GENTA INC DE/
Form 10-Q
May 10, 2005

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 March 31, 2005

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 April 29, 2005, the registrant had 95,358,215 shares of common stock outstanding.

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GENTA INCORPORATED
CONSOLIDATED BALANCE SHEETS

(In thousands, except par value data)

ASSETS	March 31, 2005	December 31, 2004
	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 15,522	$ 36,489
Marketable securities (Note 3)	15,693	5,758
Inventory (Note 4)	339	354
Prepaid expenses and other current assets	1,326	1,910
Total current assets	32,880	44,511
Property and equipment, net (Note 5)	2,335	2,847
Intangibles, net (Note 6)	142	286
Prepaid royalties	1,268	1,268
Other assets	1,626	1,620
Total assets	$ 38,251	$ 50,532
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 10,277	$ 14,424
Deferred revenues, current portion	7,790	26,228
Notes payable	289	816
Short term debt (Note 7)	4,114	7,312
Total current liabilities and total liabilities	22,470	48,780
Commitments and contingencies (Note 11)		
Stockholders equity:		
Series A convertible preferred stock, $.001 par value; 5,000 shares authorized, 10 shares issued and outstanding, liquidation value of $485 at March 31, 2005 and December 31, 2004		
Common stock, $.001 par value; 150,000 shares authorized, 95,358 shares issued and outstanding at March 31, 2005 and December 31, 2004	95	95
Additional paid-in capital	357,714	357,714
Accumulated deficit	(341,959)	(355,984)
Deferred compensation	(30)	(41)
Accumulated other comprehensive loss	(39)	(32)
Total stockholders equity	15,781	1,752
Total liabilities and stockholders equity	$ 38,251	$ 50,532

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)	Three Months Ended March 31, 2005	2004
	(Unaudited)	
Revenues:		
License fees and royalties	$ 3,684	$ 261
Development funding	14,754	1,049
Product sales - net	76	372
Total revenues	18,514	1,682
Cost of goods sold	15	93
Gross margin	18,499	1,589
Costs and expenses:		
Research and development (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of $52 for the three months ended March 31, 2004)	3,870	12,353
Selling, general and administrative (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of $11 and $18 for the three months ended March 31, 2005 and March 31, 2004, respectively)	3,986	9,224
Total costs and expenses - gross	7,856	21,577
Aventis reimbursement	(3,252)	(7,433)
Total costs and expenses - net	4,604	14,144
Other income	130	23
Net income/(loss)	14,025	(12,532)
Net income/(loss) per basic and diluted share (Note 9)	$ 0.15	$ (0.16)
Shares used in computing net income/(loss) per basic and diluted share	95,358	76,859

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Three Months Ended March 31, 2005	2004
	(Unaudited)	
Operating activities:		
Net income/(loss)	$ 14,025	$ (12,532)
Items reflected in net income/(loss) not requiring cash:		
Depreciation and amortization	663	787
Non-cash reimbursement of research & development expense (Note 7)	(3,252)	
Amortization of deferred revenues	(18,438)	(1,309)
Compensation expense related to certain stock options issued in 1999 and 2000	11	70
Changes in operating assets and liabilities:		
Accounts receivable		7,730
Inventory (Note 4)	15	(6,178)
Notes receivable		(845)
Prepaid expenses and other current assets	584	1,099
Accounts payable and accrued expenses	(4,093)	(3,114)
Other assets	(6)	
Net cash used in operating activities	(10,491)	(14,292)
Investing activities:		
Purchase of marketable securities (Note 3)	(9,942)	(7,281)
Maturities and sales of marketable securities (Note 3)		33,735
Purchase of property and equipment	(7)	(1,409)
Net cash (used in)/provided by investing activities	(9,949)	25,045
Financing activities:		
Repayments of note payable	(527)	
Deferred financing costs		(33)
Issuance of common stock upon exercise of warrants and options		276
Net cash (used in)/provided by financing activities	(527)	243
Decrease/(increase) in cash and cash equivalents	(20,967)	10,996
Cash and cash equivalents at beginning of period	36,489	25,153
Cash and cash equivalents at end of period	$ 15,522	$ 36,149

See accompanying notes to consolidated financial statements

GENTA INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2005
(Unaudited)

1. Organization and Business

Genta Incorporated (Genta or the Company) is a biopharmaceutical company engaged in pharmaceutical (drug) research and development, its sole reportable segment. The Company is dedicated to the identification, development and commercialization of novel drugs for the treatment of cancer and related diseases.

