GENTA INC DE/
Form 10-Q
November 09, 2004

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

FORM 10-Q

(Mark One)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2004

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number 0-19635

GENTA INCORPORATED

(Exact name of Registrant as specified in its charter)

Delaware	33-0326866
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
Two Connell Drive Berkeley Heights, NJ	07922
(Address of principal executive offices)	**(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 þ No o

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 þ No o

As of October 31, 2004, the registrant had 80,358,215 shares of common stock outstanding.

Genta Incorporated
INDEX TO FORM 10-Q

GENTA INCORPORATED
CONSOLIDATED BALANCE SHEETS

(In thousands, except par value data)

ASSETS	September 30, 2004	December 31, 2003
	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 30,930	$ 25,153
Marketable securities (Note 3)	5,773	57,776
Accounts receivable - net	4,951	16,675
Notes receivable	200	200
Inventory (Note 4)	1,016	518
Prepaid expenses and other current assets	784	3,313
Total current assets	43,654	103,635
Property and equipment, net (Note 5)	3,382	4,917
Notes receivable (Note 10)		3,542
Intangibles, net (Note 6)	430	863
Prepaid royalties	1,268	1,268
Other assets	1,631	450
Total assets	$ 50,365	$ 114,675
LIABILITIES AND STOCKHOLDERS DEFICIT/EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 18,073	$ 15,319
Notes payable	279	748
Deferred revenues, current portion	5,273	5,287
Short term debt (Note 7)	19,001	
Total current liabilities	42,626	21,354
Deferred revenues	32,154	36,067
Convertible debt (Note 8)	10,000	10,000
Long term debt (Note 7)		35,000
Total liabilities	84,780	102,421
Commitments and contingencies (Note 11)		
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 September 30, 2004 and December 31, 2003 respectively		
Common stock, $.001 par value; 155,000 shares authorized, 80,358 and 75,927 shares issued and outstanding at September 30, 2004 and December 31, 2003, respectively	80	76
Additional paid-in capital	336,189	335,713
Deferred financing costs	(48)	
Accumulated deficit	(370,567)	(323,299)

Deferred compensation	(52)	(261)
Accumulated other comprehensive (loss)/income	(17)	25
Total stockholders (deficit)/equity	(34,415)	12,254
Total liabilities and stockholders deficit/equity	$ 50,365	$ 114,675

See accompanying notes to consolidated financial statements

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)	Three Months Ended September 30, 2004	Three Months Ended September 30, 2003	Nine Months Ended September 30, 2004	Nine Months Ended September 30, 2003
	(Unaudited)		(Unaudited)	
Revenues:				
Product sales - net	$ 87	$	$ 711	$
License fees and royalties	261	253	783	795
Development funding	1,049	1,043	3,145	3,130
Total revenues	1,397	1,296	4,639	3,925
Cost of goods sold	19		165	
Provision for excess inventory	693		693	
Total cost of goods sold	712		858	
Gross margin	685	1,296	3,781	3,925
Costs and expenses:				
Research and development (including non-cash compensation expense of $53 and $52 for the three months ended September 30, 2004 and 2003, respectively and $158 and $157 for the nine months ended September 30, 2004 and 2003, respectively)	20,643	21,061	61,940	54,733
Selling, general and administrative (including non-cash compensation expense of $11 and $22 for the three months ended September 30, 2004 and 2003, respectively and $50 and $205 for the nine months ended September 30, 2004 and 2003, respectively)	4,721	9,309	24,228	20,403
Total costs and expenses - gross	25,364	30,370	86,168	75,136
Aventis reimbursement	(20,489)	(11,760)	(36,453)	(40,350)
Total costs and expenses - net	4,875	18,610	49,715	34,786
Loss on disposition of property and equipment	(1,254)	(2)	(1,254)	(2)
Other (expense)/income	(136)	151	(79)	677
Net loss	$ (5,580)	$ (17,165)	$ (47,267)	$ (30,186)
Net loss per basic and diluted share	$ (0.07)	$ (0.23)	$ (0.60)	$ (0.40)
Shares used in computing net loss per basic and diluted share	80,358	75,409	78,758	74,699

