

Edgar Filing: Genesis Pharmaceuticals Enterprises, Inc. - Form 10-Q

Genesis Pharmaceuticals Enterprises, Inc.  
Form 10-Q  
February 13, 2009

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: December 31, 2008

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 333-86347

GENESIS PHARMACEUTICALS ENTERPRISES, INC.  
(Exact name of small business issuer as specified in its charter)

Florida  
(State or other jurisdiction of  
incorporation or organization)

65-1130026  
(IRS Employer Identification No.)

Middle Section, Longmao Street, Area A, Laiyang Waixiangxing Industrial Park  
Laiyang City, Yantai, Shandong Province, People's Republic of China 265200  
(Address of principal executive offices)

(0086) 535-7282997  
(issuer's telephone number)

(Former name, former address and former fiscal year, if changed since last report)

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 ☒ No ☐

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.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ (Do not check if smaller reporting company)  
Smaller reporting company ☒

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):  
Yes ☐ No ☒

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. The total shares outstanding at February 12, 2009 were 10,351,448.

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## GENESIS PHARMACEUTICALS ENTERPRISES, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

## A S S E T S

	December 31, 2008 (Unaudited)	June 30, 2008
<b>CURRENT ASSETS:</b>		
Cash	\$ 76,379,860	\$ 48,195,798
Restricted cash	6,580,962	7,839,785
Investments	532,724	2,055,241
Accounts receivable, net of allowance for doubtful accounts of \$ 267,957 and \$155,662, respectively	26,101,618	24,312,077
Accounts receivable - related parties	188,022	673,808
Inventories	4,978,846	3,906,174
Other receivables	2,324,562	152,469
Other receivables-related parties	237,343	-
Advances to suppliers and other assets	124,578	1,718,504
Total current assets	117,448,515	88,853,856
 PLANT AND EQUIPMENT, net	 11,125,526	 11,225,844
 <b>OTHER ASSETS:</b>		
Restricted investments	600,075	2,481,413
Financing costs, net	1,576,793	1,916,944
Intangible assets, net	9,823,785	9,916,801
Total other assets	12,000,653	14,315,158
 Total assets	 \$ 140,574,694	 \$ 114,394,858
 <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 2,924,891	\$ 2,341,812
Short term bank loans	2,200,500	2,772,100
Notes payable	6,580,962	5,843,295
Other payables	5,613,441	3,671,703
Other payables - related parties	391,793	324,972
Accrued liabilities	231,715	173,604
Liabilities assumed from reorganization	1,771,650	1,084,427
Taxes payable	14,014,450	166,433
Total current liabilities	33,729,402	16,378,346
 CONVERTIBLE DEBT, net of discount \$31,364,174 and \$32,499,957 as of December 31, 2008 and June 30, 2008, respectively	 3,986,278	 2,500,043
Total liabilities	37,715,680	18,878,389

## COMMITMENTS AND CONTINGENCIES

## SHAREHOLDERS' EQUITY:

Preferred stock Series (\$0.001 par value; 20,000,000 shares authorized; none issued or outstanding )	-	-
Common stock (\$0.001 par value, 22,500,000 and 15,000,000 shares authorized, respectively; 9,791,448 and 9,767,844 shares issued and outstanding, respectively)	9,792	9,770
Paid-in-capital	73,566,519	45,554,513
Capital contribution receivable	(27,845,000)	(11,000)
Retained earnings	46,109,412	39,008,403
Statutory reserves	4,685,539	3,253,878
Accumulated other comprehensive income	6,332,752	7,700,905
Total shareholders' equity	102,859,014	95,516,469
Total liabilities and shareholders' equity	\$ 140,574,694	\$ 114,394,858

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

GENESIS PHARMACEUTICALS ENTERPRISES, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF INCOME AND OTHER COMPREHENSIVE INCOME  
(UNAUDITED)