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.

Genta has completed and announced the results of Phase 3 trials of Genasense in combination with chemotherapy in the treatment of malignant melanoma, chronic lymphocytic leukemia (CLL) and multiple myeloma. The Company is currently evaluating possible regulatory filings in the U.S. and/or Europe for approvals of Genasense in combination with chemotherapy for the treatment of CLL and malignant melanoma. In addition to the three Phase 3 trials, the Company is conducting (under its own sponsorship or in conjunction with various cooperative groups) randomized trials in non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), acute myeloid leukemia (AML) and prostate cancer. Genta is also conducting a number of non-randomized clinical trials in patients with various types of cancer, either under its own sponsorship or in collaboration with the National Cancer Institute (NCI).

Genta markets Ganite® (gallium nitrate injection) for the treatment of cancer-related hypercalcemia. In May 2004, the Company eliminated its sales force and significantly reduced its marketing support for Ganite®.

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 Aventis gave six-month notice to Genta that it was terminating its collaborative agreements with the Company. Pursuant to those agreements, Aventis continued to fund ongoing development activities through the termination notice period. Although no assurances can be expressed, management believes that at the current rate of spending, the Company should have sufficient cash funds to maintain its present operations through 2005. There are a number of alternatives available to the Company to sustain its operations beyond 2005 should there be a delay in approval of Genasense®.

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 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 the 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, 2004. Results for interim periods are not necessarily indicative of results for the full year. The Company has experienced significant quarterly fluctuations in operating results and it expects those 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 would jointly develop and commercialize Genasense® in the U.S., and Aventis would have exclusive development and marketing rights to the compound in all countries outside of the U.S. Under the Collaborative Agreement, Aventis would pay 75% of U.S. New Drug Application (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. On November 8, 2004 Aventis gave six-month notice to Genta that it was terminating its Collaborative Agreement with the Company. Under the terms of the agreement, Aventis continued to fund ongoing development activities through the termination notice period.

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

In accordance with EITF No. 00-21 the Company analyzes its multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. The Company recognizes 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. The Company s 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 the Company has no other performance obligations.

The Company determined that, due to the nature of the ongoing development work related to its Collaborative Agreement with Aventis, the end of the development phase and the fair value of the undelivered elements were not determinable. Accordingly, the Company 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 agreement with Aventis, the Company determined that the period over which the remaining deferred revenue should be recognized will be through May 8, 2005. In accordance with EITF No. 00-21 and SAB No. 104, the Company has reclassified the remaining deferred revenue as current and will recognize such revenue through May 8, 2005.

Genta recognizes revenue from product sales when title to product and associated risk of loss has passed to the customer and the Company is 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. The Company allows return of its product for up to twelve months after product expiration. In December 2004, a wholesaler contacted the Company to return a significant portion of its inventory of Ganite®. The Company agreed to the return of this product and recorded a provision for sales returns, as well as provided for potential returns from other wholesalers. In January 2005, the wholesaler returned $0.5 million of Ganite®. At March 31, 2005, the Company s provision for sales returns was $0.8 million.

