

GENTA INC DE/  
Form 10-Q  
August 06, 2004

---

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

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2004

OR

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

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

Commission File Number 0-19635

**GENTA INCORPORATED**

(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

33-0326866  
(I.R.S. Employer  
Identification Number)

Two Connell Drive  
Berkeley Heights, NJ  
(Address of principal executive offices)

07922  
(Zip Code)

(908) 286-9800

(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  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934).

Yes  No

As of July 30, 2004, the registrant had 80,358,215 shares of common stock outstanding.

---

**Genta Incorporated**  
**INDEX TO FORM 10-Q**

		Page
<b>PART I.</b>	<b>FINANCIAL INFORMATION</b>	
Item 1.	Financial Statements:	
	<u>Consolidated Balance Sheets at June 30, 2004 and December 31, 2003</u>	3
	<u>Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2004 and 2003</u>	4
	<u>Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2004 and 2003</u>	5
	<u>Notes to Consolidated Financial Statements</u>	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3.	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	21
Item 4.	<u>Controls and Procedures</u>	21
<b>PART II.</b>	<b><u>OTHER INFORMATION</u></b>	
Item 1.	<u>Legal Proceedings</u>	22
Item 2.	<u>Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities</u>	22
Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>	22
Item 6.	<u>Exhibits and Reports on Form 8-K</u>	23
	<b><u>SIGNATURES</u></b>	25
	<b><u>CERTIFICATIONS</u></b>	28

**GENTA INCORPORATED**  
**CONSOLIDATED BALANCE SHEETS**

	June 30, 2004	December 31, 2003
(In thousands, except par value data)		
	(Unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents (Note 2)	\$ 44,429	\$ 25,153
Marketable securities (Note 3)	5,758	57,776
Accounts receivable - net	8,574	16,675
Notes receivable	200	200
Inventory (Note 4)	1,728	518
Prepaid expenses and other current assets	781	3,313
Total current assets	61,470	103,635
Property and equipment, net	5,296	4,917
Notes receivable	4,348	3,542

Edgar Filing: GENTA INC DE/ - Form 10-Q

Intangibles, net (Note 5)	574	863
Prepaid royalties	1,268	1,268
Other assets	1,627	450
	<u>          </u>	<u>          </u>
Total assets	\$ 74,583	\$ 114,675
	<u>          </u>	<u>          </u>

LIABILITIES AND STOCKHOLDERS EQUITY

Current liabilities:		
Accounts payable and accrued expenses	\$ 19,747	\$ 15,319
Notes payable	-	748
Deferred revenues, current portion	5,277	5,287
Short-term debt (Note 6)	35,000	-
	<u>          </u>	<u>          </u>
Total current liabilities	60,024	21,354
Deferred revenues	33,458	36,067
Convertible debt (Note 7)	10,000	10,000
Long-term debt (Note 6)	-	35,000
	<u>          </u>	<u>          </u>
Total liabilities	103,482	102,421
	<u>          </u>	<u>          </u>

Commitments and contingencies

Stockholders (deficit) equity:		
Series A convertible preferred stock, \$.001 par value; 5,000 shares authorized, 10 shares and 261 shares issued and outstanding, liquidation value of \$485 and \$13,025 at June 30, 2004 and December 31, 2003 respectively	-	-
Common stock, \$.001 par value; 150,000 and 120,000 shares authorized, 80,358 and 75,927 shares issued and outstanding at June 30, 2004 and December 31, 2003, respectively	80	76
Additional paid-in capital	336,189	335,713
Deferred financing costs	(33)	-
Accumulated deficit	(364,986)	(323,299)
Deferred compensation	(117)	(261)
Accumulated other comprehensive (loss) income	(32)	25
	<u>          </u>	<u>          </u>
Total stockholders (deficit) equity	(28,899)	12,254
	<u>          </u>	<u>          </u>
Total liabilities and stockholders (deficit) equity	\$ 74,583	\$ 114,675
	<u>          </u>	<u>          </u>

See accompanying notes to consolidated financial statements

**GENTA INCORPORATED**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	<u>          </u>		<u>          </u>	
(In thousands, except per share data)	(Unaudited)		(Unaudited)	
Revenues:				
Product sales - net	\$ 251	\$ -	\$ 624	\$ -

Edgar Filing: GENTA INC DE/ - Form 10-Q

License fees and royalties	261	276	522	542
Development funding	1,049	1,044	2,097	2,087
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total revenues				

1,561

1,320

3,243

2,629

Cost of goods sold

52

-

146

-

---

---

---

---

---

---

---

---

Gross margin

1,509

1,320

3,097

2,629

Costs and expenses:

Research and development (including non-cash compensation expense of \$52 for the three months and \$104 for the six months ended June 30, 2004 and June 30, 2003, respectively)

28,945

18,163

41,297

33,672

---

Selling, general and administrative (including non-cash compensation expense of \$22 and \$92 for the three months ended June 30, 2004 and June 30, 2003, respectively and \$40 and \$184 for the six months ended June 30, 2004 and June 30, 2003, respectively)

10,284

6,223

19,507

11,095

---

---

---

---

---

---

---

---

---

---

Total costs and expenses - gross

39,229

24,386

60,804

44,767



Aventis reimbursement

) (8,531

) (19,433

) (15,964

) (28,590

---

---

---

---

---

---

---

---

Total costs and expenses - net

30,698

4,953

44,840

16,177

Other income

34

215

10

---

---

---

---

---

---

---

---

---

---

Net loss

\$		(29,155
)		
\$		(3,418
)		
\$		(41,687
)		
\$		(13,021
)		

---

---

---

---

---

---

---

---

---

---

Net loss per basic and diluted share

\$

(0.37

)

\$

(0.05

)

\$

(0.53

)

\$

(0.18

)

---

---

---

---

---

---

---

---

---

---

Shares used in computing net loss per  
basic and diluted share

79,016

74,442

77,945

See accompanying notes to consolidated financial statements

4

**GENTA INCORPORATED**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)	Six Months Ended June 30,	
	2004	2003
	(Unaudited)	
<b>Operating activities:</b>		
Net loss	\$ (41,687)	\$ (13,021)
Items reflected in net loss not requiring cash:		
Depreciation and amortization	1,626	1,040
Compensation expense related to stock options (Note 2)	143	288
Changes in operating assets and liabilities:		
Accounts, notes and loan receivable	8,101	(6,551)
Inventory (Note 4)	(1,210)	-
Notes receivable	(806)	-
Accounts payable, accrued expenses and other current liabilities	3,681	(23,066)
Deferred revenue	(2,619)	-
Other assets	1,355	(606)
Net cash used in operating activities	(31,416)	(41,916)
<b>Investing activities:</b>		
Purchase of marketable securities	(7,281)	(38,000)
Maturities and sales of marketable securities	59,242	60,698
Purchase of property and equipment	(1,716)	(1,060)