See accompanying notes to consolidated financial statements

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Nine Months Ended September 30, 2004	2003
	(Unaudited)	
Operating activities:		
Net loss	$ (47,267)	$ (30,186)
Items reflected in net loss not requiring cash:		
Depreciation and amortization	2,323	1,666
Loss on disposition of property and equipment	1,254	2
Non-cash reimbursement of research and development expense	(15,541)	
Provision for excess inventory	693	
Compensation expense related to stock options	208	362
Changes in operating assets and liabilities:		
Accounts receivable	10,558	(399)
Inventory	(1,191)	
Notes receivable	3,542	
Accounts payable, accrued expenses and other current liabilities	3,463	(21,270)
Deferred revenue	(3,928)	
Other assets	1,349	(425)
Net cash used in operating activities	(44,537)	(50,250)
Investing activities:		
Purchase of marketable securities	(7,281)	(48,400)
Maturities and sales of marketable securities	59,242	61,052
Purchase of property and equipment	(1,767)	(2,615)
Proceeds from disposition of property and equipment	157	
Payment to stockholders in conjunction with acquisition		(56)
Net cash provided by investing activities	50,351	9,981
Financing activities:		
Borrowings under long-term debt		25,000
Borrowings under note payable	419	
Repayments of note payable	(888)	(490)
Purchase of treasury stock		(303)
Deferred financing costs	(48)	
Issuance of common stock upon exercise of warrants and options	480	2,397
Net cash (used in)/provided by financing activities	(37)	26,604
Increase/(decrease) in cash and cash equivalents	5,777	(13,665)
Cash and cash equivalents at beginning of period	25,153	32,700
Cash and cash equivalents at end of period	$ 30,930	$ 19,035

See accompanying notes to consolidated financial statements

GENTA INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
September 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 in one or more indications. Achievement of profitability for the Company is dependent on the timing of Genasense® regulatory approvals in the U.S. and outside the U.S. A significant source of funds during the last several years has been from the Company s collaboration with Aventis, a member of the sanofi-aventis Group (Aventis) regarding the development and commercialization of Genasense®. On November 8, 2004 the Company received from Aventis notice of termination of the agreements between Genta and Aventis. Pursuant to those agreements, Aventis will continue to support the development of Genasense® for a six-month period lasting until May 8, 2005. The Company is evaluating the impact of the Aventis notice of termination on capital resources.

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 September 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 to 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 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.

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., 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. On November 8, 2004 the Company received from Aventis notice of termination of the agreements between Genta and Aventis. Pursuant to those agreements, Aventis will continue to support the development of Genasense® for a six-month period lasting until May 8, 2005.

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 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 deferred recognition of the initial licensing fee and up-front development funding received from Aventis and recognized these payments on a straight-line basis over the original estimated useful life of the related first-to-expire patent of 115 months. As a result of the notice of termination of the agreements with Aventis, the Company is evaluating the period over which the remaining deferred revenue should be recognized. 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 consist 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.

Property and Equipment

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.*

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:

($ thousands, except per share data)	Three months ended September 30, 2004	Three months ended September 30, 2003	Nine months ended September 30, 2004	Nine months ended September 30, 2003
Net loss applicable to common shares, as reported	$ (5,580)	$ (17,165)	$ (47,267)	$ (30,186)
Add: Equity related employee compensation expense included in reported net income, net of related tax effects	65	74	208	362
Deduct: Total stock-based employee compensation expense determined under fair values based method for all awards, net of related tax effects	(2,455)	(2,119)	(7,254)	(5,508)
Pro forma net loss	$ (7,970)	$ (19,210)	$ (54,313)	$ (35,332)
Net loss per share attributable to common shareholders:				
As reported: Basic and diluted	$ (0.07)	$ (0.23)	$ (0.60)	$ (0.40)
Pro forma: Basic and diluted	$ (0.10)	$ (0.25)	$ (0.69)	$ (0.47)

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 September 30, 2004	Three Months Ended September 30, 2003
Risk-free interest rate	3.5%	2.9%
Dividend yield		
Expected life (years)	4.0	4.0
Volatility	76.6%	64.2%