	For the Three Months Ended December 31,		For the Six Months Ended December 31,	
	2008	2007	2008	2007
<b>REVENUES:</b>				
Sales	\$ 32,944,809	\$ 25,154,071	\$ 60,265,493	\$ 40,416,860
Sales- related parties	-	1,394,662	243,909	2,742,757
<b>TOTAL REVENUE</b>	<b>32,944,809</b>	<b>26,548,733</b>	<b>60,509,402</b>	<b>43,159,617</b>
Cost of sales	7,138,166	6,524,403	12,851,210	10,730,348
Cost of sales -related parties	-	292,040	54,493	676,209
<b>COST OF SALES</b>	<b>7,138,166</b>	<b>6,816,443</b>	<b>12,905,703</b>	<b>11,406,557</b>
<b>GROSS PROFIT</b>	<b>25,806,643</b>	<b>19,732,290</b>	<b>47,603,699</b>	<b>31,753,060</b>
<b>RESEARCH AND DEVELOPMENT EXPENSE</b>	<b>1,098,525</b>	<b>937,390</b>	<b>2,196,450</b>	<b>1,202,310</b>
<b>SELLING, GENERAL AND ADMINISTRATIVE EXPENSES</b>	<b>13,282,421</b>	<b>10,311,750</b>	<b>26,634,396</b>	<b>17,133,166</b>
<b>INCOME FROM OPERATIONS</b>	<b>11,425,697</b>	<b>8,483,150</b>	<b>18,772,853</b>	<b>13,417,584</b>
<b>OTHER (INCOME) EXPENSE:</b>				
Other (income) expense, net	429,559	(40,185)	1,344,529	(27,507)
Other (income)-related parties	(92,774)	(26,944)	(236,724)	(53,436)
Non-operating (income) expense	(225,558)	(59,606)	(150,937)	297
Interest expense, net	1,549,331	339,484	2,902,125	399,484
Loss from discontinued operations	1,545,607	112,931	1,590,823	112,931
<b>OTHER EXPENSE , NET</b>	<b>3,206,165</b>	<b>325,680</b>	<b>5,449,816</b>	<b>431,769</b>
<b>INCOME BEFORE PROVISION FOR INCOME TAXES</b>	<b>8,219,532</b>	<b>8,157,470</b>	<b>13,323,037</b>	<b>12,985,815</b>
<b>PROVISION FOR INCOME TAXES</b>	<b>2,820,346</b>	<b>3,004,007</b>	<b>4,790,367</b>	<b>4,597,360</b>
<b>NET INCOME</b>	<b>\$ 5,399,186</b>	<b>\$ 5,153,463</b>	<b>\$ 8,532,670</b>	<b>\$ 8,388,455</b>
<b>OTHER COMPREHENSIVE INCOME:</b>				
Unrealized holding (loss) gain	\$ (384,650)	\$ 1,618,203	\$ (1,947,617)	\$ 1,618,203
Foreign currency translation adjustment	248,823	1,050,485	579,464	1,467,831
<b>COMPREHENSIVE INCOME</b>	<b>\$ 5,263,359</b>	<b>\$ 7,822,151</b>	<b>\$ 7,164,517</b>	<b>\$ 11,474,489</b>
	9,771,883	9,641,742	9,770,615	5,907,192

BASIC WEIGHTED AVERAGE NUMBER OF  
SHARES

BASIC EARNINGS PER SHARE	\$	0.55	\$	0.53	\$	0.87	\$	1.42
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DILUTED WEIGHTED AVERAGE NUMBER OF  
SHARES

10,418,317	10,206,553	10,443,463	6,472,003
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DILUTED EARNINGS PER SHARE	\$	0.11	\$	0.02	\$	0.41	\$	0.53
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The accompanying notes are an integral part of these consolidated financial statements.

