corporation (the Company), have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the SEC). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. These statements should be read in conjunction with the financial statements and notes thereto included in the Company s latest audited annual financial statements. The audited statements for the year ended December 31, 2007 are included in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2007 filed with the SEC on March 14, 2008 (the Annual Report).

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the six months ended June 30, 2008 may not be indicative of the results that may be expected for the full year.

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

Business MannKind Corporation 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 investigational product candidate, the Technosphere Insulin System, is currently in Phase 3 clinical trials in the United States, Europe and Latin America to study its safety and efficacy in the treatment of diabetes. The Technosphere Insulin System 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 MedTone inhaler.

Basis of Presentation The Company is considered to be in the development stage as its primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, and raising capital. Since its inception through June 30, 2008, the Company has reported accumulated net losses of $1.2 billion, which include a goodwill impairment charge of $151.4 million, and negative cash flow from operations of $888.6 million. It is costly to develop therapeutic products and conduct clinical trials for these products. Based upon the Company s current expectations, management believes the Company s existing capital resources, including the $350.0 million loan arrangement with our principal stockholder, will enable it to continue planned operations through the fourth quarter of 2009. 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 its Technosphere Insulin System and other product candidates and to support its other ongoing activities.

Recently Issued Accounting Standards In December 2007, the Financial Accounting Standards Board (FASB) ratified the Emerging Issues Task Force (EITF) consensus on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements,* that discusses how parties to a collaborative arrangement (which does not establish a legal entity within such arrangement) should account for various activities. The consensus indicates that costs incurred and revenues generated from transactions with third parties (i.e. parties outside of the collaborative arrangement) should be reported by the collaborators on the respective line items in their income statements pursuant to EITF Issue

No. 99-19, *Reporting Revenue Gross as a Principal Versus Net as an Agent.* Additionally, the consensus provides that income statement characterization of payments between the participants in a collaborative arrangement should be based upon existing authoritative pronouncements; analogy to such pronouncements if not within their scope; or a reasonable, rational, and consistently applied accounting policy election. EITF Issue No. 07-1 is effective beginning January 1, 2009 and is to be applied retrospectively to all periods presented for collaborative arrangements existing as of the date of adoption. The Company is evaluating the impact, if any, the adoption of this consensus will have on its results of operations, financial position or cash flows.

In December 2007, the FASB issued Statement of Financial Accounting Standard (SFAS) No. 141(R), *Business Combinations* and SFAS No. 160, *Accounting and Reporting of Noncontrolling Interests to Consolidated Financial Statements an amendment of ARB No. 51* (SFAS No. 160). These standards will significantly change the accounting and reporting for business combination transactions and noncontrolling (minority) interests in consolidated financial statements, including capitalizing at the acquisition date the fair value of acquired in-process research and development, and remeasuring and writing down the assets, if necessary, in subsequent periods during their development. These new standards will be applied prospectively for business combinations that occur on or after January 1, 2009, except that presentation and disclosure requirements of SFAS No. 160 regarding noncontrolling interests shall be applied retrospectively.

In September 2006, the FASB issued SFAS No. 157*, Fair Value Measurements* (SFAS No. 157), which defines fair value, establishes a framework for consistently measuring fair value for accounting purposes, and expands disclosures about fair value measurements. SFAS No. 157 is effective for the Company beginning January 1, 2008, and the provisions of SFAS No. 157 will be applied prospectively as of that date. In February 2008, FASB Staff Position (FSP) 157-2 was issued, which delays the effective date of SFAS No. 157 to fiscal years beginning after November 15, 2008 and interim periods with those fiscal years for all nonfinancial assets and liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The Company has already adopted this Statement except as it applies to nonfinancial assets and liabilities as noted in FSP 157-2. The partial adoption of SFAS No. 157 did not have a material impact on the Company s results of operations, financial position or cash flows. The Company is evaluating the impact, if any, that the adoption of SFAS No. 157, as it relates to nonfinancial assets and liabilities, will have on its results of operations, financial position or cash flows.