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 primarily consist of government securities, all of which are classified as available-for-sale marketable securities. Management determines the appropriate classification of 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. If such evaluation were to indicate an impairment of 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 of 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. 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 evaluation, 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 has two stock-based compensation plans. The Company accounts for stock-based compensation arrangements in accordance with 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 Consensus on Issue 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 (FIN) 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 SFAS 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 SFAS 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:

	Three Months Ended March 31,	
($ thousands, except per share data)	**2005**	**2004**
Net income/(loss) applicable to common shares, as reported	$ 14,025	$ (12,532)
Add: Equity related employee compensation expense included in reported net income, net of related tax effects	11	70
Deduct: Total stock-based employee compensation expense determined under fair values based method for all awards, net of related tax effects	(1,547)	(2,345)
Pro forma net income/(loss)	$ 12,489	$ (14,807)
Net income/(loss) per share attributable to common shareholders:		
As reported: Basic and diluted	$ 0.15	$ (0.16)
Pro forma: Basic and diluted	$ 0.13	$ (0.19)

The Company estimated the fair value of options at the date of grant using a Black-Scholes option valuation model with the following assumptions:

	Three Months Ended March 31,	
	2005	**2004**
Risk-free interest rate	4.1%	2.9%
Dividend yield		
Expected life (years)	6.25	4.00
Expected volatility	119%	61%

In December 2004, the FASB issued SFAS No. 123(R) *Share-Based Payment* that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. With limited exceptions, the amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. In addition, liability awards will be remeasured each reporting period. Compensation cost will be recognized over the period that an employee provides service in exchange for the award. SFAS No. 123(R) replaces SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*. In April 2005, the Securities and Exchange Commission announced the adoption of a rule that defers the required date of SFAS No 123 (R). The Company will adopt the provisions of SFAS No. 123R in 2006. The Company is evaluating the impact that the adoption of this standard will have on its results of operations, financial position or cash flows.

Net Income/(Loss) Per Common Share

Net income/(loss) per common share for the three months ended March 31, 2005 and 2004 is based on the weighted average number of shares of common stock outstanding during the periods (see Note 9 to our financial statements). For 2004 the calculation of diluted net loss per share excludes potentially dilutive securities, including options, warrants and convertible preferred stock 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):

	March 31, 2005	December 31, 2004
Amortized cost	$ 15,732	$ 5,790
Gross unrealized gains	3	10
Gross unrealized losses	(42)	(42)
Estimated fair value	$ 15,693	$ 5,758

The estimated fair value of each marketable security has been compared to its cost, and therefore, a net unrealized loss of approximately $39 thousand has been recognized in accumulated other comprehensive loss at March 31, 2005.

4. Inventories

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):

	March 31, 2005	December 31, 2004
Raw materials	$ 21	$ 21
Work in process		
Finished goods	318	333
	$ 339	$ 354

5. Property and Equipment

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

	Estimated Useful Lives	March 31, 2005	December 31, 2004
Computer equipment	3	$ 2,860	$ 2,860
Software	3	3,349	3,349
Furniture and fixtures	5	936	936
Leasehold improvements	Life of lease	443	443
Equipment	5	166	166
		7,754	7,754
Less accumulated depreciation and amortization		(5,419)	(4,907)
		$ 2,335	$ 2,847

Intangible assets consist of the following ($ thousands):

6. Intangibles, net

	March 31, 2005	December 31, 2004
Patent and patent applications	$ 3,992	$ 3,992
Less accumulated amortization	(3,850)	(3,706)
	$ 142	$ 286

The remaining intangible asset amount will be fully amortized at June 30, 2005.

7. Short Term Debt

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 was considered an advance against both past and future costs and the borrowing base was adjusted on a monthly basis. With the Aventis six-month notice of termination, Genta could not borrow additional funds and the Line of Credit must be repaid by no later than the termination notice period. All payments otherwise due to Genta are applied against any balance on the Line of Credit until the Line of Credit is repaid. The Company expects that a portion of the $4.1 million outstanding on the Line of Credit will be repaid through the application of reimbursements. During the three months ended March 31, 2005, $3.2 million of reimbursement due from Aventis was applied to the balance of the Line of Credit.

