

GENTA INC DE/
Form 10-Q
August 09, 2005

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2005

OR

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

For the transition period from _____ to _____

Commission File Number 0-19635

GENTA INCORPORATED

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

07922
(Zip Code)

(908) 286-9800
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes

No

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

Yes

No

As of August 4, 2005, the registrant had 95,358,215 shares of common stock outstanding.

Genta Incorporated
INDEX TO FORM 10-Q

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements:

Consolidated Balance Sheets at June 30, 2005
and December 31, 2004 3

Consolidated Statements of Operations for the
Three and Six Months Ended June 30, 2005 and 2004 4

Consolidated Statements of Cash Flows for the
Six Months Ended June 30, 2005 and 2004 5

Notes to Consolidated Financial Statements 6

Item 2. Management's Discussion and Analysis of Financial Condition
and Results of Operations 15

Item 3. Quantitative and Qualitative Disclosures about Market Risk 24

Item 4. Controls and Procedures 25

PART II. OTHER INFORMATION

Item 1. Legal Proceedings 26

Item 4. Submission of Matters to a Vote of Security Holders 26

Item 6. Exhibits 27

SIGNATURES 28

CERTIFICATIONS 30

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements:

Consolidated Balance Sheets at June 30, 2005
and December 31, 2004

Consolidated Statements of Operations for the
Three and Six Months Ended June 30, 2005 and 2004

Consolidated Statements of Cash Flows for the
Six Months Ended June 30, 2005 and 2004

Notes to Consolidated Financial Statements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Item 4. Controls and Procedures

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 6. Exhibits

SIGNATURES

CERTIFICATIONS

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

GENTA INCORPORATED
CONSOLIDATED BALANCE SHEETS (unaudited)

(In thousands, except par value data)

	June 30, 2005	December 31, 2004
	<u> </u>	<u> </u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,415	\$ 36,489
Marketable securities (Note 3)	15,737	5,758
Accounts receivable	18	--
Inventory (Note 4)	341	354
Prepaid expenses and other current assets	1,085	1,910
	<u> </u>	<u> </u>
Total current assets	21,596	44,511
Property and equipment, net (Note 5)	1,786	2,847
Intangibles, net	--	286
Prepaid royalties	1,268	1,268
Other assets	1,630	1,620
	<u> </u>	<u> </u>
Total assets	<u>\$ 26,280</u>	<u>\$ 50,532</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,298	\$ 14,424
Deferred revenues, current portion	--	26,228
Notes payable	227	816
Short term debt (Note 6)	--	7,312
	<u> </u>	<u> </u>
Total current liabilities and total liabilities	8,525	48,780
	<u> </u>	<u> </u>
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Series A convertible preferred stock, \$.001 par value; 5,000 shares authorized, 10 shares issued and outstanding, liquidation value of \$485 at June 30, 2005 and December 31, 2004	--	--
Common stock, \$.001 par value; 150,000 shares authorized, 95,358 shares issued and outstanding at June 30, 2005 and December 31, 2004	95	95
Additional paid-in capital	357,714	357,714
Accumulated deficit	(340,040)	(355,984)
Deferred compensation	(19)	(41)
Accumulated other comprehensive income/(loss)	5	(32)
	<u> </u>	<u> </u>
Total stockholders' equity	17,755	1,752
	<u> </u>	<u> </u>
Total liabilities and stockholders' equity	<u>\$ 26,280</u>	<u>\$ 50,532</u>

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(Unaudited)		(Unaudited)	
Revenues:				
License fees and royalties	\$ 1,556	\$ 261	\$ 5,241	\$ 522
Development funding	6,234	1,049	20,988	2,097
Product sales - net	97	251	172	624
Total revenues	7,887	1,561	26,401	3,243
Cost of goods sold	18	52	33	146
Provision for excess inventory	(21)	--	(21)	--
Total cost of goods sold	(3)	52	12	146
Gross margin	7,890	1,509	26,389	3,097
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 and \$104 for the six months ended June 30, 2004)	5,551	28,945	9,421	41,297
Selling, general and administrative (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of \$11 and \$22 for the three months ended June 30, 2005 and June 30, 2004, respectively and \$22 and \$39 for the six months ended June 30, 2005 and June 30, 2004 respectively)	4,635	10,284	8,621	19,507
Total costs and expenses - gross	10,186	39,229	18,042	60,804
Aventis reimbursement	(2,838)	(8,531)	(6,090)	(15,964)
Total costs and expenses - net	7,348	30,698	11,952	44,840
Gain on forgiveness of debt	1,297	--	1,297	--
Other income	80	34	210	56
Net income/(loss)	1,919	(29,155)	15,944	(41,687)
Net income/(loss) per basic and diluted share (Note 8)	\$ 0.02	\$ (0.37)	\$ 0.17	\$ (0.53)
Shares used in computing net income/(loss) per basic share	95,358	79,016	95,358	77,945
Shares used in computing net income/(loss) per diluted share	95,531	79,016	95,535	77,945