Edgar Filing: GENTA INC DE/ - Form 10-Q

Net cash provided by investing activities	50,245	21,638
<b>Financing activities:</b>		
Proceeds from the line of credit (Note 7)	-	25,000
Purchase of treasury stock	-	(303)
Deferred financing costs	(33)	-
Issuance of common stock upon exercise of warrants and options	480	1,796
Net cash provided by financing activities	447	26,493
Increase in cash and cash equivalents	19,276	6,215
Cash and cash equivalents at beginning of period	25,153	32,700
Cash and cash equivalents at end of period	\$ 44,429	\$ 38,915

See accompanying notes to consolidated financial statements

5

**GENTA INCORPORATED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**June 30, 2004**  
**(Unaudited)**

**1. Organization and Business**

Genta Incorporated ( Genta , we , us or the Company ) is a biopharmaceutical company engaged in research and development of anticancer drugs, its sole reportable segment. The Company is dedicated to developing innovative drugs to treat cancer. In the past, the Company's research efforts have focused primarily on the development of antisense drugs that are designed to selectively prevent the production of specific proteins that contribute to the cause or progression of disease. More recently, the Company has broadened its research portfolio into drugs that are comprised of chemically modified DNA or RNA (which includes antisense, decoys, and small interfering RNA) as well as small molecules (which currently include the Company's gallium products).

The Company has had recurring operating losses since its inception. Management expects that such losses will continue at least until its lead product, Genasense®, receives approval from the U.S. Food and Drug Administration ( FDA ) for commercial sale, and we receive a full year of royalties from Aventis Pharmaceuticals Inc. ( Aventis ), our commercial partner on this product, on worldwide sales. Although no assurances can be expressed, management believes that at the current rate of spending, after giving effect to our recent cost-control steps and coupled with our relationship with Aventis, the Company should have sufficient cash funds to maintain its present operations through mid-2005. If we obtain New Drug Application ( NDA ) approval of Genasense, Aventis milestone payments and other funding available to the Company should provide sufficient capital resources. It is likely that the Company will seek additional external financing sometime in 2005.

The Company may also seek collaborative agreements, equity financing and other financing arrangements with potential corporate partners and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available on favorable terms, if at all. The Company will need substantial additional funds before it can expect to realize significant product revenue.

**2. Summary of Significant Accounting Policies**

*Basis of Presentation*

The consolidated financial statements are presented on the basis of accounting principles generally accepted in the United States. All professional accounting standards that are effective as of June 30, 2004 have been considered in preparing the consolidated financial statements. Such financial statements include the accounts of the Company and all majority-owned subsidiaries. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make certain estimates and assumptions that affect reported earnings, financial position and various disclosures. Actual results could differ from those estimates. Certain reclassifications have been made to prior-year amounts to conform with current-year presentation. The unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim financial information have read or have access to the audited

## Edgar Filing: GENTA INC DE/ - Form 10-Q

financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003. Results for the interim periods are not necessarily indicative of results for the full years.

The Company has experienced significant quarterly fluctuations in operating results and it expects that these fluctuations will continue.

6

---

---

### *Revenue Recognition*

In April 2002, the Company entered into a development and commercialization agreement ( Collaborative Agreement ) with Aventis. Under the terms of the Collaborative Agreement, the Company and Aventis will jointly develop and commercialize Genasense® in the U.S. (the Alliance ), and Aventis will have exclusive development and marketing rights to the compound in all countries outside of the U.S. Under the Collaborative Agreement, Aventis will pay 75% of U.S. NDA-directed development costs incurred by either Genta or Aventis, subsequent to the execution of the Collaborative Agreement, and 100% of all other development, marketing, and sales costs incurred within the U.S. and elsewhere as subject to the Collaborative Agreement . Reimbursements are to be made pursuant to a single net payment from one party to the other. Such payments are due and payable 60 days following the end of the quarter in which such expenses are incurred.

We follow the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin No. 104 ( SAB No. 104 ), *Revenue Recognition*, and Emerging Issues Task Force No. 00-21 ( EITF No. 00-21 ), *Accounting for Revenue Arrangements with Multiple Deliverables*.

In accordance with EITF No. 00-21 we analyze our multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. We recognize license payments as revenue if the license has stand-alone value and the fair value of the undelivered items can be determined. If the license is considered to have stand-alone value but the fair value on any of the undelivered items cannot be determined, the license payments are recognized as revenue over the period of performance for such undelivered items or services. Our estimate of the period of performance involves management judgment. Amounts received for milestones are recognized upon achievement of the milestone, as long as the milestone is deemed to be substantive and we have no other performance obligations.

We have determined that, due to the nature of the on-going development work related to our Collaborative Agreement with Aventis, the end of the development phase and the fair-value of the undelivered elements are not determinable. Accordingly, we have deferred recognition of the initial licensing fee and up-front development funding received from Aventis and are recognizing these payments on a straight-line basis over the original estimated useful life of the related first-to-expire patent of 115 months. Any subsequent milestone payments that may be received from Aventis will also be recognized over the then remaining estimated useful life of the first-to-expire patent.

Genta recognizes revenue from product sales when title to product and associated risk of loss has passed to the customer and we are reasonably assured of collecting payment for the sale. All revenue from product sales are recorded net of applicable allowances for returns rebates and other applicable discounts and allowances. We allow return of our product for up to twelve months after product expiration.

### *Research and Development*

Research and development costs are expensed as incurred, including raw material costs required to manufacture products for clinical trials. Reimbursements for applicable Genasense®-related costs, under the Collaborative Agreement, have been recorded as a reduction to expenses in the consolidated statement of operations.

### *Cash, Cash Equivalents and Marketable Securities*

The carrying amounts of cash, cash equivalents and marketable securities approximate fair value due to the short-term nature of these instruments. Marketable securities consisted primarily of government securities, all of which are classified as available-for-sale marketable securities. Management determines the appropriate classification of debt and equity securities at the time of purchase and reassesses the classification at each reporting date.

7

---

---

### *Property and Equipment*



## Edgar Filing: GENTA INC DE/ - Form 10-Q

Property and equipment is stated at cost and depreciated on the straight-line method over the estimated useful lives of the assets, ranging from three to five years. Leasehold improvements incurred in the renovation of the Company's current offices are being amortized over the remaining life of the leases. The Company's policy is to evaluate the appropriateness of the carrying value of the undepreciated value of long-lived assets on the basis of estimated future cash flows (undiscounted) and other factors. If such evaluation were to indicate an impairment of these assets, such impairment would be recognized by a write-down of the applicable assets. Based on the valuation, no impairment was indicated in accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*.

### *Intangible Assets*

Intangible assets, consisting primarily of licensed technology and capitalized patent costs, are amortized using the straight-line method over their estimated useful lives of five years. The Company's policy is to evaluate the appropriateness of the carrying values of the unamortized balances of intangible assets on the basis of estimated future cash flows (undiscounted) and other factors. If such evaluation were to indicate an impairment of these assets, such impairment would be recognized by a write-down of the applicable assets. The Company evaluates, each financial reporting period, the continuing value of patents and patent applications. Through this evaluation, the Company may elect to continue to maintain these patents, seek to out-license them, or abandon them. Based on the valuation, no impairment was indicated in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*.