## GENESIS PHARMACEUTICALS ENTERPRISES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)

	For the six months ended December 31,	
	2008	2007
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income	\$ 8,532,670	\$ 8,388,455
Loss from discontinued operations	1,590,823	112,931
Income from continuing operations	10,123,493	8,501,386
Adjustments to reconcile net income to cash provided by (used in) operating activities:		
Depreciation	289,749	241,282
Amortization of intangible assets	147,120	58,289
Amortization of deferred debt issuance costs	340,151	18,049
Amortization of debt discount	1,646,235	254,630
Bad debt expense	111,237	-
Gain on sale of marketable securities	(115,128)	(64,742)
Unrealized loss (gain) on trading securities	1,459,656	(8,893)
Other non-cash settlement	(20,000)	-
Stock-based compensation	38,028	28,750
Changes in operating assets and liabilities		
Accounts receivable	(1,764,421)	(5,314,103)
Accounts receivable - related parties	488,580	(1,093,483)
Notes receivables	-	58,893
Inventories	(1,049,318)	738,910
Other receivables	(2,175,378)	(84,925)
Other receivables- related parties	(236,724)	-
Advances to suppliers and other assets	1,608,131	(2,129,298)
Accounts payable	569,601	(453,390)
Accrued liabilities	153,587	311,785
Other payables	1,815,563	(879,701)
Other payables - related parties	66,028	13,359
Liabilities assumed from reorganization	(903,600)	(689,022)
Taxes payable	13,821,621	3,363,650
Net cash provided by operating activities	26,414,211	2,871,426
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Proceeds from sale of marketable securities	117,614	376,205
Prepayment for land use right	-	(2,544,100)
Cash receipt from reverse acquisition	-	534,950
Purchase of equipment	(128,179)	(293,487)
Net cash used in investing activities	(10,565)	(1,926,432)
<b>CASH FLOWS FINANCING ACTIVITIES:</b>		
Decrease in restricted cash	1,292,162	4,270,071
Proceeds from sale of common stock and options exercised	-	180,000
Proceeds from convertible debt	-	5,000,000



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Payments on debt issuance costs	-	(354,408)
Payments for dividends	-	(10,596,800)
Proceeds from short term bank loans	2,196,450	3,183,560
Principal payments on short term bank loans	(2,782,170)	(2,649,200)
Payment to escrow account	-	(325,000)
Increase (Decrease) in notes payable	704,328	(4,270,071)
Net cash provided (used) in financing activities	1,410,770	(5,561,848)

33

%

**Total Product Sales**

\$

84.7

\$

90.7

(7

)%

*Synagis* - Synagis accounted for approximately 60% and 62% of our product sales in Q2 2005 and Q2 2004, respectively. Due to the seasonal nature of Synagis sales, only five to six percent of the respective overall seasonal sales (July 1 through June 30) typically occur in the second quarter. In Q2 2005, domestic sales of Synagis increased 10% to \$43.5 million from Q2 2004 sales of \$39.7 million. The growth over Q2 2004 primarily resulted from higher sales volumes, with higher sales allowances offsetting the impact of price increases.

We record Synagis international product sales based on AI's sales price to customers, as defined in our distribution agreement. Our reported international sales of Synagis decreased 55% to \$7.4 million for Q2 2005 as compared to \$16.4 million in Q2 2004. The decrease is primarily attributable to the early stocking of inventories by AI for the 2004/2005 RSV season during Q2 2004. We currently expect that stocking of inventories by AI for the 2005/2006 RSV season will resume a more normal pattern.

**Ethyol** - Ethyol accounted for approximately 27% and 28% of our product sales in Q2 2005 and Q2 2004, respectively. Domestic sales of Ethyol declined 13% to \$21.0 million in Q2 2005, compared to \$24.1 million in Q2 2004. Of the overall decline, approximately 19 percentage points resulted from a decrease in domestic sales volume. We believe that the lower domestic sales volumes are primarily due to the depletion of wholesaler inventories to accommodate end-user demand that was 2% stronger than in the first quarter of 2005. End-user demand in Q2 2005 declined from Q2 2004 levels due partially to a temporary surge in demand in the prior year quarter, and in part to the on-going impact of the adoption of a relatively new form of radiation treatment in the head and neck cancer market. The decrease in domestic sales volume was partially offset by an increase in domestic sales prices that contributed five growth points, and the remaining increase was due to lower sales allowances that added one growth point. We recorded growth in international sales of Ethyol of \$0.7 million to \$1.6 million in Q2 2005.

**FluMist** Our Q2 2004 product sales of FluMist amounted to \$1.2 million, representing the final agreed-upon reconciliation of sales discounts and returns with Wyeth as part of the dissolution of our collaboration, relating to the 2003/2004 influenza season. Due to the seasonal nature of influenza, the majority of FluMist sales are expected to occur between October and January. Our results for Q2 2005 reflect that seasonality, and we expect that our results will reflect that seasonality going forward.