See accompanying notes to consolidated financial statements

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six Months Ended June 30,	
(In thousands)	2005	2004
	(Unaudited)	
Operating activities:		
Net income/(loss)	\$ 15,944	\$ (41,687)
Items reflected in net income/(loss) not requiring cash:		
Depreciation and amortization	1,337	1,626
Loss on disposition of property and equipment	3	--
Non-cash reimbursement of research & development expense	(6,090)	--
Provision for excess inventory	(21)	--
Gain on forgiveness of debt	(1,297)	--
Amortization of deferred revenues	(26,228)	(2,619)
Compensation expense related to certain stock options issued in 1999 and 2000	22	143
Changes in operating assets and liabilities:		
Accounts receivable	(18)	8,101
Inventory (Note 4)	33	(1,210)
Notes receivable	--	(806)
Prepaid expenses and other current assets	825	1,503
Accounts payable and accrued expenses	(6,051)	3,681
Other assets	(10)	(148)
	(21,551)	(31,416)
Net cash used in operating activities	(21,551)	(31,416)
Investing activities:		
Purchase of marketable securities (Note 3)	(9,942)	(7,281)
Maturities and sales of marketable securities (Note 3)	--	59,242
Purchase of property and equipment	(26)	(1,716)
Proceeds from sale of property and equipment	34	--
	(9,934)	50,245
Net cash (used in)/provided by investing activities	(9,934)	50,245
Financing activities:		
Repayments of note payable	(589)	--
Deferred financing costs	--	(33)
Issuance of common stock upon exercise of warrants and options	--	480
	(589)	447
Net cash (used in)/provided by financing activities	(589)	447
(Decrease)/increase in cash and cash equivalents	(32,074)	19,276
Cash and cash equivalents at beginning of period	36,489	25,153
	\$ 4,415	\$ 44,429
Cash and cash equivalents at end of period	\$ 4,415	\$ 44,429

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
June 30, 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 annual operating losses since its inception. Management expects that such losses will continue at least until its lead product, Genasense®(oblimersen sodium) Injection, 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. 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 hormone refractory prostate cancer (HRPC). 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).

On June 30, 2005, the Company announced that it had initiated submission of a New Drug Application (NDA) with the FDA seeking marketing approval of Genasense®. The NDA seeks accelerated approval for the use of Genasense® in combination with fludarabine plus cyclophosphamide for the treatment of patients with chronic lymphocytic leukemia (CLL) who have previously received fludarabine. Genasense® has received Fast Track designation by the FDA in CLL, meaning that the indication represents an unmet medical need. Upon agreement with the FDA, Fast Track designation enables the Company to submit the NDA on a rolling basis as specific sections are completed. Genta has submitted the initial section and the Company anticipates that the NDA will be completed by the end of the fourth quarter of 2005. Genasense® has also received designation as an Orphan Drug in CLL, which provides for a period of marketing exclusivity if the product is approved, certain tax benefits and exemption from certain fees at the time of NDA submission. If accelerated approval is granted, it would require the Company to conduct a confirmatory study and Genta plans to discuss the design of that study with the FDA. Although Fast Track designation, orphan drug designation and accelerated approval provisions are beneficial, there can be no assurance that the NDA will be reviewed faster by the FDA or that the NDA will be approved.