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. As security for the repayment of the Line of Credit, Genta has granted Aventis a security interest in all of its rights to payments under the Collaborative Agreement, as well as all inventory related to Genasense®.

8. Comprehensive Income/(Loss)

An analysis of comprehensive income/(loss) is presented below:

($ in thousands)	**Three Months Ended March 31,**	
	2005	**2004**
Net income/(loss)	$ 14,025	$ (12,532)
Change in market value on available-for-sale marketable Securities	3	16
Total comprehensive income/(loss)	$ 14,028	$ (12,516)

9. Net Income/(Loss) per Share

The information required to compute basic and diluted net income/(loss) per share is as follows:

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

As a result of the Aventis notice of termination, all payments otherwise due to Genta are contractually applied against the balance of the Line of Credit until the Line of Credit is repaid. During the three months ended March 31, 2005, $3.2 million of reimbursement due to Genta was applied to the balance of the Line of Credit.

No interest or income taxes were paid for the three months ended March 31, 2005 and 2004.

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 have been consolidated into a single action and allege that the Company and certain of its principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of malignant melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action complaint in the various actions seeks 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 or liquidity.

12. Subsequent Event

On May 10, 2005 the Company announced that Genta and Aventis had signed an agreement to terminate their development and commercialization collaboration for Genasense®. On November 8 2004, Aventis had provided Genta six-month notice of termination of the Genasense® agreements. The termination agreement provides no future financial obligations by either party and the Line of Credit established by Aventis to Genta will be retired. Aventis will also return its current inventory of Genasense® drug supply to Genta. In addition, Genta will assume responsibility for the randomized clinical trial of Genasense in combination with docetaxel (Taxotere®; sanofi-aventis) in patients with hormone-refractory prostate cancer, which is currently ongoing in Europe. Among other provisions, the Standstill and Voting Agreement and Registration Rights Agreement that were established pursuant to the Aventis investment in Genta common stock in 2002 will not terminate at this time.

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 U.S. Food and Drug Administration (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 adequacy of the Company s patents and proprietary rights;
- 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, 2004.

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 Form 10-Q.

Overview

Genta Incorporated is a biopharmaceutical company engaged in pharmaceutical research and development. The Company is dedicated to the identification, development and commercialization of novel drugs for the treatment of cancer and related diseases. 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. We have experienced significant quarterly fluctuations in operating results and we expect that these fluctuations in revenues, expenses and losses will continue.

During the three months ended March 31, 2005, Genta reported total revenues of $18.5 million and net income of $14.0 million or $0.15 per share. Net income was driven largely by the accelerated recognition of deferred revenue related to the sanofi-aventis notice of termination of the 2002 collaboration agreements related to Genasense®. As of March 31, 2005, the Company had cash, cash equivalents and marketable securities totaling $31.2 million.

Our financial results in 2005 have been and will continue to be significantly affected by FDA action with respect to Genasense®. In late 2003 we filed a New Drug Application (NDA) for Genasense® to be used in combination with dacarbazine for the treatment of patients with malignant 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 malignant melanoma who have not received prior chemotherapy. In May 2004, the Company withdrew its NDA from further consideration. At the same time, we 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 and reduced most non-Genasense® related programs. In August 2004, Genta closed its research facility in Salt Lake City, Utah, with a further reduction of 15 employees.

The Company has continued long-term follow-up of patients who were enrolled in the malignant melanoma trial. Genta is conducting additional analysis of those data and expects to provide an update of these results in 2005. The Company is also exploring the feasibility of filing regulatory applications in this indication in Europe and the U.S.