### *Inventories*

Inventories are stated at the lower of cost or market with cost being determined using the first-in, first-out (FIFO) method.

### *Stock Options*

The Company accounts for stock-based compensation arrangements in accordance with the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* and complies with the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*. Under APB Opinion No. 25, compensation expense is based on the difference, if any, on the date of grant, between the fair value of the Company's stock and the exercise price. The Company accounts for stock options issued to non-employees in accordance with the provisions of SFAS No. 123 and 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*. The Company is amortizing deferred stock compensation using the graded vesting method, in accordance with Financial Accounting Standards Board Interpretation No. 28, over the vesting period of each respective option, which is generally four years.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure - Amendment of FASB Statement No. 123*, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation and amend the disclosure requirements of Statement No. 123. The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

8

(\$thousands, except per share data)	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Net loss applicable to common shares, as reported	\$ (29,155)	\$ (3,418)	\$ (41,687)	\$ (13,021)
Add: Equity related employee compensation expense included in reported net income, net of related tax effects	74	144	144	288
Deduct: Total stock-based employee compensation expense determined under fair values based method for all awards, net of related tax effects	(2,455)	(1,907)	(4,800)	(3,455)

Edgar Filing: GENTA INC DE/ - Form 10-Q

Pro forma net loss	\$ (31,536)	\$ (5,181)	\$ (46,343)	\$ (16,188)
--------------------	-------------	------------	-------------	-------------

Net loss per share attributable to common shareholders:				
As reported: Basic and diluted	\$ (0.37)	\$ (0.05)	\$ (0.53)	\$ (0.18)
Pro forma: Basic and diluted	\$ (0.40)	\$ (0.07)	\$ (0.59)	\$ (0.22)

The pro-forma disclosure shown above was calculated for all options using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended June 30,	
	2004	2003
Risk-free interest rate	3.7%	2.5%
Dividend yield	-	-
Expected life (years)	4.0	4.0
Volatility	117%	65%

*Net Loss Per Common Share*

Basic earnings per share are based upon the weighted-average number of shares outstanding during the period. Diluted earnings per share includes the weighted average number of all potentially dilutive common shares such as shares outstanding, options, warrants and convertible preferred stock outstanding.

Net loss per common share for the three months ended June 30, 2004 and 2003 is based on the weighted average number of shares of common stock outstanding during the periods. Basic and diluted loss per share are identical for all periods presented as potentially dilutive securities, including options, warrants and convertible preferred stock have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would be antidilutive.

**3. Marketable Securities**

The carrying amounts of the Company's marketable securities, which are government securities, approximate fair value due to the short-term nature of these instruments. The fair value of available-for-sale marketable securities is as follows (\$ thousands):

	June 30, 2004	December 31, 2003
Amortized cost	\$ 5,790	\$ 57,751
Gross unrealized gains	10	29
Gross unrealized losses	(42)	(4)
Estimated fair value	\$ 5,758	\$ 57,776

9

The estimated fair value of each marketable security has been compared to its cost, and therefore, a net unrealized loss of approximately \$32 thousand has been recognized in accumulated other comprehensive income at June 30, 2004.

**4. Inventories**

Inventories, consisting of Ganite® and Genasense®, are stated at the lower of cost or market with cost being determined using the first-in, first-out (FIFO) method. Inventories consisted of the following (\$ thousands):

	June 30, 2004	December 31, 2003
--	------------------	----------------------

Edgar Filing: GENTA INC DE/ - Form 10-Q

Raw materials	\$ 1,634	\$ 189
Work in process	-	318
Finished goods	94	11
	<u>          </u>	<u>          </u>
	\$ 1,728	\$ 518
	<u>          </u>	<u>          </u>

In May 2004, approximately \$7.0 million of vialled Genasense<sup>®</sup> product, which had been produced to be commercial inventory, was expensed, as the vials will now be used in clinical trials. In addition, in accordance with accounting practice, \$11.7 million of Genasense<sup>®</sup> bulk drug substance has also been expensed. This material can be used to produce commercial supplies of Genasense<sup>®</sup> drug product should one of the pending clinical trials be positive and form the basis for a Genasense<sup>®</sup> NDA submission. Accordingly, \$1.7 million in inventory at June 30, 2004 solely consists of Ganite<sup>®</sup> raw materials and finished goods. The valuation of this inventory is consistent with management's outlook for Ganite<sup>®</sup>, including strategic options being explored by the Company.

**5. Intangibles, net**

Intangible assets consist of the following (\$ thousands):

	<u>June 30, 2004</u>	<u>December 31, 2003</u>
Patent and patent applications	\$ 3,992	\$ 3,992
Less accumulated amortization	(3,418)	(3,129)
	<u>          </u>	<u>          </u>
	<u>\$ 574</u>	<u>\$ 863</u>

Future amortization expense related to intangibles at June 30, 2004 are as follows (\$ thousands):

	<u>Amortization Expense</u>
2004	\$ 288
2005	286
	<u>          </u>
Total	<u>\$ 574</u>

**6. Short-Term Debt**

At June 30, 2004, the Company had \$35.5 million outstanding on a line of credit that was issued in connection with an amendment, dated March 14, 2003, to the Collaborative Agreement that established a line of credit related to the development, manufacturing and commercialization of Genasense<sup>®</sup> (Aventis Line of Credit). Of the \$35.5 million, \$35.0 million is recorded as short-term debt and \$0.5 million is recorded as accrued interest. At December 31, 2003, the Aventis Line of Credit was classified as long-term debt. This revolving debt is considered an advance against both past and future costs and the borrowing base is adjusted on a monthly basis. At the time of Genasense<sup>®</sup> NDA approval in the U.S., any outstanding balance will be offset against the first milestone payment that is due to Genta from Aventis. The terms of the Aventis Line of Credit provide for a favorable interest rate, which is set two days prior to the first day of each calendar quarter. The Aventis Line of Credit terminates upon the earlier of (1) the receipt of Genasense<sup>®</sup> NDA approval in the U.S., (2) notice given by either Genta or Aventis of the termination of the Collaborative Agreement, (3) notice given by Genta of the termination of the Aventis Line of Credit, (4) various default provisions or (5) December 31, 2004. Depending on the circumstances, repayment is due immediately or up to six months after the termination of the Aventis Line of Credit. As security for the repayment of the Aventis Line of Credit, Genta has granted Aventis a security interest in all of its accounts and/or other rights to payments under the Collaborative Agreement, as well as all inventory related to Genasense<sup>®</sup>.