2. Accrued expenses and other current liabilities

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

	June 30, 2008	December 31, 2007
Salary and related expenses	$ 9,392	$ 11,989
Research and clinical trial costs	12,613	11,657
Accrued interest	192	192
Construction in progress	3,926	4,736
Other	5,751	3,521
Accrued expenses and other current liabilities	$ 31,874	$ 32,095

3. Accounting for stock-based compensation

Total stock-based compensation expense recognized in the accompanying condensed statements of operations for the three and six months ended June 30, 2008 and 2007 was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Stock-based compensation	$ 6,634	$ 4,254	$ 12,068	$ 8,803

As of June 30, 2008, there were $18.9 million and $20.8 million of unrecognized compensation costs related to options and restricted stock units, respectively, which are expected to be recognized over the remaining weighted average vesting period of 2.4 years.

On May 22, 2008, the Company s stockholders approved an amendment to the 2004 Equity Incentive Plan to increase the number of shares of common stock available for issuance under the plan by 5,000,000 shares.

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 2004 Equity Incentive Plan. These units will remain unvested until June 30, 2009, at which point they will fully vest. Stock compensation expense associated with these grants will be recorded on a straight line basis from February 6, 2008 through June 30, 2009 and is estimated to total approximately $11.0 million.

Table of Contents

4. Net loss per common share

Basic net loss per share excludes dilution for potentially dilutive securities and is computed by dividing loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Potentially dilutive securities are excluded from the computation of diluted net loss per share for all of the periods presented in the accompanying condensed statements of operations because the reported net loss in each of these periods results in their inclusion being antidilutive. Antidilutive securities, which consist of outstanding stock options, unvested restricted stock units, unexercised warrants, and shares that could be issued upon conversion of the senior convertible notes, that are not included in the diluted net loss per share calculation consisted of an aggregate of 17,985,754 shares and 15,242,217 shares as of June 30, 2008 and 2007, respectively.

5. State research and development credit exchange receivable

The State of Connecticut provides certain companies with the opportunity to exchange certain research and development income tax credit carryforwards for cash in exchange for forgoing the carryforward of the research and development income tax credits. The program provides for an exchange of research and development income tax credits for cash equal to 65% of the value of corporation tax credit available for exchange. Estimated amounts receivable under the program are recorded as a reduction of research and development expenses. At June 30, 2008, the estimated amount receivable under the program was $2.3 million.

6. Property and equipment net

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

	Estimated Useful Life (Years)	June 30, 2008	December 31, 2007
Land		$ 5,273	$ 5,273
Buildings	39-40	9,566	9,566
Building improvements	5-40	64,048	52,438
Machinery and equipment	3-10	35,279	30,172
Furniture, fixtures and office equipment	5-10	3,668	3,657
Computer equipment and software	3	8,039	7,559
Leasehold improvements		184	205
Construction in progress		121,733	89,657
Deposits on equipment		4,946	4,882
		252,736	203,409
Less accumulated depreciation and amortization		(43,994)	(40,726)
Property and equipment net		$ 208,742	$ 162,683

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

Depreciation expense related to property and equipment for the three and six months ended June 30, 2008 and 2007 was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007

Depreciation expense	$ 1,807	$ 1,878	$ 3,561	$ 3,909

Capitalized interest added to property and equipment during the three and six months ended June 30, 2008 and 2007 was as follows (in thousands):

	Three months ended June 30,		**Six months ended June 30,**	
	2008	**2007**	**2008**	**2007**
Capitalized Interest	$ 1,076	$ 294	$ 1,937	$ 368

Table of Contents

7. Warrants

In connection with the sale of common stock in the private placement which closed in August 2005, the Company concurrently issued warrants to purchase up to 3,426,000 shares of common stock at an exercise price of $12.228 per share. These warrants became exercisable in February 2006 and expire in August 2010. During the six months ended June 30, 2008, no warrants were exercised. As of June 30, 2008, warrants to purchase 2,882,873 shares of common stock remained outstanding.

8. Commitments and contingencies

Supply Commitments As of June 30, 2008, the Company had a binding annual commitment for insulin purchases aggregating approximately $116.0 million. These purchases are expected to be delivered from 2009 through 2012.

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 m