Net Loss Per Common Share

Net loss per common share for the three and nine months ended September 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 primarily 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):

	September 30, 2004	December 31, 2003
Amortized cost	$ 5,790	$ 57,751
Gross unrealized gains	10	29
Gross unrealized losses	(27)	(4)
Estimated fair value	$ 5,773	$ 57,776

The estimated fair value of each marketable security has been compared to its cost, and therefore, a net unrealized loss of approximately $17 thousand has been recognized in Accumulated other comprehensive income at September 30, 2004.

4. Inventory

Inventories 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):

	September 30, 2004	December 31, 2003
Raw materials	$ 889	$ 189
Work in process		318
Finished goods	127	11
	$ 1,016	$ 518

In May 2004, the Company eliminated its sales force and significantly reduced its marketing support for Ganite®. After evaluating various options, the Company decided during the third quarter to continue selective marketing support of the product and updated its sales projections to reflect that level of support. Based on the new sales projections, the Company recorded in September 2004 a provision for excess Ganite® inventory of approximately $0.7 million. In the event that sales of Ganite® exceed current projections, it is anticipated that the excess drug substance can still be used to produce commercial supplies of Ganite®, as well as vials for future clinical trials.

5. Property and equipment, net

Property and equipment is comprised of the following ($ thousands):

	Estimated Useful Lives	September 30, 2004	December 31, 2003
Computer equipment	3	$ 2,860	$ 3,337
Software	3	3,349	2,632
Furniture and fixtures	5	936	1,009
Leasehold improvements	Life of lease	443	767
Equipment	5	166	299
		7,754	8,044
Less accumulated depreciation and amortization		(4,372)	(3,127)
		$ 3,382	$ 4,917

In August 2004, the Company completed the closure of its research facility in Salt Lake City, Utah, sold all related equipment and assigned its lease on this facility to another company. Additionally, the Company disposed of excess equipment at its corporate headquarters. As a result of these actions, the Company recorded a loss on disposition of property and equipment of approximately $1.3 million for the three months ended September 30, 2004.

6. Intangibles, net

Intangible assets consist of the following ($ thousands):

	September 30, 2004	December 31, 2003
Patent and patent applications	$ 3,992	$ 3,992
Less accumulated amortization	(3,562)	(3,129)
	$ 430	$ 863

Future amortization expense related to intangibles at September 30, 2004 is as follows ($ thousands):

	Amortization Expense
2004	144
2005	286
Total	$ 430

7. Short term debt

This revolving debt 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® (Line of Credit). The debt is considered an advance against both past and future costs and the borrowing base is adjusted on a monthly basis. Prior to June 30, 2004 the Line of Credit was long term debt and beginning June 30, 2004, it was classified as short term debt. During the three months ended September 30, 2004, as a result of certain non-cash transactions, the Company reduced amounts owed under the Line of Credit by $16.0 million. As a result of Aventis purchase commitments to Genta, both companies agreed in the third quarter that Genta would supply $15.5 million of vialed Genasense® drug product and Genasense® bulk drug substance to Aventis and the material was supplied in September. This amount is included in the Company s Consolidated Statement of Operations as Aventis reimbursement. The companies agreed to offset amounts owed under the Line of Credit by $14.8 million and accrued interest on the Line of Credit by $0.7 million.

The terms of the Line of Credit provide for a favorable interest rate, which is set two days prior to the first day of each calendar quarter. The Line of Credit terminates upon the earlier of (1) the receipt of Genasense® 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 Line of Credit, (4) various default provisions or (5) December 31, 2004. On November 8, 2004 the Company received from Aventis notice of termination of the agreements between Genta and Aventis. With the Aventis notice of termination, Genta cannot borrow additional funds and the Line of Credit must be repaid no later than May 8, 2005. Aventis is able to retain payments due to Genta and apply them against any balance on the Line of Credit until the Line of Credit is repaid. As security for the repayment of the 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®.