**7. Convertible Debt**

At June 30, 2004, the Company had \$10.0 million in outstanding convertible debt that was issued in connection with the Collaborative Agreement. The Company received \$10.0 million in debt proceeds from Aventis, and issued a \$10.0 million convertible promissory note to

Aventis ( Aventis Note ). Interest accrues at the rate of 5.63% per annum until April 26, 2009 (the Maturity Date ) and compounds annually on each anniversary date of the Aventis Note through the Maturity Date. The Company may redeem the Aventis Note for cash in whole or in part (together with any accrued and unpaid interest with respect to such principal amount) in amounts of not less than \$0.5 million. In addition, the Company may convert the Aventis Note on or prior to the Maturity Date in whole or in part into fully paid and non-assessable shares of common stock. As of any date, the number of shares of common stock into which the Aventis Note may be converted shall be determined by a formula based on the then market value of the common stock (the Conversion Price ), subject to a minimum Conversion Price of \$8.00 per share.

10

As of June 30, 2004, the Company has accrued interest of \$1.3 million on the Aventis Note.

## 8. Comprehensive Loss

An analysis of comprehensive loss is presented below:

(\$in thousands)	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Net loss	\$ (29,155)	\$ (3,418)	\$ (41,687)	\$ (13,021)
Change in market value on available-for-sale marketable securities	(73)	(28)	(57)	(44)
<b>Total comprehensive loss</b>	<b>\$ (29,228)</b>	<b>\$ (3,446)</b>	<b>\$ (41,744)</b>	<b>\$ (13,065)</b>

## 9. Supplemental Disclosure of Cash Flows Information and Non-cash Investing and Financing Activities

No interest or income taxes were paid for the six months ended June 30, 2004 and 2003.

11

## 10. Commitments and Contingencies

### Litigation and Potential Claims

During the months of May and June 2004, numerous complaints were filed in the United States District Court for the District of New Jersey against Genta and certain of our principal officers on behalf of purported classes of our shareholders who purchased our securities during several class periods. The complaints generally allege that we and certain of our principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of advanced melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action complaints in the various actions seek monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. In addition, two shareholder derivative actions have been filed against the directors and certain officers of Genta in New Jersey state and federal courts. Based on facts substantially similar to those asserted in the shareholder class actions, the derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and other violations of New Jersey law. The Company believes these litigations are without merit and will vigorously defend against these suits. Management does not believe that this litigation will have a material adverse impact on the Company's financial results and liquidity.

12

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

### Certain Factors Affecting Forward-Looking Statements Safe Harbor Statement

## Edgar Filing: GENTA INC DE/ - Form 10-Q

The statements contained in this Quarterly Report on Form 10-Q that are not historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. The Company intends that all forward-looking statements be subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect the Company's views as of the date they are made with respect to future events and financial performance, but are subject to many risks and uncertainties, which could cause actual results to differ materially from any future results expressed or implied by such forward-looking statements. Forward-looking statements include, without limitation, statements about:

- FDA approval or failure to approve Genasense®;
- the Company's ability to develop, manufacture and sell its products;
- Aventis and Sanofi-Synthelabo's continued collaboration in the development and commercialization of Genasense®;
- the safety and efficacy of the Company's products;
- the commencement and completion of clinical trials;
- the Company's ability to obtain necessary regulatory approvals;
- the adequacy of the Company's capital resources and the Company's ability to obtain sufficient financing to maintain the Company's planned operations;
- the impact of litigation that has been brought against the Company and its officers and directors;
- the other risks described under Certain Risks and Uncertainties Related to the Company's Business in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003.

The Company does not undertake to update any forward-looking statements.

We make available free of charge on our Internet website (<http://www.genta.com>) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. The content on the Company's website is available for informational purposes only. It should not be relied upon for investment purposes, nor is it incorporated by reference into this Quarterly Report on Form 10-Q.

### Overview

Since its inception in February 1988, Genta has devoted its principal efforts toward drug discovery and research and development. Genta's strategy is to build a product and technology portfolio primarily focused on its cancer-related products. Genta has been unprofitable to date and expects to incur substantial operating losses due to continued requirements for ongoing and planned research and development activities, pre-clinical and clinical testing, manufacturing activities, regulatory activities and establishment of a sales and marketing organization. From our inception to June 30, 2004, we have incurred a cumulative net loss of \$365.0 million. We have experienced significant quarterly fluctuations in operating results and we expect that these fluctuations in revenues, expenses and losses will continue.

Our financial condition and results of operations in 2004 have been and will continue to be significantly affected by FDA action with respect to Genasense®. In late 2003 we filed a NDA for Genasense® to be used in combination with dacarbazine for the treatment of patients with advanced melanoma who have not previously received chemotherapy. The FDA accepted our NDA filing on February 5, 2004 and granted Priority Review status to the application, which targeted an agency action on or before June 8, 2004. On February 10, 2004, we were invited by the FDA to meet on May 3, 2004 with the FDA Oncology Drugs Advisory Committee ( ODAC ). On May 3, 2004 we presented results of our Phase 3 trial of Genasense®

13

---

in combination with dacarbazine versus dacarbazine alone to the ODAC. In the absence of increased survival, the committee voted that the evidence presented did not provide substantial evidence of effectiveness, as measured by response rate and progression-free survival, to outweigh the increased toxicity of administering Genasense® for the treatment of patients with metastatic melanoma who have not received prior chemotherapy. On May 13, 2004 the Company announced that it had withdrawn its NDA. On the same day, the Company initiated a series of steps that are designed to conserve cash in order to focus on Genasense®. The Company reduced its workforce by 85 employees, or approximately 45%, including its field sales employees. The Company also ceased actively marketing Ganite®, its only marketed product.

Genasense® is currently being studied in a number of clinical trials. Together with Aventis and the National Cancer Institute ( NCI ), the Company and its collaborators have completed or are currently running randomized clinical trials in 6 different cancer indications. Highlights of the randomized trials sponsored directly by the Company follow:

The Company expects to report results in the fourth quarter of 2004 from a Phase 3 trial of Genasense® plus chemotherapy in patients with multiple myeloma. This trial is directed at patients whose disease has progressed despite chemotherapy. A total of 224 patients were enrolled and a minimum of one year of follow-up from time of randomization is now available for all patients. The primary goal of this trial is to increase

## Edgar Filing: GENTA INC DE/ - Form 10-Q

the time to progression of disease in patients treated with Genasense® plus high-dose dexamethasone compared with dexamethasone alone, secondary endpoints include overall response, response duration, survival, and safety.

The Company also expects to report results in the fourth quarter of 2004 from a Phase 3 trial of Genasense® plus chemotherapy in patients with chronic lymphocytic leukemia. This trial is directed at patients whose disease has progressed despite chemotherapy. A total of 241 patients were enrolled and a minimum of one year of follow-up for randomization is now available in all patients. The primary goal of this trial is to increase the proportion of patients who achieve a complete (or nodular partial) response after treatment with Genasense® plus fludarabine/cyclophosphamide compared with fludarabine/cyclophosphamide alone.

Successful results on either or both trials may enable the Company to file a NDA with the FDA. If the FDA approves the NDA and qualifies our contract manufacturer, (Avecia), then Aventis (Genta's commercialization partner) will begin to market the product in the United States, Avecia will begin to manufacture the product, and Genta will sell the product to Aventis. Genta will also earn a royalty from Aventis on all sales of Genasense®.

