MEDIMMUNE INC /DE
Form 10-Q
November 07, 2003

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2003

MedImmune, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-19131**	**52-1555759**
(State or other jurisdiction of incorporation or organization)	(Commission File No.)	(I. R. S. Employer Identification No.)

35 West Watkins Mill Road, Gaithersburg, MD 20878

(Address of principal executive offices) (Zip Code)

Registrant s telephone number, including area code **(301) 417-0770**

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 ý No o

Indicate by check mark whether the registrant is an accelerated filer (as defined by Rule 12b-2 of the Exchange Act). Yes ý No o

As of November 5, 2003, 247,535,950 shares of Common Stock, par value $0.01 per share, were outstanding.

MEDIMMUNE, INC.

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Unless otherwise indicated, this quarterly report is as of September 30, 2003. This quarterly report will not be updated as a result of new information or future events.

PART I FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

MEDIMMUNE, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2003 (Unaudited)	December 31, 2002
ASSETS:		
Cash and cash equivalents	$ 351,326	$ 130,056
Marketable securities	242,320	396,882
Trade receivables, net	71,115	113,774
Inventory, net	106,528	59,963
Deferred tax assets	22,204	25,735
Other current assets	12,651	17,023
Total Current Assets	806,144	743,433
Marketable securities	1,119,181	896,118
Property and equipment, net	241,148	183,992
Deferred tax assets, net	206,309	222,038
Intangible assets, net	100,795	113,275
Goodwill	15,970	15,970
Other assets	35,817	13,463
Total Assets	$ 2,525,364	$ 2,188,289
LIABILITIES AND SHAREHOLDERS EQUITY:		
Accounts payable	$ 18,709	$ 19,773
Accrued expenses	96,941	157,359
Product royalties payable	18,429	74,048
Advances from Wyeth	13,096	
Deferred revenue	6,067	6,789
Other current liabilities	20,825	8,684
Total Current Liabilities	174,067	266,653
Long-term debt	701,118	217,554
Obligations to Evans	21,490	24,755
Other liabilities	1,928	2,093
Total Liabilities	898,603	511,055
Commitments and Contingencies		
SHAREHOLDERS EQUITY:		
Preferred stock, $.01 par value; authorized 5,525 shares; none issued or outstanding		
Common stock, $.01 par value; authorized 420,000 shares; outstanding 247,632 at September 30, 2003 and 251,262 at December 31, 2002	2,535	2,513
Paid-in capital	2,663,226	2,613,075
Deferred compensation	(2,152)	(6,823)
Accumulated deficit	(849,535)	(956,140)
Accumulated other comprehensive income	31,626	24,609
	1,845,700	1,677,234

Less: Treasury stock at cost; 5,910 shares at September 30, 2003 and no shares at December 31, 2002		(218,939)		
Total Shareholders Equity		1,626,761		1,677,234
Total Liabilities and Shareholders Equity	$	2,525,364	$	2,188,289

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

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MEDIMMUNE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(in thousands, except per share data)

	For the three months ended September 30, 2003	For the three months ended September 30, 2002	For the nine months ended September 30, 2003	For the nine months ended September 30, 2002
Revenues:				
Product sales	$ 82,283	$ 60,842	$ 593,988	$ 439,903
Other revenue	17,076	13,401	52,522	28,758
Total revenues	99,359	74,243	646,510	468,661
Costs and expenses:				
Cost of sales	30,060	22,296	156,088	117,815
Research and development	52,734	31,822	112,302	110,436
Selling, general and administrative	53,380	52,806	220,367	196,863
Other operating expenses	1,935	24,118	24,806	68,111
Acquired in-process research and development				1,179,321
Total expenses	138,109	131,042	513,563	1,672,546
Operating (loss) income	(38,750)	(56,799)	132,947	(1,203,885)
Interest income	14,523	13,275	41,823	37,181
Interest expense	(2,971)	(2,326)	(6,374)	(6,964)
Gain (loss) on investment activities	1,214	(10,557)	818	(10,666)
(Loss) earnings before income taxes	(25,984)	(56,407)	169,214	(1,184,334)
(Benefit) provision for income taxes	(9,614)	(20,115)	62,609	(1,728)
Net (loss) earnings	$ (16,370)	$ (36,292)	$ 106,605	$ (1,182,606)
Basic (loss) earnings per share	$ (0.07)	$ (0.14)	$ 0.42	$ (4.75)
Shares used in calculation of basic (loss) earnings per share	249,371	250,830	250,981	249,080
Diluted (loss) earnings per share	$ (0.07)	$ (0.14)	$ 0.42	$ (4.75)
Shares used in calculation of diluted (loss) earnings per share	249,371	250,830	254,684	249,080

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

MEDIMMUNE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)