8. Convertible debt

At September 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 (the 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. As of September 30, 2004, the Company has accrued interest of $1.4 million on the Aventis note. On November 8, 2004 the Company received from Aventis notice of termination of the agreements between Genta and Aventis. Under the terms of one of the Genasense® alliance agreements, if Aventis elects to terminate the agreement, which it has done, Aventis is required to forgive the $10 million principal balance and any

accrued interest.

9. Comprehensive loss

An analysis of comprehensive loss is presented below:

($ in thousands)	Three months ended September 30, 2004	Three months ended September 30, 2003	Nine months ended September 30, 2004	Nine months ended September 30, 2003
Net loss	$ (5,580)	$ (17,165)	$ (47,267)	$ (30,186)
Change in market value on available-for-sale marketable securities	15	42	(42)	(2)
Total comprehensive loss	$ (5,565)	$ (17,123)	$ (47,309)	$ (30,188)

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

During the three months ended September 30, 2004, as a result of certain non-cash transactions, the Company reduced amounts owed under the Line of Credit by $16.0 million. During this time period, the Company shipped $15.5 million of vialed Genasense® drug product and Genasense® bulk drug substance to Aventis. The companies agreed to offset amounts owed under the Line of Credit by $14.8 million and accrued interest on the Line of Credit by $0.7 million.

Based on negotiations between the Company and Avecia, our contract manufacturer, amounts owed to us under a note receivable from Avecia were offset against amounts payable to Avecia, resulting in a non-cash reduction to Note receivable and Accounts payable and accrued expenses of approximately $4.2 million.

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

11. Commitments and Contingencies

Litigation and Potential Claims

In 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, three 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. Subsequent Events

On November 8, 2004 the Company received from Aventis notice of termination of the agreements between Genta and Aventis regarding the development and commercialization of Genasense®. Pursuant to those agreements, Aventis will continue to support the development of Genasense® for a six-month period lasting until May 8, 2005. During this period, the Companies will cooperate to ensure a smooth and orderly transition of the Genasense® program. Genta intends to continue the development of Genasense®. The Company is evaluating the impact of the Aventis notice of termination on capital resources.

On November 8, 2004, the Company reported that the Company's randomized Phase 3 clinical trial of Genasense® (oblimersen sodium) Injection in patients with relapsed or refractory chronic lymphocytic leukemia (CLL) met its primary endpoint. In this study, patients who received Genasense® plus chemotherapy were significantly more likely to achieve a complete or nodular partial remission compared with patients who received chemotherapy alone. As of the data cutoff date, there was no significant difference in key secondary end-points, including time-to-progression and overall survival.

Patients were eligible for this trial if they had failed standard treatment for CLL that had included fludarabine. Two hundred forty one patients were randomized to receive standard chemotherapy with fludarabine and cyclophosphamide with or without Genasense®. The primary objective of the study was to evaluate whether the addition of Genasense® would increase the proportion of patients who attained major objective responses (defined as complete remission or a nodular partial remission). Analysis of study results has shown that the addition of Genasense® to chemotherapy was associated with a statistically significant increase in the major objective response rate compared with the rate observed in patients who were treated with chemotherapy alone. The incidence of certain serious adverse reactions, including but not limited to nausea, fever and catheter-related complications, was increased in patients treated with Genasense®. Reactions leading to death that were specific to the Genasense® treatment group included single episode of renal failure, cytokine release reation, and tumor lysis syndrome.

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

Certain Factors Affecting Forward-Looking Statements Safe Harbor Statement

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:

- the Company s ability to obtain necessary regulatory approval, especially FDA approval or failure to approve Genasense®;
- the safety and efficacy of the Company s products;
- the commencement and completion of clinical trials;
- the Company s ability to develop, manufacture and sell its products;
- 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.

In mid-2004, the Company became aware of an episode of employee misconduct that involved an unauthorized attempt by the employee to analyze data from the Company s Phase 3 trial of Genasense® in patients with chronic lymphocytic leukemia (CLL). The episode was fully investigated by the Company. Two external independent experts separately reviewed reports of that investigation, and the episode was reported by the Company to the FDA. While there can be no assurance, the Company does not currently believe the episode will have a material impact on the analysis or interpretation of the study results, nor that it will affect whether or not the company will receive marketing approval for Genasense® in CLL.