Two other randomized trials are being conducted by either the Company or the Cancer and Leukemia Group B ( CALGB ), a major NCI-sponsored oncology cooperative group. These trials differ from previous studies in that they were not prospectively reviewed by FDA for registration suitability prior to initiation. Details of these trials are as follows:

During June 2004, Genta completed enrollment in a randomized trial of Genasense® plus docetaxel in patients with non-small cell lung cancer. The study is jointly sponsored by Genta and Aventis. Patients who have failed front-line chemotherapy were eligible for randomization into this study. Patients were to receive a standard dose of docetaxel and were randomly assigned to receive Genasense® or no additional therapy. A total of 298 patients were enrolled into this study. The primary objective is to increase overall survival in patients treated with Genasense® plus chemotherapy compared with patients treated with chemotherapy alone. Key secondary objectives include comparisons of progression-free survival and objective response.

The CALGB is running a trial in previously untreated patients with acute myeloid leukemia who are over the age of 60. All patients in this trial receive standard chemotherapy with daunorubicin and cytarabine and they are randomly assigned to receive additional treatment with Genasense® or no other treatment. This trial is currently projected to enroll up to approximately 500 patients. As yet, the CALGB has not released expectations for enrollment completion. The primary endpoint is overall survival.

14

Two oncology cooperative groups, including a large European group (EORTC) and the CALGB, are conducting exploratory randomized trials, as follows:

During the second half of 2004, the Company anticipates completing enrollment in a randomized trial of Genasense® plus chemotherapy in patients with small cell lung cancer. The trial evaluates patients with extensive disease who have not previously received chemotherapy. The trial will include approximately 55 patients and randomly assigns patients to receive Genasense® plus chemotherapy with carboplatin and etoposide or chemotherapy alone. The endpoint of the trial is to determine the proportion of patients who have survived at least twelve months from the date of randomization. Given these timelines, the minimum follow-up is currently projected to conclude during 2005.

A randomized study in patients with hormone-refractory prostate cancer who have not previously received chemotherapy is also being conducted. In this study, all patients receive standard therapy with docetaxel and are randomly assigned to receive Genasense® or no other treatment. The current sample size is projected at 102 patients; the primary objective is to compare response rates.

### Results of Operations for the Three Months Ended June 30, 2004 and 2003

(\$ thousands)	<b>Summary Operating Results</b>			
	<b>For the three months ended June 30,</b>			
	<b>Increase (Decrease)</b>			
	<b>2004</b>	<b>\$</b>	<b>%</b>	<b>2003</b>
Revenues:				
Product sales - net	\$ 251	\$ 251	100%	\$ -
License fees and royalties	261	(15)	(5)%	276

Edgar Filing: GENTA INC DE/ - Form 10-Q

Development funding	1,049	5	-%	1,044
Net revenues	1,561	241	18%	1,320
Cost of goods sold	52	52	100%	-
Gross margin	1,509	189	14%	1,320
Costs and expenses:				
Research and development (including non-cash compensation expense of \$52 for the three months ended June 30, 2004 and June 30, 2003)	28,945	10,782	59%	18,163
Selling, general and administrative (including non-cash compensation expense of \$21 and \$92 for the three months ended June 30, 2004 and June 30, 2003, respectively)	10,284	4,061	65%	6,223
Total costs and expenses - gross	39,229	14,843	61%	24,386
Less: Aventis reimbursement	(8,531)	10,902	56%	(19,433)
Total costs and expenses - net	30,698	25,745	520%	4,953
Other income, principally net interest income	34	(181)	(84)%	215
Net loss	\$ (29,155)	\$ (25,737)	(753)%	\$ (3,418)

Net Revenues

Net revenues, consisting of license fees and royalties, development funding and product sales were \$1.6 million for the three months ended June 30, 2004 compared to \$1.3 million in for the three months ended June 30, 2003. The increase resulted from sales of Ganite®, which we ceased actively marketing in May 2004. License fees and development funding revenues are generated by the initial \$10.0 million licensing fee and \$40.0 million development funding received from Aventis in 2002 under the Collaborative Agreement while royalties are generated by non-exclusive sub-license agreements involving antisense technology. The initial payments received from Aventis are being recognized over the original estimated useful life of the related first-to-expire patent of 115 months.

15

Research and Development Expenses

Research and development expenses before reimbursement were \$28.9 million for the three months ended June 30, 2004 compared to \$18.2 million from the same period one year ago. Approximately \$27.4 million or 95% of research and development expenses before reimbursement were incurred on the Genasense® project for the three months ended June 30, 2004. In May, approximately \$7.0 million of viald Genasense® product, which had been produced to be commercial inventory, was expensed, as the vials will now be used in clinical trials. Also, in accordance with accounting practice, \$11.7 million of Genasense® bulk drug substance was expensed. This material can be used to produce commercial supplies of Genasense® drug product should one of the pending clinical trials be positive and form the basis for a Genasense NDA submission. For the three months ended June 30, 2004 and 2003, \$9.0 million and \$19.8 million, respectively, of our research and development expenses are reimbursable pursuant to our collaborative agreement with Aventis, with a net expense reimbursement of \$8.5 million expected to be paid by Aventis in the third quarter of 2004. In May, as a part of the Company's reduction in workforce, the Company eliminated 27 positions classified as research and development positions, incurring severance expenses of approximately \$273 thousand. Research and development expenses for severance committed to in May that will be paid after June 30 were approximately \$56 thousand.

In July, Genta closed its laboratory operations in Salt Lake City, which had originated in the August 2003 acquisition of Salus Therapeutics, Inc. With the elimination of its Salt Lake City operations, the May reduction in staff and the elimination of most programs other than Genasense®-related programs, research and development expenses over future quarters are expected to be below prior-year levels. However, purchases of drug material for clinical purposes and other non-routine activity may result in fluctuations in any one particular quarter.

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are not reasonably estimable. Results from clinical trials may not be favorable. Data from clinical trials are subject to varying interpretation and may be deemed insufficient by the regulatory bodies reviewing

## Edgar Filing: GENTA INC DE/ - Form 10-Q

applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

### Selling, general and administrative expenses

Selling, general and administrative expenses were \$10.3 million for the three months ended June 30, 2004 compared to \$6.2 million for the three months ended June 30, 2003. Expenses substantially increased due to the existence of a sales force, sales activities for Ganite<sup>®</sup>, and a larger administrative staff through May. In May, the company eliminated its sales force and reduced other administrative positions, incurring severance expenses of \$664 thousand. Selling, general and administrative expenses for severance committed to in May that will be paid after June 30 were \$171 thousand. There were no sales and marketing related expenses reimbursable at 100% pursuant to our collaborative agreement with Aventis for the three months ended June 30, 2004, as sales and marketing related expenses related to Genasense<sup>®</sup> are incurred by, billed to and paid by Aventis.

In addition to eliminating its sales force, the Company withdrew marketing and other support for Ganite<sup>®</sup> and began exploring its strategic options as they relate to Ganite<sup>®</sup>. The elimination of the sales force, reduction of other administrative positions and cessation of marketing support for Ganite<sup>®</sup> is expected to lead to lower selling, general and administrative expenses in future quarters.