**Other Products** - Sales of other products in Q2 2005, which include sales of CytoGam, NeuTrexin, and by-products that result from the CytoGam manufacturing process, increased 33% to \$11.2 million in Q2 2005 from \$8.4 million in Q2 2004, driven by a 35% increase in CytoGam sales.

#### **Cost of Sales**

Cost of sales was \$28.0 million for Q2 2005 compared to \$37.3 million in Q2 2004. Gross margins on product sales for Q2 2005 were 67%, up eight percentage points from Q2 2004. Gross margins for all products, excluding FluMist, were 71% and 76% in Q2 2005

and Q2 2004, respectively, primarily reflecting the favorable impact of higher international Synagis sales during Q2 2004 on margins. Gross margins for FluMist did not materially impact overall gross margins for Q2 2005, but reduced gross margins in Q2 2004 by 17 percentage points. The lower impact of FluMist on gross margins for Q2 2005 was due to improved sales volume estimates and lower manufacturing cost estimates for the 2005/2006 influenza season (see Critical Accounting Estimates Inventory).

#### **Research and Development Expenses**



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Research and development expenses increased 17% to \$79.3 million in Q2 2005, compared to \$67.8 million in Q2 2004. The increase in our drug discovery and development expenses is related to a large number of ongoing clinical and preclinical studies, particularly for Numax and CAIV-T which we advanced into Phase 3 in late 2004, as well as costs associated with the expansion of infrastructure to support these studies. During Q2 2005 and Q2 2004, research and development expenses also include approximately \$0.5 million and \$10.8 million, respectively, in connection with the technology transfer and transition activities associated with reacquisition of the influenza vaccines franchise from Wyeth.

During Q2 2005, we completed the Phase 3 study to bridge refrigerator-stable CAIV-T to frozen FluMist, with preliminary data showing comparable immunogenicity. In addition, we continued the preparatory steps required for unblinding the Phase 3 efficacy trial results with CAIV-T in the fall. In our pivotal Phase 3 trial for Numax in which we are comparing it to Synagis, we enrolled 605 additional patients in the Southern Hemisphere component of the trial during Q2 2005. Also during Q2 2005, we initiated and completed enrollment for a Phase 2 study for Numax in the southern hemisphere to evaluate the safety of re-dosing children for a second season, and we completed enrollment in the Vitaxin Phase 2 study in prostate cancer.

During Q2 2005, we entered into a collaboration agreement with Avalon Pharmaceuticals, Inc. to discover and develop small molecule therapeutic compounds in the area of inflammatory disease. In addition, we entered into a collaboration with Seattle Genetics to utilize their proprietary technology to develop antibody-based therapeutics to treat cancer. Under the terms of these agreements, we made upfront payments (that are reflected as Research and Development expenses) and are contingently obligated to provide research and development support, milestone payments and royalties on potential future product sales related to these collaborations.

### **Selling, General and Administrative Expenses**



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Selling, general and administrative ( SG&A ) expenses increased 3% to \$60.9 million in Q2 2005 compared to \$58.9 million in Q2 2004. The increase is largely attributable to the expansion of the pediatric commercial organization, increased marketing activities, and increased co-promotion expense, corresponding to the increase in domestic Synagis sales.

### Impairment of Intangible Asset

As a result of entering into agreements to dissolve the collaboration with Wyeth during April 2004, we recorded a permanent impairment charge of \$73.0 million that represented the remaining unamortized cost originally recorded for the original collaboration with Wyeth.

### Acquired IPR&D

We recorded a charge of \$24.7 million for acquired IPR&D during Q2 2004 in conjunction with our reacquisition of the influenza vaccines franchise from Wyeth. The charge represented the relative fair value of purchased in-process technologies at the acquisition date, calculated utilizing the income approach, of certain IPR&D projects, primarily CAIV-T.

### Taxes

We recorded an income tax benefit of \$23.9 million for Q2 2005, resulting in an effective tax rate of 35%. We recorded an income tax benefit of \$54.9 million for Q2 2004, resulting in an effective rate of 37% for the period, excluding the impact of \$6.9 million of IPR&D charges incurred during Q2 2004 that are not deductible for tax purposes. The decline in the effective tax rate reflects additional tax credits available for certain research and development activities, including credits earned for orphan drug status of certain research and experimentation activities.