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 September 30, 2004, we have incurred a cumulative net loss of $370.6 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. In the absence of increased survival, the FDA Oncology Drugs Advisory 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 were 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 significantly reduced its marketing support of Ganite®, its only marketed product.

A significant source of funds during the last several years has been provided by the Company s collaboration with Aventis regarding the development and commercialization of Genasense®. On November 8, 2004 the Company received from Aventis notice of termination of the agreements between Genta and Aventis. Pursuant to those agreements, Aventis will continue to support the development of Genasense® for a six-month period lasting until May 8, 2005. The Company is evaluating the impact of the Aventis notice of termination on capital resources and will provide additional information at a later date.

Genasense® is currently being studied in a number of clinical trials. Together with Aventis and various oncology cooperative groups, the Company and its collaborators have completed or are currently running randomized clinical trials in six different cancer indications. Highlights of the randomized trials sponsored directly by the Company follow:

On November 8, 2004, the Company reported that the Company s randomized Phase 3 trial of Genasense® (oblimersen sodium) injection in patients with relapsed of refractory chronic lymphocytic leukemia (CLL) met its primary endpoint. In this study, patients who received Genasense® plus chemotherapy were significantly more likely to achieve a complete or nodular partial remission compared with patients who received chemotherapy alone. As of the data cutoff date, there was no significant difference in key secondary end-points, including time-to-progression and overall survival.

Patients were eligible for this trial if they had failed standard treatment for CLL that had included fludarabine. Two hundred forty one patients were randomized to receive standard chemotherapy with fludarabine and cyclophosphamide with or without Genasense®. The primary objective of the study was to evaluate whether the addition of Genasense® would increase the proportion of patients who attained major objective responses (defined as complete remission or a nodular partial remission). Analysis of study results has shown that the addition of Genasense® to chemotherapy was associated with a statistically significant increase in the major objective response rate compared with the rate observed in patients who were treated with chemotherapy alone. The incident of certain serious adverse reactions, including but not limited to nausea, fever and catheter-related complications, was increased in patients treated with Genasense®. Reactions leading to death that were specific to the Genasense® treatment group included single episodes of renal failure, cytokine release reaction, and tumor lysis syndrome.

Genta plans to discuss the feasibility of submitting a NDA based on these data with the FDA. Study results will be presented at the annual meeting of the American Society of Hermatology (ASH) in San Diego from December 4 through December 7, 2004.

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 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.

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 we expect the product to be marketed in the United States and Avecia to begin to manufacture the product.

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.

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

During the fourth quarter 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.

In addition to these randomized trials, the Company, either under its own sponsorship or in collaboration with Aventis or NCI, is also conducting a number of non-randomized clinical trials in patients with various types of cancer.

The Company had been conducting several clinical trials with Ganite® in order to develop its use as a cancer chemotherapy drug. Most of these trials were terminated in the third quarter 2004. The Company continues to supply Ganite® for one of these clinical trials that is continuing.

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

	Summary Operating Results For the three months ended September 30,			
($ thousands)		Increase (Decrease)		
	2004	**$**	**%**	**2003**
Revenues:				
Product sales net	$ 87	$ 87	100%	$
License fees and royalties	261	8	3%	253
Development funding	1,049	6	1%	1,043
Total revenues	1,397	101	8%	1,296
Cost of goods sold	19	19	100%	
Provision for excess inventory	693	693	100%	
Total cost of goods sold	712	712	100%	
Gross margin	685	(611)	(47)%	1,296
Costs and expenses:				
Research and development (including non-cash compensation expense of $53 and $52 for the three months ended September 30, 2004 and 2003, respectively)	20,643	(418)	(2)%	21,061
Selling, general and administrative (including non-cash compensation expense of $11 and $22 for the three months ended September 30, 2004 and 2003, respectively)	4,721	(4,588)	(50)%	9,309
Total costs and expenses gross	25,364	(5,006)	(16)%	30,370
Less: Aventis reimbursement	(20,489)	(8,729)	(74)%	(11,760)
Total costs and expenses net	(4,875)	13,735	74%	(18,610)
Loss on disposition of property and equipment	(1,254)	(1,252)	(626)%	(2)
Other (expense)/income, principally net interest income	(136)	(287)	(190)%	151