During the months of May and June 2004, numerous complaints were filed in the United States District Court for the District of New Jersey against Genta and certain of our principal officers on behalf of purported classes of our shareholders who purchased our securities during several class periods. The complaints generally allege that we and certain of our principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense<sup>®</sup> for the treatment of advanced melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action

16

complaints in the various actions seek monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. In addition, two shareholder derivative actions have been filed against the directors and certain officers of Genta in New Jersey state and federal courts. Based on facts substantially similar to those asserted in the shareholder class actions, the derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and other violations of New Jersey law. All of these actions are in their earliest stages and we intend to defend them vigorously.

Under Genta's directors and officers' liability insurance coverage, the Company is liable for the first \$1.0 million of legal expenses. As it is reasonably certain that the Company will incur these expenses, \$1.0 million was recorded during the three months ended June 30, 2004.

### Aventis Reimbursement

Under the Collaborative Agreement with Aventis, Aventis will pay 75% of U.S. NDA-directed development costs incurred by either Genta or Aventis and 100% of all other development, marketing and sales costs incurred within the U.S. and elsewhere, as subject to the Collaborative Agreement. A breakdown of the various third-party, drug supply costs and internal costs of scientific and technical personnel, ( Full-Time Equivalents or FTE's ) that Aventis is required to reimburse under our collaborative agreement with Aventis, follows:

(\$ thousands)	Three months ended June 30,	
	2004	2003
Reimbursement to Genta		
Third-party costs	\$ 4,589	\$ 8,822
Drug supply costs	2,837	9,192
FTE's	1,604	1,793
	9,030	19,807
Reimbursement to Aventis	(499)	(374)
	\$ 8,531	\$ 19,433



Edgar Filing: GENTA INC DE/ - Form 10-Q

Purchases of drug material for clinical purposes are expensed as incurred and are not reimbursable pursuant to our collaborative agreement with Aventis until they are used in clinical trials. Reimbursement to Aventis consists of our 25% share of third party costs incurred by Aventis and internal costs of Aventis's scientific and technical personnel.

Other Income

Net other income for the three months ended June 30, 2004 declined \$0.2 million, or 84% from the comparable period in 2003, principally as a result of lower investment balances.

Net Loss

Genta incurred a net loss of \$29.2 million, or \$0.37 per share, for the three months ended June 30, 2004, compared to a net loss of \$3.4 million, or \$0.05 per share, for the three months ended June 30, 2003. The increase in net loss and per share net loss to common shareholders was primarily due to the reclassification of inventory to research and development expense, lower Aventis reimbursement of research and development expenses and higher selling, general and administrative expenses described above.

17

**Results of Operations for the Six Months Ended June 30, 2004 and 2003**

(\$ thousands)	Summary Operating Results For the six months ended June 30,			
	Increase (Decrease)			2003
	2004	\$	%	
<b>Revenues:</b>				
Product sales net	\$ 624	\$ 624	100%	\$ -
License fees and royalties	522	(20)	(4)%	542
Development funding	2,097	10	-%	2,087
<b>Net revenues</b>	<b>3,243</b>	<b>614</b>	<b>23%</b>	<b>2,629</b>
Cost of goods sold	146	146	100%	-
<b>Gross margin</b>	<b>3,097</b>	<b>468</b>	<b>18%</b>	<b>2,629</b>
<b>Costs and expenses:</b>				
Research and development (including non-cash compensation expense of \$104 for the six months ended June 30, 2004 and June 30, 2003)	41,297	7,625	23%	33,672
Selling, general and administrative (including non-cash compensation expense of \$39 and \$184 for the six months ended June 30, 2004 and June 30, 2003, respectively)	19,507	8,412	76%	11,095
<b>Total costs and expenses - gross</b>	<b>60,804</b>	<b>16,037</b>	<b>36%</b>	<b>44,767</b>
Less: Aventis reimbursement	(15,964)	12,626	44%	(28,590)
<b>Total costs and expenses - net</b>	<b>44,840</b>	<b>28,663</b>	<b>177%</b>	<b>16,177</b>
Other income, principally net interest income	56	(471)	(89)%	527
<b>Net loss</b>	<b>\$ (41,687)</b>	<b>\$ (28,666)</b>	<b>(220)%</b>	<b>\$ (13,021)</b>

Net Revenues

## Edgar Filing: GENTA INC DE/ - Form 10-Q

Net revenues, consisting of license fees and royalties, development funding and product sales were \$3.2 million for the six months ended June 30, 2004 compared to \$2.6 million in for the six months ended June 30, 2003. The increase resulted from sales of Ganite<sup>®</sup>, which we ceased actively marketing in May 2004. License fees and development funding revenues are generated by the initial \$10.0 million licensing fee and \$40.0 million development funding received from Aventis in 2002 under the Collaborative Agreement while royalties are generated by non-exclusive sub-license agreements involving antisense technology. The initial payments received from Aventis are being recognized over the original estimated useful life of the related first-to-expire patent of 115 months.

### Research and Development Expenses

Research and development expenses before reimbursement were \$41.3 million for the six months ended June 30, 2004 compared to \$33.7 million for the six months ended June 30, 2003. Approximately \$38.2 million or 92% of research and development expenses before reimbursement were incurred on the Genasense<sup>®</sup> project for the six months ended June 30, 2004. Of the \$41.3 million in research and development expenses for the six months ended June 30, 2004, \$16.9 million is reimbursable pursuant to our collaborative agreement with Aventis, with a net expense reimbursement of \$8.5 million expected to be paid by Aventis in the third quarter of 2004.

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are not reasonably estimable. Results from clinical trials may not be favorable. Data from clinical trials are subject to varying interpretation and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

18

### Selling, general and administrative expenses

Selling, general and administrative expenses were \$19.5 million for the six months ended June 30, 2004 compared to \$11.1 million for the six months ended June 30, 2003. Expenses substantially increased due to the existence of a sales force through May, Ganite<sup>®</sup> selling activities through May, a larger administrative staff through May and the \$1.0 million legal charge related to the class-action lawsuits.

### Aventis Reimbursement

Under the Collaborative Agreement with Aventis, Aventis will pay 75% of U.S. NDA-directed development costs incurred by either Genta or Aventis and 100% of all other development, marketing and sales costs incurred within the U.S. and elsewhere as subject to the Collaborative Agreement. A breakdown of the various third-party, drug supply costs and internal costs of scientific and technical personnel, ( Full-Time Equivalents or FTE s ) that Aventis is required to reimburse under our collaborative agreement with Aventis, follows:

(\$ thousands)	Six months ended June 30,	
	2004	2003
Reimbursement to Genta		
Third-party costs	\$ 10,953	\$ 14,870
Drug supply costs	2,593	11,240
FTE s	3,334	3,333
Amount due to Genta	16,880	29,443
Reimbursement to Aventis	(916)	(853)
Net reimbursement to Genta	\$ 15,964	\$ 28,590

Reimbursement to Aventis is comprised of our 25% share of third party costs incurred by Aventis and internal costs of Aventis s scientific and technical personnel.