### Net Loss

The reported net loss for Q2 2005 was \$44.2 million, or \$0.18 per share, compared to net loss for Q2 2004 of \$100.3 million or \$0.40 per share. Shares used in computing net loss per share in Q2 2005 were 247.4, while shares used in computing net loss per share for Q2 2004 were 248.7 million.

## YTD 2005 compared to YTD 2004

## Revenues   Product Sales

(in millions)	YTD 2005	YTD 2004	Change
<b>Synagis</b>			
Domestic	\$ 483.0	\$ 429.8	12%
International	39.5	48.0	(18)%
	522.5	477.8	9%
<b>Ethyol</b>			
Domestic	42.6	47.4	(10)%
International	2.7	2.0	39%
	45.3	49.4	(8)%
<b>FluMist</b>	2.8	27.1	(90)%
<b>Other Products</b>	22.8	19.6	16%
<b>Total Product Sales</b>	\$ 593.4	\$ 573.9	3%

**Synagis** - Synagis accounted for approximately 88% and 83% of our product sales for YTD 2005 and YTD 2004, respectively. We achieved a 12% increase in domestic Synagis sales to \$483.0 million for YTD 2005, up from \$429.8 million in YTD 2004. The growth over the prior year period resulted from higher unit sales volumes, as the impact of price increases was largely offset by higher sales allowances during Q2 2005. Our reported international sales of Synagis decreased to \$39.5 million in YTD 2005 compared to \$48.0 million in YTD 2004, primarily due to the early stocking of inventories for 2004/2005 Synagis season by AI during YTD 2004.

**FluMist** FluMist accounted for approximately 0.5% and 4.7% of our product sales for YTD 2005 and YTD 2004, respectively. Sales of FluMist were \$2.8 million in YTD 2005, as compared to \$27.1 million in YTD 2004, a decrease primarily due to the timing of revenue recognition for product shipped during 2003. During Q1 2005, we shipped estimated net doses of approximately 0.3 million resulting in product sales of \$2.8 million. Our YTD 2004 sales of FluMist amounted to \$27.1 million and include transfer price for product shipped to Wyeth for the entire 2003/2004 season. During 2003, we shipped 4.1 million doses of FluMist to Wyeth, our former collaboration partner, who was contractually responsible for distributing the product to third parties. At December 31, 2003, we concluded that the variables associated with FluMist product revenues were not determinable, largely due to low sales volume and the lack of returns history and comparable rebate redemption rates for the new product. As a result, product revenues associated with the doses that were shipped to Wyeth in 2003 were not recognized until the first quarter of 2004. Our Q2 2004 product sales of FluMist amounted to \$1.2 million, representing the final agreed-upon reconciliation of sales discounts and returns with Wyeth as part of the dissolution of our collaboration.

**Ethyol** - Ethyol accounted for approximately 8% and 9% of our product sales for YTD 2005 and YTD 2004, respectively. Worldwide Ethyol sales declined 8% to \$45.3 million in YTD 2005, as compared to \$49.4 million in YTD 2004, primarily driven by a 10% decline in domestic sales due to lower unit sales volumes for YTD 2005. We



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believe that the lower domestic unit volumes for YTD 2005 as compared to YTD 2004 are partially due to the depletion of wholesaler inventories from December 31, 2004 levels to accommodate end-user demand. In contrast, we experienced an increase in wholesaler inventories from December 31, 2003 levels. Domestic end-user demand in the YTD 2005 period declined approximately 3% over YTD 2004, due to the ongoing impact of the adoption of a relatively new form of radiation treatment in the head and neck cancer market. International sales grew from \$2.0 million in YTD 2004 to \$2.7 million in YTD 2005.

**Other Products** - Sales of other products include sales of CytoGam, RespiGam, NeuTrexin, and by-products that result from the CytoGam manufacturing process and amounted to \$22.8 million in YTD 2005 as compared to \$19.6 million for YTD 2004. The increase is primarily due to a 25% increase in sales of CytoGam.