Net loss	$ (5,580)	$ 11,585	68%	$ (17,165)

Total revenues

Total revenues, consisting of license fees and royalties, development funding and product sales were $1.4 million for the three months ended September 30, 2004 compared to $1.3 million for the three months ended September 30, 2003. The increase resulted from sales of Ganite®, for which we significantly reduced marketing support 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. As a result of the notice of termination of the agreements with Aventis, the Company is evaluating the period over which the remaining deferred revenue will be recognized.

Cost of goods sold

Cost of goods sold for the three months ended September 30, 2004 includes a provision for excess Ganite® inventory of approximately $0.7 million. In the event that sales of Ganite® exceed current projections, it is anticipated that the excess drug substance can still be used to produce commercial supplies of Ganite®, as well as vials for future clinical trials.

Research and development expenses

Research and development expenses before reimbursement were $20.6 million for the three months ended September 30, 2004 compared to $21.1 million from the same period one year ago. During the three months ended September 30, 2004, the Company incurred research and development expenses of $13.3 million related to purchases of Genasense® bulk drug substance. This increase was offset by a favorable comparison to the prior-year quarter, where expenses were significantly higher resulting from Genasense® Phase 3 clinical trials and NDA preparation activities. Approximately $20.1 million or 97% of research and development expenses before reimbursement were incurred on the Genasense® project for the three months ended September 30, 2004. For the three months ended September 30, 2004 and 2003, $7.2 million and $15.1 million, respectively, of our research and development expenses are reimbursable pursuant to our collaborative agreement with Aventis, with a net expense reimbursement of $4.9 million.

In August, Genta completed the closure of its research facility in Salt Lake City, which had originated from the August 2003 acquisition of Salus Therapeutics, Inc. As a result, the Company eliminated an additional 15 positions classified as research and development positions, incurring severance expenses of approximately $79 thousand.

With the significant reduction of most programs other than Genasense®-related programs, research and development expenses before reimbursement over future quarters are expected to be below prior-year levels. However, purchases of drug material 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 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 $4.7 million for the three months ended September 30, 2004 compared to $9.3 million for the three months ended September 30, 2003. Expenses substantially decreased due to the May 2004 elimination of the sales force, reduction of other administrative positions and significant reduction of marketing support for Ganite®. There were no sales and marketing related expenses reimbursable at 100% pursuant to our collaborative agreement with Aventis for the three months ended September 30, 2004, as sales and marketing related expenses related to Genasense® are incurred by, billed to and paid by Aventis.

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:

	Three months ended September 30,	
($ thousands)	**2004**	**2003**
Reimbursement to Genta		
Third-party costs	$ 3,982	$ 8,491
Drug supply costs	15,620	1,759
FTE s	1,333	1,942
Amount due to Genta	20,935	12,192
Reimbursement to Aventis	(446)	(432)
Net reimbursement to Genta	20,489	11,760

Purchases of drug material are expensed as incurred and are not reimbursable pursuant to our collaborative agreement with Aventis until they are used in clinical trials. In September 2004 the Company shipped $15.5 million of vialed Genasense® drug product and Genasense® bulk drug substance to Aventis; this material had been expensed in May 2004. The companies agreed to offset amounts owed under the Line of Credit by $14.8 million and accrued interest on the Line of Credit by $0.7 million. 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.

On November 8, 2004 the Company received from Aventis notice of termination of the agreements between Genta and Aventis. Pursuant to those agreements, Aventis will continue to support the development of Genasense® for a six-month period lasting until May 8, 2005.

Loss on disposition of property and equipment

In August 2004 the Company completed the closure of its research facility in Salt Lake City, sold all related equipment and assigned its lease on the facility to another company. Additionally, the Company disposed of excess equipment at its corporate headquarters. As a result of these actions, the Company recorded a loss on disposition of property and equipment of approximately $1.3 million for the three months ended September 30, 2004.