### Other Income

## Edgar Filing: GENTA INC DE/ - Form 10-Q

Net other income for the six months ended June 30, 2004 declined \$0.5 million, or 89% from the comparable period in 2003, principally as a result of lower investment balances and higher borrowings from Aventis.

### Net Loss

Genta incurred a net loss of \$41.7 million, or \$0.53 per share, for the three months ended June 30, 2004, compared to a net loss of \$13.0 million, or \$0.18 per share, for the three months ended June 30, 2003. The increase in net loss and per share net loss to common shareholders was primarily due to the reclassification of inventory to research and development expense, lower Aventis reimbursement of research and development expenses and higher selling, general and administrative expenses described above.

### **Liquidity and Capital Resources**

At June 30, 2004, the Company had cash, cash equivalents and marketable securities totaling \$50.2 million compared to \$82.9 million at December 31, 2003.

During the first six months of 2004, cash flow used in operating activities was \$31.4 million, primarily resulting from a net loss of \$29.9 million. The Company had proceeds of \$59.2 million from the sale of marketable securities.

19

---

At June 30, 2004, the Company had \$35.5 million outstanding on a line of credit that was issued in connection with an amendment, dated March 14, 2003, to the Collaborative Agreement that established a line of credit related to the development, manufacturing and commercialization of Genasense<sup>®</sup> ( Aventis Line of Credit ). Of the \$35.5 million, \$35.0 million is recorded as short-term debt and \$0.5 million is recorded as accrued interest. This revolving debt is considered an advance against both past and future costs and the borrowing base is adjusted on a monthly basis. At the time of Genasense<sup>®</sup> NDA approval in the U.S., any outstanding balance will be offset against the first milestone payment that is due to Genta from Aventis. The terms of the Aventis Line of Credit provide for a favorable interest rate, which is set two days prior to the first day of each calendar quarter. The Aventis Line of Credit terminates upon the earlier of (1) the receipt of Genasense<sup>®</sup> NDA approval in the U.S., (2) notice given by either Genta or Aventis of the termination of the Collaborative Agreement, (3) notice given by Genta of the termination of the Aventis Line of Credit, (4) various default provisions or (5) December 31, 2004. Depending on the circumstances, repayment is due immediately or up to six months after the termination of the Aventis Line of Credit. As security for the repayment of the Aventis Line of Credit, Genta has granted Aventis a security interest in all of its accounts and/or other rights to payments under the Collaborative Agreement as well as all inventory related to Genasense<sup>®</sup>.

As a result of the reclassification of the \$35.0 million outstanding under the Aventis Line of Credit as short-term debt, working capital as of June 30, 2004 was \$1.4 million.

Although no assurances can be expressed, management believes that at the current rate of spending, after giving effect to our recent cost-control steps and coupled with our Aventis relationship, the Company should have sufficient cash funds to maintain its present operations through mid-2005. Our principal expenditures relate to our research and development activities, primarily focused on Genasense<sup>®</sup>, which include our ongoing and future clinical trials. We expect these expenditures to continue. If we obtain NDA approval of Genasense<sup>®</sup>, Aventis milestone payments and other funding available to the Company should provide sufficient capital resources. It is likely that the Company will seek additional external financing sometime in 2005.

If we obtain NDA approval of Genasense<sup>®</sup> we also anticipate seeking additional product development opportunities through potential acquisitions or investments. Such acquisitions or investments may consume cash reserves or require additional cash or equity. Our working capital and additional funding requirements will depend upon numerous factors, including: (i) the progress of our research and development programs; (ii) the timing and results of pre-clinical testing and clinical trials; (iii) the level of resources that we devote to sales and marketing capabilities; (iv) technological advances; (v) the activities of competitors; (vi) our ability to establish and maintain collaborative arrangements with others to fund certain research and development efforts, to conduct clinical trials, to obtain regulatory approvals and, if such approvals are obtained, to manufacture and market products and (vii) legal costs and the outcome of outstanding legal proceedings.

### **Recent Accounting Pronouncements**

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Liabilities, Equity, or Both*. This limited scope statement prescribes changes to the classification of mandatorily redeemable preferred stock, preferred securities of subsidiary trusts and the accounting for forward purchase contracts issued by a company in its own stock among other issues. SFAS No. 150 does not apply to features that are embedded in a financial instrument that is not a derivative in its entirety and requires all preferred securities of subsidiary trusts to be classified as debt on the consolidated balance sheet and the related dividends as interest expense. The Company adopted

the provisions of SFAS No. 150, including the deferral of certain effective dates as a result of the provisions of FASB Staff Position 150-3, *Effective Date, Disclosures, and Transition for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests Under FASB Statement No. 150 Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. The adoption of this statement did not have any impact on the Company's results of operations, financial position or cash flows.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively

20

---

---

referred to as derivatives) and for hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. In particular, SFAS No. 149 (1) clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative discussed in paragraph 6(b) of SFAS No. 133, (2) clarifies when a derivative contains a financing component, (3) amends the definition of an underlying to conform it to language used in FIN 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, and (4) amends certain other existing pronouncements. SFAS No. 149 is to be applied prospectively to contracts entered into or modified after June 30, 2003, with certain exceptions, and for hedging relationships designated after June 30, 2003. The adoption of this statement did not have any impact on the Company's results of operations, financial position or cash flows.

In January 2003, the FASB issued Interpretation No. 46 *Consolidation of Variable Interest Entities*. This interpretation defines when a business must consolidate a variable interest entity. This interpretation applies immediately to variable interest entities created after January 31, 2003 and became effective for all other transactions as of July 1, 2003. However, in October 2003 the FASB permitted companies to defer the July 1, 2003 effective date to December 31, 2003. Again in December 2003, the FASB permitted companies to defer the December 31, 2003 effective date, in certain circumstances, to the first interim or annual period ending after March 15, 2004. The Company has determined that it is not reasonably probable that it will be required to consolidate or disclose information about a variable interest entity.

### **Item 3. *Quantitative and Qualitative Disclosures about Market Risk***

Our carrying values of cash, marketable securities, accounts payable, accrued expenses and debt are a reasonable approximation of their fair value. The estimated fair values of financial instruments have been determined by us using available market information and appropriate valuation methodologies (see Note 2 to our financial statements).

However, considerable judgment is required in interpreting market data to develop the estimates of fair value. Accordingly, the estimates utilized in the consolidated financial statements are not necessarily indicative of the amounts that we could realize in a current market exchange. We have not entered into, and do not expect to enter into, financial instruments for trading or hedging purposes. We do not currently anticipate entering into interest rate swaps and/or similar instruments.

Genta's primary market risk exposure with regard to financial instruments is to changes in interest rates, which would impact interest income earned on such instruments. We have no material currency exchange or interest rate risk exposure as of June 30, 2004. Therefore there will be no ongoing exposure to material adverse effect on our business, financial condition or results of operation for sensitivity to changes in interest rates or to changes in currency exchange rates.