**Revenues   Other Revenues**



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Other revenues of \$4.9 million for YTD 2005 are lower than YTD 2004 other revenues of \$8.7 million largely due to decreased revenues under collaborative agreements. Other revenues in YTD 2004 are largely comprised of contractual payments received from Wyeth prior to dissolution of our collaboration, including royalties related to the 2003/2004 influenza season and corporate funding for clinical development and sales and marketing programs.

**Cost of Sales**

Cost of sales for YTD 2005 decreased 24% to \$147.8 million from \$195.5 million for YTD 2004. Gross margins on product sales were 75% for YTD 2005, up nine percentage points from gross margins of 66% for YTD 2004. Gross margins for all products, excluding FluMist, were 76% and 75% in YTD 2005 and YTD 2004, respectively. Gross margins for FluMist did not materially impact overall gross margins for YTD 2005, but reduced gross margins in YTD 2004 by nine percentage points. The lower impact of FluMist on gross margins for YTD 2005 was due to improved sales volume estimates and lower manufacturing cost estimates for the 2005/2006 influenza season (see Critical Accounting Estimates).

**Research and Development Expenses**



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Research and development expenses of \$148.6 million in YTD 2005 increased 26% from \$117.6 million in YTD 2004. The increase is due largely to direct costs associated with ongoing and additional clinical and preclinical trials for product candidates, as well as increases in headcount and related expenses in support of increased research and development activities. Also included in research and development expenses in YTD 2005 and 2004 are \$1.4 million and \$10.8 million, respectively, in costs for technology transfer and transition activities associated with our assumption of research and development activities related to the influenza vaccines franchise.

### **Selling, General, and Administrative Expenses**

Selling, general and administrative ( SG&A ) expenses increased 20% to \$218.4 million in YTD 2005 compared to \$182.6 million in YTD 2004. The increase is largely attributable to increased co-promotion expense, corresponding to the increase in domestic Synagis sales, and the expansion of the pediatric commercial organization. Also included in SG&A expense in YTD 2004 is \$0.8 million for other Wyeth-related transition activities. As a percentage of product sales, SG&A expense increased to 37% of product sales for YTD 2005 compared to 32% of products sales in YTD 2004.

### **Impairment of Intangible Asset**

As a result of entering into agreements to dissolve the collaboration with Wyeth during April 2004, we recorded a permanent impairment loss of \$73.0 million that represented the remaining unamortized cost originally recorded for the original collaboration with Wyeth.

### **Acquired IPR&D**

We recorded a charge of \$24.7 million for acquired IPR&D for YTD 2004 in conjunction with our reacquisition of the influenza vaccines franchise from Wyeth. The charge represented the relative fair value of purchased in-process technologies at the acquisition date, calculated utilizing the income approach, of certain IPR&D projects, primarily CAIV-T.

### **(Loss) Gain on Investment Activities**

We recorded a net loss on investment activities of \$0.9 million during YTD 2005, compared to a net gain of \$7.3 million during YTD 2004. The YTD 2004 net gain principally consists of realized gains on the sale of certain of our publicly traded equity investments.

### **Taxes**

We recorded income tax expense of \$37.6 million for YTD 2005, resulting in an effective tax rate of 35%. Comparatively, we recorded income tax expense of \$10.3 million for YTD 2004, which resulted in an effective tax rate of 37%, excluding the impact of approximately \$6.9 million of non-deductible charges for IPR&D incurred during the second quarter of 2004. Our effective tax rate in both years is impacted by the availability of the estimated credits available for research and development activities, including credits earned for orphan drug status of certain research and development activities, relative to our earnings growth. These credits will vary from year to year depending on the activities of the

Company.

**Net Earnings**

We reported net earnings for YTD 2005 of \$69.9 million, or \$0.28 per share compared to net earnings for YTD 2004 of \$10.7 million, or \$0.04 per share.

Shares used in computing basic and diluted earnings per share for YTD 2005 were 247.7 million and 257.0 million, while shares used for computing basic and diluted earnings per share for YTD 2004 were 248.5 million and 249.8 million, respectively.

We do not believe inflation had a material effect on our financial statements.