Net loss

Genta incurred a net loss of $5.6 million, or $0.07 per share, for the three months ended September 30, 2004, compared to a net loss of $17.2 million, or $0.23 per share, for the three months ended September 30, 2003. The decrease in net loss and per share net loss to common shareholders was primarily due to the shipment of vialed drug product and bulk drug substance to Aventis and lower selling, general and administrative expenses described above.

Results of Operations for the Nine Months Ended September 30, 2004 and 2003

($ thousands)	Summary Operating Results For the nine months ended September 30, 2004	Increase (Decrease) $	Increase (Decrease) %	2003
Revenues:				
Product sales net	$ 711	$ 711	100%	$
License fees and royalties	783	(12)	(2)%	795
Development funding	3,145	15	1%	3,130
Total revenues	4,639	714	19%	3,925
Cost of goods sold	165	165	100%	
Provision for excess inventory	693	693	100%	
Total cost of goods sold	858	858	100%	
Gross margin	3,781	(144)	(4)%	3,925
Costs and expenses:				
Research and development (including non-cash compensation expense of $158 and $157 for the nine months ended September 30, 2004 and 2003, respectively)	61,940	7,207	14%	54,733
Selling, general and administrative (including non-cash compensation expense of $50 and $205 for the nine months ended September 30, 2004 and 2003, respectively)	24,228	3,885	19%	20,403
Total costs and expenses gross	86,168	11,032	15%	75,136
Less: Aventis reimbursement	(36,453)	3,897	10%	(40,350)
Total costs and expenses net	49,715	14,929	43%	34,786
Loss on disposition of property and equipment	(1,254)	(1,252)	(626)%	(2)
Other (expense)/income, principally net interest income	(79)	(756)	(112)%	677
Net loss	$ (47,267)	$ (17,081)	(57)%	$ (30,186)

Total revenues

Total revenues, consisting of license fees and royalties, development funding and product sales were $4.6 million for the nine months ended September 30, 2004 compared to $3.9 million for the nine months ended September 30, 2003. The increase resulted from sales of Ganite®, for which we significantly reduced marketing support 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 $61.9 million for the nine months ended September 30, 2004 compared to $54.7 million for the nine months ended September 30, 2003. Approximately $58.0 million or 94% of research and development expenses before reimbursement were incurred on the Genasense® project for the nine months ended September 30, 2004. Research and development expenses for the nine months ended September 30, 2004 have been significantly increased by the expensing of vialed Genasense® drug product and Genasense® bulk drug substance in May 2004 and expenses relating to purchases of Genasense® bulk drug substance in the past three

months. These increases have been partially offset by the Company s decision in May 2004 to reduce its staff and reduce most non-Genasense® related programs as well as the comparison to a prior-year period where expenses were significantly higher resulting from Genasense® Phase 3 clinical trials and NDA preparation activities. Of the $61.9 million in research and development expenses for the nine months ended September 30, 2004, $46.0 million is reimbursable pursuant to our collaborative agreement with Aventis, with a net expense reimbursement of $4.9 million.

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.

Selling, general and administrative expenses

Selling, general and administrative expenses were $24.2 million for the nine months ended September 30, 2004 compared to $20.4 million for the nine months ended September 30, 2003. Expenses increased primarily due to the impact, through May 2004, of a larger sales force and Ganite® selling activities, a larger administrative staff and a $1.0 million legal charge related to the ongoing 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:

	Nine months ended September 30,	
($ thousands)	**2004**	**2003**
Reimbursement to Genta		
Third-party costs	$ 14,936	$ 23,361
Drug supply costs	18,211	12,999
FTE s	4,668	5,275
Amount due to Genta	37,815	41,635
Reimbursement to Aventis	(1,362)	(1,285)
Net reimbursement to Genta	36,453	40,350

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

On November 8, 2004 the Company received from Aventis notice of termination of the agreements between Genta and Aventis. Pursuant to those agreements, Aventis will continue to support the development of Genasense® for a six-month period lasting until May 8, 2005.