### **Item 4. *Controls and Procedures***

**Evaluation of disclosure controls and procedures.** Genta's Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of the Company's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report (the Evaluation Date), have concluded that as of the Evaluation Date, our disclosure controls and procedures were adequate and designed to ensure that material information relating to the Company would be made known to them by others within the Company.

**Changes in internal controls.** There were no significant changes in our internal controls or, to our knowledge, in other factors that could significantly affect the Company's disclosure controls and procedures during the period covered by this report.

21

---

---

**PART II OTHER INFORMATION****Item 1. Legal Proceedings**

During the months of May and June 2004, numerous complaints were filed in the United States District Court for the District of New Jersey against Genta and certain of our principal officers on behalf of purported classes of our shareholders who purchased our securities during several class periods. The complaints generally allege that we and certain of our principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of advanced melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action complaints in the various actions seek monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. In addition, two shareholder derivative actions have been filed against the directors and certain officers of Genta in New Jersey state and federal courts. Based on facts substantially similar to those asserted in the shareholder class actions, the derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and other violations of New Jersey law. All of these actions are in their earliest stages and we intend to defend them vigorously.

**Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities**

(c) During the three months ended June 30, 2004, the Company issued and sold 2,571,704 shares of Common Stock upon exercise of warrants without registration in reliance upon Section 4(2) of the Securities Act.

**Item 4. Submission of Matters to a Vote of Security Holders**

(a) The Company held its Annual Meeting of Stockholders (the Annual Meeting) on June 23, 2004.

(b) Proxies for the meeting were solicited pursuant to Regulation 14A of the Exchange Act. There was no solicitation in opposition to the Board of Directors' nominees for directors listed in the definitive proxy statement of the Company dated as of April 30, 2004. All of the Board of Directors' nominees were elected.

(c) Briefly described below is each matter voted upon at the Annual Meeting.

(i) Election of eight directors. Total combined voting power of the shares of Common Stock voted and withheld for the election of each director was as follows:

Directors	Votes For	Withheld
Raymond P. Warrell, Jr., M.D.	63,647,091	4,618,699
Jerome E. Groopman, M.D.	64,063,871	4,201,919
Betsy McCaughey, Ph.D.	64,068,166	4,197,624
Peter T. Tattle	64,079,281	4,186,509
Daniel D. Von Hoff, M.D.	63,812,826	4,452,964
Harlan J. Wakoff	64,045,985	4,219,805
Douglas G. Watson	63,765,394	4,500,396
Michael S. Weiss	63,784,352	4,481,438

(ii) Approval of an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of Common Stock available for issuance. The result of the voting was as follows:

For:	62,403,291 votes
Against:	5,275,493 votes
Abstain:	587,006 votes

22

(iii) Approval of an amendment to the Company's 1998 Stock Incentive Plan to increase the number of shares authorized for issuance thereunder. The result of the voting was as follows:

For:	30,432,857 votes
Against:	7,359,562 votes
Abstain:	957,746 votes

## Edgar Filing: GENTA INC DE/ - Form 10-Q

(iv) Approval of an amendment to the Company's Non-Employee Director's 1998 Stock Option Plan with respect to the annual stock options granted under the plan. The result of the voting was as follows:

For:	31,286,433 votes
Against:	6,813,368 votes
Abstain:	650,364 votes

(v) Ratification of the selection of Deloitte & Touche LLP as the Company's independent auditors for the fiscal year ending December 31, 2004. The result of the voting was as follows:

For:	66,893,850 votes
Against:	760,611 votes
Abstain:	611,329 votes

### Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

Exhibit Number	Description of Document
3.1.a	Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1995, Commission File No. 0-19635)
3.1.b	Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i) to the Company's Current Report on Form 8-K filed on February 28, 1997, Commission File No. 0-19635)
3.1.c	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.d	Amended Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.e	Certificate of Increase of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).5 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.f	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)
3.1.g	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)
3.1.h	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).8 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)

23

Exhibit Number	Description of Document
3.1.i	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.i to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)
3.1.j	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.j to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)
3.1.k	Certificate of Amendment of Restated Certificate of Incorporation of the Company
3.2	Amended and Restated Bylaws of the Company
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

24

**SIGNATURES**

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

Date: August 6, 2004

Genta Incorporated

/s/ RAYMOND P. WARRELL, JR., M.D.

Raymond P. Warrell, Jr., M.D.  
Chairman and Chief Executive Officer

Date: August 6, 2004

/s/ WILLIAM P. KEANE

William P. Keane  
Vice President, Chief Financial Officer and  
Corporate Secretary

**Exhibit Index**

Exhibit Number	Description of Document	Sequentially Numbered Pages
3.1.a	Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1995, Commission File No. 0-19635)	
3.1.b	Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i) to the Company's Current Report on Form 8-K filed on February 28, 1997, Commission File No. 0-19635)	
3.1.c	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
3.1.d	Amended Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
3.1.e	Certificate of Increase of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).5 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
3.1.f	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)	
3.1.g	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to	

## Edgar Filing: GENTA INC DE/ - Form 10-Q

	Exhibit 3(i).3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)
3.1.h	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).8 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.i	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.i to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)
3.1.j	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.j to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)
3.1.k	Certificate of Amendment of Restated Certificate of Incorporation of the Company
3.2	Amended and Restated Bylaws of the Company
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

26

---

### (b) Reports on Form 8-K.

On April 30, 2004 the Company furnished a current report on Form 8-K disclosing a press release regarding the Company's first quarter 2004 financial results.

On April 30, 2004 the Company filed a current report on Form 8-K disclosing a press release that announced that the United States Food and Drug Administration (FDA) had posted on its website briefing documents for the Oncologic Drugs Advisory Committee (ODAC) meeting on Monday, May 3, 2004.

On May 3, 2004 the Company filed a current report on form 8-K disclosing a press release that announced that Genta and Aventis had presented results of their Phase 3 trial of Genasense® in combination with dacarbazine versus dacarbazine alone at the ODAC. On May 13, 2004 the Company filed a current report on Form 8-K disclosing a press release that announced that the Company had initiated a series of steps that are designed to conserve cash in order to focus on Genasense®.

On May 14, 2004 the Company filed a current report on Form 8-K disclosing a press release that announced that the Company had notified the U.S. Food and Drug Administration (FDA) of its decision to withdraw a New Drug Application (NDA) for Genasense®.

On June 1, 2004 the Company filed a current report on Form 8-K disclosing a press release that announced that Genta and Aventis had terminated the Expanded Access Program (EAP) for Genasense® in combination with dacarbazine (DTIC).

On June 7, 2004 the Company filed a current report on Form 8-K disclosing a press release that announced the presentation of updated results from its Phase 3 randomized trial of Genasense® plus dacarbazine in patients with advanced melanoma.

On June 21, 2004 the Company filed a current report on Form 8-K disclosing a press release that announced that the Company would provide an audio webcast of its 2004 Annual Meeting of Shareholders.

27