**LIQUIDITY AND CAPITAL RESOURCES**





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**Sources and uses of cash** - Cash and marketable securities were \$1.8 billion as of June 30, 2005 as compared to \$1.7 billion as of December 31, 2004, an increase of 4%. The increase in cash is primarily due to operating cash flows generated during YTD 2005. Working capital increased to \$603.6 million at June 30, 2005 from \$330.0 million as of December 31, 2004, also due to cash generated by our operations.

### *Operating Activities*

Net cash provided by operating activities was \$188.6 million in YTD 2005 as compared to \$103.9 million in YTD 2004. The change compared to prior period is primarily the result of the increase in net earnings in YTD 2005.

### *Investing Activities*

Cash used for investing activities during YTD 2005 amounted to \$74.7 million, as compared to \$262.8 million during YTD 2004. Cash used for investing activities in YTD 2005 included net additions to our investment portfolio of \$29.8 million; capital expenditures totaling \$37.0 million, primarily for the construction of our new pilot lab in Gaithersburg, Maryland and the expansion of our FluMist manufacturing facilities in Speke, England; and minority interest investments in strategic partners totaling \$7.9 million through our venture capital subsidiary. We expect our capital expenditures for the full year to range from \$100 million to \$150 million.

### *Financing Activities*

Financing activities used \$57.2 million in cash for YTD 2005, as compared to \$163.2 million used in YTD 2004. The decrease is principally due to the use of \$172.7 million in cash during Q1 2004 to repurchase and retire the balance of the 5 1/4% Convertible Subordinated Notes. During YTD 2005, we used \$67.5 million in cash to repurchase shares of our common stock as authorized under our share repurchase program. Approximately \$10.8 million was received upon the exercise of employee stock options and through the employee stock purchase plan in YTD 2005, as compared to \$9.9 million received in YTD 2004.

Our primary source of liquidity is operating cash flow. Management continues to believe that such internally generated cash flow as well as its existing funds will be adequate to service its existing debt and other cash requirements. We expend cash to finance our research and development and clinical trial programs; to obtain access to new technologies through collaborative research and development agreements with strategic partners, through our venture capital subsidiary, or through other means; to fund capital projects; and to finance the production of inventories. In February 2005, our Board of Directors approved an additional \$100 million in funding for our venture capital subsidiary to \$200 million. Also, the BBB rating on our outstanding indebtedness, considered to be investment grade, will contribute to our ability to access capital markets, should we desire or need to do so. We may raise additional capital in the future to take advantage of favorable conditions in the market or in connection with our development activities.

During Q2 2005, we recouped approximately \$12 million from licensors related to overpayments under various royalty agreements. This amount has been deferred until fully realizable and recorded in Other Current Liabilities.

Our Board of Directors has authorized the repurchase of up to \$500 million of the Company's common stock during the period from July 2003 through June 2006 in the open market or in privately negotiated transactions, pursuant to terms management deems appropriate and at such times it may designate. During YTD 2005, we repurchased approximately 2.6 million shares of common stock under the stock repurchase program at a cost of \$67.5 million, or an average cost of \$25.56 per share. Through July 18, 2005, we have repurchased an additional 0.4 million shares at an average cost of \$27.33 per share. As of July 18, 2005, approximately \$163 million was available under the authorization for additional repurchases of stock. We are holding repurchased shares as treasury shares and are using them for general corporate purposes, including but not limited to acquisition-related transactions and for issuance upon exercise of outstanding stock options.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We believe our primary market risks as of June 30, 2005 continue to be the exposures to loss resulting from changes in interest rates, foreign currency exchange rates, and equity prices. Our market risks at June 30, 2005 have not changed significantly from those discussed in our Form 10-K for the year ended December 31, 2004. For other information regarding the Company's market risk exposure, please refer to Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk of the Company's Annual Report on Form 10-K for the year ended December 31, 2004.

**ITEM 4. CONTROLS AND PROCEDURES**

The Company maintains disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's

rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer, President and Vice Chairman ( CEO ), and Senior Vice President and Chief Financial Officer ( CFO ), as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable, and not absolute, 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. Accordingly, no evaluation or implementation of a control system can provide complete assurance that all control issues and all possible instances of fraud have been or will be detected.