Other (expense)/income

For the nine months ended September 30, 2004 the Company had $0.1 million net other expense compared to $0.7 million net other income for the nine months ended September 30, 2003. The decline is principally the result of lower investment balances and higher average outstanding borrowing from Aventis.

Net loss

Genta incurred a net loss of $47.3 million, or $0.60 per share, for the nine months ended September 30, 2004, compared to a net loss of $30.2 million, or $0.40 per share, for the nine months ended September 30, 2003. The increase in net loss and per share net loss to common shareholders was primarily due to higher research and development expenses and selling, general and administrative expenses described above.

Liquidity and Capital Resources

At September 30, 2004, the Company s cash, cash equivalents and marketable securities, totaling $36.7 million had declined from $82.9 million at December 31, 2003 as we funded our operations. During the first nine months of 2004, cash flow used in operating activities was $44.5 million, primarily resulting from a net loss of $47.3 million.

At September 30, 2004, the Company had $19.0 million outstanding (compared to $35.5 million as of December 31, 2003) 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® (Line of Credit). Prior to June 30, 2004 the Line of Credit was classified as long term debt and beginning June 30, 2004, it was classified as short term debt. During the three months ended September 30, 2004, as a result of certain non-cash transactions, the Company reduced amounts owed under the Line of Credit by $16.0 million. During this time period, the Company shipped $15.5 million of vialed Genasense® drug product and Genasense® bulk drug substance to Aventis. The companies agreed to offset amounts owed under the Line of Credit by $14.8 million and accrued interest on the Line of Credit by $0.7 million.

The terms of the Line of Credit provide for a favorable interest rate, which is set two days prior to the first day of each calendar quarter. The Line of Credit terminates upon the earlier of (1) the receipt of Genasense® 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 Line of Credit, (4) various default provisions or (5) December 31, 2004. On November 8, 2004 the Company received from Aventis notice of termination of the agreements between Genta and Aventis. With the Aventis notice of termination, Genta cannot borrow additional funds and the Line of Credit must be repaid no later than May 8, 2005. Aventis is able to retain payments due to Genta and apply them against any balance on the Line of Credit until the Line of Credit is repaid. As security for the repayment of the 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®.

Under the terms of the alliance agreements, Aventis will continue to reimburse Genta for ongoing Genasense® clinical trials and development activities during the six month notice period. After May 8, 2005, all Genasense® costs will be the responsibility of Genta.

At September 30, 2004, the Company had $10.0 million in outstanding convertible debt that was issued in connection with the Aventis collaboration. Under the terms of one of the Genasense® alliance agreements, if Aventis elects to terminate the agreement, which it has done, Aventis is required to forgive the $10 million principle balance and any accrued interest.

The Company is evaluating the impact of the Aventis notice of termination on cash projections. Our principal expenditures relate to our research and development activities, primarily focused on Genasense®, which include our ongoing and future clinical trials. We expect these expenditures to continue.

If we obtain NDA approval of Genasense® 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 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 September 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.

PART II OTHER INFORMATION

Item 1. ***Legal Proceedings***

In 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 have been consolidated into a single action and 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 consolidated shareholder class action complaint seeks monetary damages in an unspecified amount and recovery of plaintiffs costs and attorneys fees. In addition, 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 an early stage and we intend to defend them vigorously.

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)
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

Exhibit Number	Description of Document
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004)
10.1	Genta Incorporated 1998 Stock Incentive Plan (incorporated by reference to the Company s Proxy Statement for its Annual Meeting of Stockholders on June 23, 2004, Commission File No. 000-19635)
10.2	Genta Incorporated Non-Employee Directors 1998 Stock Incentive Plan (incorporated by reference to the Company s Proxy Statement for its Annual Meeting of Stockholders on June 23, 2004, Commission File No. 000-19635)
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

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

Genta Incorporated

Date: November 9, 2004

/s/ RAYMOND P. WARRELL, JR., M.D.
Raymond P. Warrell, Jr., M.D.
Chairman and Chief Executive Officer

Date: November 9, 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)	
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