MANNKIND CORP
Form 10-Q
November 07, 2007

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

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

For the quarterly period ended September 30, 2007

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 or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer þ Non-accelerated filer o

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 November 1, 2007, there were 100,917,012 shares of the registrant s common stock, $.01 par value per share, outstanding.

MANNKIND CORPORATION
Form 10-Q
For the Quarterly Period Ended September 30, 2007
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PART 1: FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
MANNKIND CORPORATION AND SUBSIDIARY
(A Development Stage Company)
CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)
(In thousands except share data)

	September 30, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 152,298	$ 319,555
Marketable securities	51,875	116,924
State research and development credit exchange	3,171	2,418
Prepaid expenses and other current assets	11,876	10,650
Total current assets	219,220	449,547
Property and equipment net	143,244	88,328
State research and development credit exchange receivable net of current portion	1,125	1,500
Other assets	547	362
Total	$ 364,136	$ 539,737
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 36,738	$ 10,715
Accrued expenses and other current liabilities	36,109	34,244
Total current liabilities	72,847	44,959
Senior convertible notes	111,641	111,267
Other liabilities	24	24
Total liabilities	184,512	156,250
Commitments and contingencies		
Stockholders equity:		
Undesignated preferred stock, $0.01 par value 10,000,000 shares authorized; no shares issued or outstanding at September 30, 2007 and December 31, 2006		
Common stock, $0.01 par value 150,000,000 and 90,000,000 shares authorized at September 30, 2007 and December 31, 2006, respectively; 73,566,124 and 73,360,154 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively	736	734
Additional paid-in capital	1,184,914	1,170,602
Deficit accumulated during the development stage	(1,006,026)	(787,849)
Total stockholders equity	179,624	383,487

Total	$ 364,136	$ 539,737

The accompanying notes are an integral part of these consolidated financial statements

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

	Three months ended September 30, 2007	Three months ended September 30, 2006	Nine months ended September 30, 2007	Nine months ended September 30, 2006	Cumulative period from February 14, 1991 (date of inception) to September 30, 2007
Revenue	$	$	$ 10	$ 100	$ 2,968
Operating expenses:					
Research and development	64,825	50,785	190,093	132,056	680,289
General and administrative	10,744	10,349	38,207	29,943	178,183
In-process research and development costs					19,726
Goodwill impairment					151,428
Total operating expenses	75,569	61,134	228,300	161,999	1,029,626
Loss from operations	(75,569)	(61,134)	(228,290)	(161,899)	(1,026,658)
Other income (expense)	62	51	158	160	(1,526)
Interest expense on note payable to principal stockholder		(689)		(689)	(1,511)
Interest expense on senior convertible notes	(778)		(2,824)		(3,046)
Interest income	3,238	802	12,779	3,153	26,736
Loss before provision for income taxes	(73,047)	(60,970)	(218,177)	(159,275)	(1,006,005)
Income taxes				(5)	(21)
Net loss	(73,047)	(60,970)	(218,177)	(159,280)	(1,006,026)
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	$ (73,047)	$ (60,970)	$ (218,177)	$ (159,280)	$ (1,029,238)
Net loss per share applicable to common stockholders basic and	$ (0.99)	$ (1.23)	$ (2.97)	$ (3.20)	

diluted				
Shares used to compute basic and diluted net loss per share applicable to common stockholders	73,520	49,731	73,444	49,718

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

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

	Nine months ended September 30, 2007	Nine months ended September 30, 2006	Cumulative Period from February 14, 1991 (Date of Inception) to September 30, 2007
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (218,177)	$ (159,280)	$ (1,006,026)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	6,253	6,326	45,407
Stock-based compensation expense	12,957	10,680	50,142
Stock expense for shares issued pursuant to research agreement			2,074
Loss on sale and abandonment/disposal of property and equipment		51	3,446
Accrued interest on investments, net of amortization of premiums		197	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	(378)	(318)	(4,296)
Prepaid expenses and other current assets	(1,226)	(8,658)	(11,876)
Other assets	(185)	(74)	(547)
Accounts payable	14,674	3,126	25,389
Accrued expenses and other current liabilities	(1,641)	13,216	32,603
Other liabilities		(5)	22
Net cash used in operating activities	(187,723)	(134,739)	(691,116)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities	(39,851)	(37,507)	(597,000)
Sales of marketable securities	104,900	119,900	544,840
Purchase of property and equipment	(45,940)	(14,231)	(177,082)
Proceeds from sale of property and equipment		32	214