In November 2004, the Company reported results from a randomized Phase 3 clinical trial of Genasense® in patients with relapsed or refractory chronic lymphocytic leukemia (CLL). 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), as determined by review of clinical data and bone marrow biopsies using experts who were blinded as to treatment assignment. 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. A significant increase in disease-free survival was also observed. No difference was observed in overall response rate, time-to-disease progression, or overall survival. 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®. Adverse events (irrespective of relation to study drugs) during treatment or within 30 days from last dose of treatment that resulted in death occurred in 9 patients treated with Genasense plus chemotherapy compared with 5 patients treated with chemotherapy alone. The percentage of patients who experienced serious adverse events was increased in the Genasense® arm; however, the percentages of patients who discontinued treatment due to adverse events were equal in the treatment arms.

Genta is currently conducting additional analysis of data from this trial and is exploring the feasibility of filing a NDA for this indication based on existing data. Such an application would be filed using the Fast Track designation previously granted by the FDA, which allows approval of a drug based on a surrogate endpoint that is reasonably likely to be predictive of clinical benefit. Approval under this mechanism is contingent upon a company conducting one or more additional trials that would conclusively document that benefit. The Company is also exploring the feasibility of filing similar regulatory applications in this indication outside the U.S.

In November 2004, Genta reported that the Company's randomized Phase 3 clinical trial of Genasense® in patients with multiple myeloma did not meet its primary endpoint. The trial had been designed to evaluate whether the addition of Genasense® to standard therapy with high-dose dexamethasone could increase the time to development of progressive disease in patients who had previously received extensive therapy. Based on the results of the Phase 3 trial, the Company has no plans to submit an NDA in this indication at the current time. The Company has not yet determined what additional clinical trials, if any, may be undertaken in patients with multiple myeloma.

In addition to the three Phase 3 trials, the Company is conducting (under its own sponsorship or in conjunction with various cooperative groups) randomized trials in non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), acute myeloid leukemia (AML) and prostate cancer. Genta is also conducting a number of non-randomized clinical trials in patients with various types of cancer, either under its own sponsorship or in collaboration with the NCI.

In April 2002, we entered into a series of agreements with Aventis regarding the development and commercialization of Genasense®. On November 8, 2004 Aventis gave six-month notice to Genta that it was terminating its Collaborative Agreement with the Company. Under the terms of the agreement, Aventis continued to fund ongoing development activities through the termination notice period.

On May 10, 2005 the Company announced that Genta and Aventis had signed an agreement to terminate their development and commercialization collaboration for Genasense®. The termination agreement provides no future financial obligations by either party and the Line of Credit established by Aventis to Genta will be retired. Aventis will also return its current inventory of Genasense® drug supply to Genta. In addition, Genta will assume responsibility for the randomized clinical trial of Genasense in combination with docetaxel (Taxotere®; sanofi-aventis) in patients with hormone-refractory prostate cancer, which is currently ongoing in Europe. Among other provisions, the Standstill and Voting Agreement and Registration Rights Agreement that were established pursuant to the Aventis investment in Genta common stock in 2002 will not terminate at this time.

Results of Operations for the Three Months Ended March 31, 2005 and 2004

	Summary Operating Results For the three months ended March 31,			
($ thousands)		Increase (Decrease)		
	2005	**$**	**%**	**2004**
Revenues:				
License fees and royalties	$ 3,684	3,423	1,311%	$ 261
Development funding	14,754	13,705	1,306%	1,049
Product sales net	76	(296)	(80)%	372
Total revenues	18,514	16,832	1,001%	1,682
Cost of goods sold	15	(78)	(84)%	93
Gross margin	18,499	16,910	1,064%	1,589
Costs and expenses:				
Research and development (including non-cash compensation expense of $52 for the three months ended March 31, 2004)	3,870	(8,483)	(69)%	12,353
Selling, general and administrative (including non-cash compensation expense of $11 and $18 for the three months ended March 31, 2005 and March 31, 2004, respectively)	3,986	(5,238)	(57)%	9,224
Total costs and expenses gross	7,856	(13,721)	(64)%	21,577
Less: Aventis reimbursement	(3,252)	4,181	56%	(7,433)
Total costs and expenses net	4,604	(9,540)	(67)%	14,144
Other income, principally net interest income	130	107	465%	23
Net income/(loss)	$ 14,025	$ 26,557	212%	$ (12,532)

Total Revenues

Total revenues, consisting of license fees and royalties, development funding and product sales were $18.5 million for the three months ended March 31, 2005 compared to $1.7 million for the three months ended March 31, 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, along with non-exclusive sub-license agreements involving antisense technology.