	For the nine months ended September 30, 2003	2002
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net earnings (loss)	$ 106,605	$ (1,182,606)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Acquired in-process research and development		1,179,321
Deferred taxes	33,629	2,226
Deferred revenue	(5,899)	(4,505)
Advances from Wyeth	13,096	
Depreciation and amortization	26,152	25,723
Amortization of premium on marketable securities	11,457	6,964
Amortization of deferred compensation	3,067	14,414
Amortization of premium on convertible subordinated notes	(1,964)	(1,353)
(Gains) losses on investment activities	(818)	10,666
Increase (decrease) in inventory reserves	19,209	(1,299)
Decrease in sales allowances	(31,191)	(3,100)
Decrease in restructuring liability for cash employee termination costs	(415)	(4,898)
Other	2,276	1,305
Other changes in assets and liabilities, net of effects of acquisition of Aviron	(77,744)	312
Net cash provided by operating activities	97,460	43,170
CASH FLOWS FROM INVESTING ACTIVITIES:		
Increase in marketable securities	(72,438)	(227,214)
Net cash acquired in acquisition of Aviron		146,853
Capital expenditures	(74,860)	(48,431)
Investments in strategic alliances	(16,780)	(3,735)
Net cash used in investing activities	(164,078)	(132,527)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	35,989	40,936
Proceeds from issuance of long-term debt	500,000	
Debt issuance costs	(10,546)	
Repurchases of common stock	(218,939)	
Debt prepayments	(14,105)	
Repayments on long-term obligations	(4,479)	(4,434)
Net cash provided by financing activities	287,920	36,502
Effect of exchange rate changes on cash	(32)	200
Net increase (decrease) in cash and cash equivalents	221,270	(52,655)
Cash and cash equivalents at beginning of period	130,056	171,255
Cash and cash equivalents at end of period	$ 351,326	$ 118,600

Supplemental schedule of noncash investing and financing activities:

During January 2002, the Company acquired 100% of the outstanding capital stock of Aviron through an exchange offer and merger transaction. The Company exchanged approximately 34.0 million of its common shares for all of the outstanding shares of Aviron common stock and assumed Aviron s outstanding options and warrants, for which approximately 7.0 million additional shares of the Company s common stock are issuable. The estimated fair value of the net assets acquired was $1,635.1 million, and included $1,179.3 million of acquired research and development assets that were charged to our 2002 results at the date of acquisition and $211.4 million of 5 ¼ % convertible subordinated notes due in 2008.

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

MEDIMMUNE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. Organization

MedImmune, Inc., a Delaware corporation (together with its subsidiaries, the Company), is a biotechnology company headquartered in Gaithersburg, Maryland. During January 2002, the Company completed its acquisition of Aviron, subsequently renamed MedImmune Vaccines, Inc., a vaccines company headquartered in Mountain View, California, through an exchange offer and merger transaction (the Acquisition). The Acquisition was accounted for as a purchase, and the results of operations of MedImmune Vaccines are included in the results of the Company effective January 10, 2002.

On June 17, 2003, the U.S. Food and Drug Administration (FDA) approved the biologics license application for the commercial sale of FluMist, the first influenza vaccine delivered as a nasal mist available in the United States. FluMist is indicated for active immunization for the prevention of disease caused by influenza A and B viruses in healthy people, 5 to 49 years of age. MedImmune manufactures FluMist and co-promotes FluMist with a division of Wyeth.

In addition to FluMist, the Company currently actively markets three other products, Synagis, Ethyol and CytoGam, and is developing a diverse pipeline of potential future products. The Company is focused on developing new products, particularly vaccines and antibodies that address significant medical needs in the areas of infectious diseases, immunology and oncology.

2. Summary of Significant Accounting Policies

General

The financial information presented as of and for the three months and nine months ended September 30, 2003 (Q3 2003 and YTD 2003, respectively) and as of and for the three months and nine months ended September 30, 2002 (Q3 2002 and YTD 2002, respectively) is unaudited. In the opinion of the Company s management, the financial information presented herein contains all adjustments, which consist only of normal recurring adjustments, necessary for a fair presentation of results for the interim periods presented. Interim results are not necessarily indicative of results for an entire year or for any subsequent interim period. These consolidated financial statements should be read in conjunction with the Company s annual report on Form 10-K for the year ended December 31, 2002.

Inventory

Inventories are stated at the lower of cost or market, and consist of currently marketed products and certain product candidates awaiting regulatory approval. Cost is determined using a weighted-average approach that approximates the first-in, first-out method. With respect to inventory for product candidates, the Company considers the probability that revenues will be obtained from the future sale of the related inventory together with the status of the product candidate within the regulatory approval process. As of September 30, 2003, the Company does not have any inventory for product candidates on its balance sheet. The Company records an inventory reserve for estimated obsolescence, excess or unmarketable inventory in an amount equal to the difference between the cost of inventory and its estimated realizable value based upon assumptions about future demand and market conditions.

Stock-based Compensation

Compensation costs attributable to stock option and similar plans are recognized based on any excess of the quoted market price of the stock on the date of grant over the amount the employee is required to pay to acquire the stock, in accordance with the intrinsic-value method under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). Such amount, if any, is accrued over the related vesting period.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure (SFAS 148). SFAS 148 amends SFAS No. 123, Accounting for Stock-

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Based Compensation (SFAS 123), to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The alternative methods of transition and additional disclosure requirements of SFAS 148 were effective January 1, 2003.

The following table illustrates the effect on net earnings and earnings per share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation (in millions, except per share data):

		Q3 2003		**Q3 2002**		**YTD 2003**		**YTD 2002**
Net (loss) earnings, as reported	$	(16.4)	$	(36.3)	$	106.6	$	(1,182.6)
Add: stock-based employee compensation expense included in historical results for the vesting of stock options assumed in conjunction with the Acquisition, calculated in accordance with FIN 44, Accounting for Certain Transactions Involving Stock Compensation-an Interpretation of APB 25, net of related tax effect		0.3		2.3		1.9		10.8
Deduct: stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effect		(21.2)		(22.0)		(63.7)		(64.1)
Pro forma net (loss) earnings	$	(37.3)	$	(56.0)	$	44.8	$	(1,235.9)

Basic (loss) earnings per share, as reported	$	(0.07)	$	(0.14)	$	0.42	$	(4.75)

Basic (loss) earnings per share, pro forma	$	(0.15)	$	(0.22)	$	0.18	$	(4.96)
Diluted (loss) earnings per share, as reported	$	(0.07)	$	(0.14				