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's CEO and CFO, of the effectiveness of the Company's disclosure controls and procedures, as required by Rule 13a-15(b) promulgated under the Exchange Act. Based upon that evaluation, the Company's CEO and its CFO concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level.

In addition, the management of the Company, with the participation of the Company's CEO and its CFO, have determined that there was no change in the Company's internal control over financial reporting that occurred during Q2 2005 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**PART II - OTHER INFORMATION**



## ITEM 1. LEGAL PROCEEDINGS

Information with respect to legal proceedings is included in Note 10 of Part I, Item 1 Financial Statements, and is incorporated herein by reference and should be read in conjunction with the related disclosure previously reported in the Company's Annual Report on Form 10-K for the year ended December 31, 2004 as updated in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.

## ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

### (c) Issuer purchases of equity securities(1)

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value that May Yet Be Purchased Under the Plans or Programs
April 1, 2005 through April 30, 2005	445,000	\$ 24.86	445,000	\$ 211,693,000
May 1, 2005 through May 31, 2005	751,300	\$ 26.23	751,300	\$ 191,985,000
June 1, 2005 through June 30, 2005	733,680	\$ 26.30	733,680	\$ 172,690,000

(1) The Company's Board of Directors has authorized the repurchase of up to \$500 million of the Company's common stock on the open market or in privately negotiated transactions during the period from July 2003 through June 2006.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES NONE

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On May 19, 2005 the Company held its Annual Meeting of Stockholders. Nine director nominees were re-elected to one year terms by vote of the Company's stockholders at such meeting, as follows:

	For	Against	Withheld	Abstain/ Non-vote
Wayne T. Hockmeyer, Ph.D.	208,767,900		4,843,949	
David M. Mott	208,801,485		4,810,364	
David Baltimore, Ph.D.	210,405,902		3,205,947	
M. James Barrett, Ph.D.	194,158,922		19,452,927	
James H. Cavanaugh, Ph.D.	193,595,545		20,016,304	
Barbara H. Franklin	195,714,100		17,897,749	
Gordon S. Macklin	181,281,042		32,330,807	
George M. Milne, Jr., Ph.D.	210,026,074		3,585,775	
Elizabeth H. S. Wyatt	210,469,621		3,142,228	

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The following proposals were also approved by vote of the Company's stockholders at such meeting, as follows:

To approve the amendment to the 2004 Stock Incentive Plan	119,614,057	61,236,149	1,470,061
To approve and ratify PricewaterhouseCoopers LLP as the Company's independent auditors for 2005	209,283,917	3,084,296	1,243,636



**ITEM 5. OTHER INFORMATION NONE**



**ITEM 6.**

**EXHIBITS**

(a) Exhibits:

- 3.1 Company By-laws, currently in effect (as last amended as of May 19, 2005).
- 10.1(1) Patent License Agreement (Adair Patent Rights) (MedI-493), dated as of January 19, 1998, by and between Celltech Therapeutics Limited and the Company.
- 10.2(1) Patent License Agreement (Adair Patent Rights) (MedI-493), dated as of June 24, 2005, by and among Celltech R&D Limited, UCB S.A. and the Company.
- 31.1 Rule 13-14(a)/15d-14(a) Certification of CEO.
- 31.2 Rule 13-14(a)/15d-14(a) Certification of CFO.
- 32.1 Section 1350 Certifications furnished as permitted by Item 601(b)(32)(ii) of Regulation S-K. This Exhibit 32 is not filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not and should not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

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- (1) Confidential treatment has been requested. The copy filed as an exhibit omits the information subject to the confidentiality request.

**SIGNATURES**



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Pursuant to the requirements 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.

### **MEDIMMUNE, INC.**

(Registrant)

Date: July 21, 2005

/s/ David M. Mott  
David M. Mott  
Chief Executive Officer, President and Vice Chairman  
Principal Executive Officer

Date: July 21, 2005

/s/ Lota S. Zoth  
Lota S. Zoth  
Senior Vice President and Chief Financial Officer  
Principal Financial Officer

Date: July 21, 2005

/s/ Mark E. Spring  
Mark E. Spring  
Vice President, Finance and Controller  
Principal Accounting Officer