On November 8, 2004 Aventis gave six-month notice to Genta that it was terminating its Collaborative Agreement with the Company regarding the development and commercialization of Genasense®. The Company had previously determined that, due to the nature of the ongoing development work related to the Collaborative Agreement, the end of the development phase and the fair-value of the undelivered elements were 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 Collaborative Agreement, the Company has determined that the period over which the remaining deferred revenue should be recognized will be through May 8, 2005. On November 9, 2004 we began to recognize the remaining deferred revenue over a six-month period, resulting in increased revenue of $17.1 million for the three months ended March 31, 2005 compared to the three months ended March 31, 2004.

Product sales-net are generated from sales of Ganite®, the Company s commercial product for the treatment of cancer-related hypercalcemia. In May 2004, the Company eliminated its sales force and significantly reduced its marketing support for Ganite®. Sales of Ganite® during the first three months of 2005 are significantly below the prior-year period. Management believes that sales of Ganite® for the first three months of 2005 are a good indicator for the sales rate for the remainder of the year.

Research and Development Expenses

Research and development expenses before reimbursement were $3.9 million for the three months ended March 31, 2005 compared to $12.4 million for the three months ended March 31, 2004. During the first three months of 2005, approximately $3.7 million or 95% of research and development expenses before reimbursement were incurred on the Genasense® project. During the prior-year period, research and development expenses before reimbursement incurred on the Genasense® project of approximately $10.7 million were significantly higher due to several Phase 3 clinical trials and NDA preparation activity. In addition, research and development expenses in 2005 decreased due to our decision in May 2004 to reduce staff and reduce most non-Genasense® related programs. Of the $3.9 million in research and development expenses for the three months ended March 31, 2005, $3.3 million is reimbursable pursuant to our collaborative agreement with Aventis. With the Aventis notice of termination, all payments otherwise due to Genta are applied against the balance of the Line of Credit until the Line of Credit is repaid (see Note 7 to our Financial Statements).

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 $4.0 million for the three months ended March 31, 2005 compared to $9.2 million for the three months ended March 31, 2004. Expenses in 2004 were at a substantially higher rate of spending in anticipation of approval and launch of Genasense®. Expenses in 2005 reflect the impact of the May 2004 elimination of the sales force, reduction of other administrative positions and substantial reduction of marketing support for Ganite®.

Aventis Reimbursement

Under the Collaborative Agreement with Aventis, Aventis paid 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 March 31,**	
Reimbursement to Genta	**2005**	**2004**
Third-party costs	1,358	$ 6,363
Drug supply costs	908	(244)
	1,088	1,731
FTE s	3,354	7,850
Amount due to Genta Reimbursement to Aventis	(102)	(417)
Net reimbursement to Genta	$ 3,252	$ 7,433

Net expense reimbursement from Aventis of $3.3 million for the first quarter of 2005 declined from $7.4 million for the first quarter of 2004 due to lower expenses incurred on the Genasense® project.

Once Aventis provided notice of termination of the Collaborative Agreement, all payments otherwise due from Aventis have been and will continue to be applied against the balance on the Line of Credit until the Line of Credit is repaid. During the three months ended March 31, 2005, $3.2 million of reimbursement due to Genta was applied to the balance of the Line of Credit.

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

Other Income

Net other income for the three months ended March 31, 2005 increased by $0.1 million from the comparable period in 2004 as lower interest expense, resulting from lower borrowings from Aventis was partially offset by lower interest income, resulting from lower investment balances.