Net cash provided by (used in) investing activities	19,109	68,194	(229,028)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Issuance of common stock and warrants	1,557	3,594	885,465
Collection of Series C convertible preferred stock subscriptions receivable			50,000
Issuance of Series B convertible preferred stock for cash			15,000
Cash received for common stock to be issued			3,900
Repurchase of common stock			(1,028)
Put shares sold to majority stockholder			623
Borrowings under lines of credit			4,220
Proceeds from notes receivables			1,742
Borrowings on notes payable from principal stockholder		50,000	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	(200)		(540)
Net cash provided by financing activities	1,357	53,594	1,072,442

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	Nine months ended September 30, 2007	Nine months ended September 30, 2006	Cumulative Period from February 14, 1991 (Date of Inception) to September 30, 2007
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$ (167,257)	$ (12,951)	$ 152,298
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	319,555	56,037	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 152,298	$ 43,086	$ 152,298
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Cash paid for income taxes	$	$ 5	$ 21
Interest paid in cash	2,192		3,887
Accretion on redeemable convertible preferred stock			(952)
Issuance of common stock upon conversion of notes payable			3,331
Increase in additional paid-in capital resulting from merger			171,154
Issuance of common stock for notes receivable			2,758
Issuance of put option by stockholder			(2,949)
Put option redemption by stockholder			1,921
Issuance of Series C convertible preferred stock subscriptions			50,000
Issuance of Series A redeemable convertible preferred stock			4,296
Conversion of Series A redeemable convertible preferred stock			(5,248)
Non-cash construction in progress and property and equipment	14,855		14,855

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.

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

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

1. Description of business and basis of presentation

The accompanying unaudited condensed consolidated financial statements of MannKind Corporation (the Company), have been prepared in accordance with generally accepted accounting principles in the United States of America 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 generally accepted accounting principles in the United States of America for complete financial statements. These statements should be read in conjunction with the consolidated financial statements and footnotes thereto included in the Company s latest audited annual financial statements. The audited statements for the year ended December 31, 2006 are included in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2006 filed with the SEC on March 16, 2007 (the Annual Report).

In the opinion of management, all adjustments, consisting only of normal, recurring adjustments considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the nine months ended September 30, 2007 may not be indicative of the results that may be expected for the full year.

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 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 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 development and commercialization of therapeutic products for patients with 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 U.S., 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 September 30, 2007, the Company has reported accumulated net losses of $1.0 billion, which include a goodwill impairment charge of $151.4 million, and negative cash flow from operations of $691.1 million. It is costly to develop therapeutic products and conduct clinical trials for these products. Subsequent to the date of these financial statements, 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 new loan arrangement with its principal stockholder to borrow up to a total of $350.0 million before January 1, 2010. This new arrangement replaced the existing loan arrangement with its principal stockholder to borrow up to $150.0 million through August 1, 2008. See Note 12 Related-Party Loan Arrangement. Based upon the Company s current expectations, management believes the Company s existing capital resources will enable it to continue planned operations through the third quarter of 2009. 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 or biotechnology 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. 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.

Segment Information In accordance with Statement of Financial Accounting Standards (SFAS) 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

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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.

Recently Issued Accounting Standards In September 2007, the Financial Accounting Standards Board (FASB) ratified Emerging Issues Task Force (EITF) Issue No. 07-3, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 requires that nonrefundable advance payments for future research and development activities be deferred and capitalized. EITF 07-3 is effective as of the beginning of an entity s first fiscal year that begins after December 15, 2007. The Company is assessing the impact of EITF 07-3 and has not determined whether it will have a material impact on its results of operations or financial position.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS No. 159 also includes an amendment to SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* which applies to all entities with available-for-sale and trading securities. This Statement is effective as of the beginning of an entity s first fiscal year that begins after November 15, 2007. The Company is assessing the impact of SFAS No. 159 and has not determined whether it will have a material impact on its results of operations or financial position.

In September 2006, the FASB issued SFAS No. 157*, Fair Value Measurements*. The Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements, and does not require any new fair value measurements. This Statement applies under other accounting pronouncements that require or permit fair value measurements. The Statement is effective for the fiscal years beginning after November 15, 2007. The Company is assessing SFAS No. 157 and has not determined the impact the adoption of SFAS No. 157 will have on its results of operations or financial position.