Net Income/(Loss)

The Company recorded net income of $14.0 million, or $0.15 per share, for the three months ended March 31, 2005, compared to a net loss of $12.5 million, or $0.16 per share, for the three months ended March 31, 2004. The increase in net income and net income per share was due to accelerated recognition of the initial licensing fee and up-front development funding previously received from Aventis and lower research and development and selling, general and administrative expenses as described above.

Liquidity and Capital Resources

At March 31, 2005, we had cash, cash equivalents and marketable securities totaling $31.2 million compared to $42.2 million at December 31, 2004. During the three months ended March 31, 2005, cash flow used in operating activities was $10.5 million, reflecting the Company s smaller organization and focus on Genasense®.

At March 31, 2005, the Company had $4.1 million outstanding (compared to $7.3 million as of December 31, 2004) on the Line of Credit from Aventis. With the Aventis six-month notice of termination, Genta could not borrow additional funds and the Line of Credit would need to be repaid by no later than the termination notice period. All payments otherwise due to Genta are applied against any balance on the Line of Credit until the Line of Credit is repaid. During the three months ended March 31, 2005, $3.2 million of reimbursement due to Genta was applied to the balance of the Line of Credit. Under the terms of the Collaborative Agreement, Aventis will continue to reimburse Genta for ongoing Genasense® clinical trials and development activities during the six-month notice period.

The terms of the Line of Credit provided for a favorable interest rate, which is set two days prior to the first day of each calendar quarter. As security for the repayment of the Line of Credit, Genta had granted Aventis a security interest in all of its rights to payments under the Collaborative Agreement, as well as all inventory related to Genasense®.

On May 10, 2005 the Company announced that Genta and Aventis had signed an agreement to terminate their development and commercialization collaboration for Genasense®. The termination agreement provides no future financial obligations by either party and the Line of Credit established by Aventis to Genta will be retired. Aventis will also return its current inventory of Genasense® drug supply to Genta.

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. The Company currently anticipates total company average monthly cash outflow to be in the $3.0 million to $4.0 million range. Although no assurances can be expressed, management believes that at the current rate of spending, the Company should have sufficient cash funds to maintain its present operations through 2005. There are a number of alternatives available to the Company to sustain its operations beyond 2005 should there be a delay in approval of Genasense®. The Company may seek collaborative agreements 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.

If we obtain NDA approval of Genasense® we 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 December 2004, the Financial Accounting Standards Board (FASB) issued Statement (SFAS) No. 123(R), *Share-Based Payment* that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. With limited exceptions, the amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. In addition, liability awards will be remeasured each reporting period. Compensation cost will be recognized over the period that an employee provides service in exchange for the award. SFAS No. 123(R) replaces SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*. In April 2005, the Securities and Exchange Commission announced the adoption of a rule that defers the required date of SFAS No 123 (R). The Company will adopt the provisions of SFAS No. 123R in 2006. The Company is evaluating the impact that the adoption of this standard will have on its results of operations, financial position or cash flows.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Non-monetary Assets*, an amendment of APB Opinion No. 29. We do not expect that the adoption of this statement, effective June 2005, will have any impact on the Company s results of operations, financial position or cash flows.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material. As the Company uses third-party manufacturers and does not manufacture its own products, we do not expect that the adoption of this statement, effective June 2005, will have a material impact on the Company s results of operations, financial position or cash flows.

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). 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 March 31, 2005. 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***

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As required by Rule 13a-15(b), Genta Incorporated Chief Executive Officer and Chief Financial Officer conducted an evaluation as of the end of the period covered by this report of the effectiveness of the Company s disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)). Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company s disclosure controls and procedures were operating effectively as of the end of the period covered by this report.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 malignant melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action complaint in the various actions seeks 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 or liquidity.

Item 6. ***Exhibits.***

(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)

Exhibit Number	Description of Document
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)
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3(ii).1 to the Company s Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)
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: May 10, 2005

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

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

Date: May 10, 2005

/s/ WILLIAM P. KEANE

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

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