2. Investment in securities

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

	September 30, 2007		**December 31, 2006**	
	Cost Basis	**Fair Value**	**Cost Basis**	**Fair Value**
Auction rate municipal bonds	$ 51,875	$ 51,875	$ 116,924	$ 116,924

The Company s policy is to maintain a highly liquid short-term investment portfolio. The contractual maturities for auction rate municipal bonds at September 30, 2007 are between 21 and 39 years. Despite the long-term nature of their stated contractual maturities, the Company has the ability to quickly liquidate these securities. Proceeds from the sale of available-for-sale securities amounted to approximately $104.9 million and $119.9 million for the nine months ended September 30, 2007 and 2006, respectively. Gross realized gains and losses for available-for-sale securities were insignificant. Gross realized gains and losses 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 for all periods presented in the table above were not material.

3. Accounts Payable

Accounts payable is comprised of the following (in thousands):

	September 30, 2007	**December 31, 2006**
Research and clinical trial costs	19,517	6,347
Construction in progress costs	11,316	2,496
Other	5,905	1,872

Accounts payable	$	36,738	$	10,715

4. Accrued expenses and other current liabilities

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

	September 30, 2007		December 31, 2006	
Salary and related expenses	$	11,701	$	7,255
Research and clinical trial costs		16,933		18,707

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	September 30, 2007	December 31, 2006
Construction in progress costs	2,974	1,929
Accrued interest	1,270	228
Other	3,231	6,125
Accrued expenses and other current liabilities	$ 36,109	$ 34,244

5. Accounting for stock-based compensation

As of September 30, 2007, the Company has three active stock-based compensation plans the 2004 Equity Incentive Plan (the 2004 Plan), the 2004 Non-Employee Directors Stock Option Plan (the 2004 NED Plan), and the 2004 Employee Stock Purchase Plan (the ESPP). The 2004 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.

Options also remain outstanding at September 30, 2007 under the following inactive plans: the 1999 Stock Plan, the CTL ImmunoTherapies Corporation 2000 Stock Option and Stock Plan (the CTL Plan), and the Allecure Corporation 2000 Stock Option and Stock Plan (the Allecure Plan). There are also options outstanding to our principal stockholder at September 30, 2007 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 our stock-based award plans as of September 30, 2007:

	Outstanding Options	Outstanding Restricted Stock Units	Shares Available for Future Issuance
2004 Plan	6,674,322	1,525,850	226,459
2004 NED Plan	447,500		352,500
1999 Stock Plan	122,715		
CTL and Allecure Plans	37,129		
Options outside of any plan granted to principal stockholder	240,972		
Total	7,522,638	1,525,850	578,959

The Company s board of directors determines eligibility, vesting schedules and exercise prices (based upon the NASDAQ closing price on grant date) for stock awards granted under the 2004 Plan. Options and other stock awards under the 2004 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 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. The 2004 Plan provides for full acceleration of vesting if an employee is terminated within thirteen months of a change in control, as defined.

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. During the nine months ended September 30, 2007 and 2006, the Company sold 56,563 shares and 50,894 shares, respectively, of its common stock to employees participating in the plan.

Upon adoption of SFAS No. 123R, *Share-based Payment: an Amendment of FASB Statement 123 and 95* (SFAS No. 123R), the Company selected the modified prospective transition method whereby unvested awards at the date of adoption as well as awards that are granted, modified, or settled after the date of adoption will be measured and accounted for in accordance with SFAS No. 123R. Measurement and attribution of compensation cost for awards unvested as of January 1, 2006 is based on the same estimate of the grant-date or modification-date fair value and the same attribution method (straight-line) used previously under SFAS No. 123. The Company continues to account for non-employee stock-based compensation expense based on the estimated fair value of the options, determined using the Black-Scholes option valuation model, in accordance with EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and amortizes such expense on a straight-line basis. As of September 30, 2007, there were 358,937 options outstanding to all consultants.

Total stock-based compensation expense recognized in the accompanying statements of operations is as follows (in thousands):

	Three months ended September 30,		**Nine months ended September 30,**	
	2007	**2006**	**2007**	**2006**
Employee-related	$ 4,284	$ 3,183	$ 12,266	$ 10,446

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	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Consultant-related	(130)	0	691	234
Total	$ 4,154	$ 3,183	$ 12,957	$ 10,680