Also on June 30, 2005, the Company announced that it had filed a formal Letter of Intent with the European Medicines Agency (EMEA) as the initial step for submission of a Marketing Authorization Application (MAA) for Genasense®. In the submission, the Company will seek approval for use of Genasense® plus dacarbazine for the treatment of patients with metastatic melanoma who have not previously received chemotherapy. The letter, which is required under centralized registration procedures when marketing authorization is requested concurrently in all EU member states, initiates a six-month process that concludes with filing the completed application. The Company anticipates that the MAA will be filed by the end of the fourth quarter of 2005.

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, the Company received from Aventis notice of termination of the agreements between Genta and Aventis. Pursuant to those agreements, Aventis continued to support the development of Genasense[®] for a six-month period. On May 10, 2005, the Company announced that Genta and Aventis had signed an agreement to finalize the termination of their development and commercialization collaboration for Genasense[®].

During the second quarter of 2005, the Company commenced discussions with other companies on a partnership regarding the development and commercialization of Genasense[®]. Those discussions are ongoing.

On August 8, 2005 the Company announced that it had entered into a definitive agreement with institutional investors to sell approximately 19.1 million shares of its common stock for gross proceeds of approximately \$17.5 million, before fees and expenses. The closing is expected to take place on August 11, 2005, subject to the satisfaction of customary closing conditions. After deducting placement fees, the Company expects to receive net proceeds of approximately \$16.5 million, (before expenses). With the completion of this financing, 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 well into 2006. There are a number of alternatives available to the Company to sustain its operations beyond 2006 should there be a delay in approval of Genasense[®].

The Company may also seek other 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 of America. 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 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 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 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 for a six-month 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 remaining deferred revenue should be recognized over the six-month termination notice period from November 2004 to May 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 June 30, 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*.

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.

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

The following table illustrates the effect on net income/(loss) and net income/(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 June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net income/(loss) applicable to common shares, as reported	\$ 1,919	\$ (29,155)	\$ 15,944	\$ (41,687)
Add: Equity related employee compensation expense included in reported net income, net of related tax effects	11	74	22	144
Deduct: Total stock-based employee compensation expense determined under fair values based method for all awards, net of related tax effects	(1,408)	(2,455)	(2,954)	(4,800)
Pro forma net income/(loss)	\$ 522	\$ (31,536)	\$ 13,012	\$ (46,343)
Net income/(loss) per share attributable to common shareholders:				
As reported: Basic and diluted	\$ 0.02	\$ (0.37)	\$ 0.17	\$ (0.53)
Pro forma: Basic and diluted	\$ 0.01	\$ (0.40)	\$ 0.14	\$ (0.59)

The Company estimated the fair value of options at the date of each grant during the three months ended June 30, 2005 and 2004, respectively, using a Black-Scholes option valuation model with the following assumptions:

	Three Months Ended June 30,	
	2005	2004
Risk-free interest rate	4.8%	3.7%
Dividend yield	--	--
Expected life (years)	6.2	4.0
Expected volatility	117%	117%

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 and supersedes APB Opinion No. 25. 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. 123(R) 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.

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):

	June 30, 2005	December 31, 2004
Cost	\$ 15,732	\$ 5,790
Gross unrealized gains	26	10
Gross unrealized losses	(21)	(42)
Fair value	<u>\$ 15,737</u>	<u>\$ 5,758</u>

The estimated fair value of each marketable security has been compared to its cost, and therefore, a net unrealized gain of approximately \$5 thousand and an unrealized loss of approximately \$32 thousand have been recognized in Accumulated other comprehensive income/(loss) at June 30, 2005 and December 31, 2004, respectively.

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):

	June 30, 2005	December 31, 2004
Raw materials	\$ 8	\$ 21
Work in process	--	--
Finished goods	333	333
	<u>\$ 341</u>	<u>\$ 354</u>

On May 10, 2005, the Company announced that Genta and Aventis had signed an agreement to finalize the termination of their development and commercialization collaboration for Genasense®. The termination agreement provided for no future financial obligations by either party and the retirement of the Line of Credit established by Aventis to Genta. Aventis returned its current inventory of Genasense® drug supply to Genta. With this returned drug supply, the Company has substantial quantities of Genasense® which are recorded at zero cost. Such inventory would be available for the commercial launch of this product, should Genasense® be approved.

5. Property and Equipment

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

Estimated Useful Lives	June 30, 2005	December 31, 2004
	<u> </u>	<u> </u>

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

Computer equipment	3	\$	2,862	\$	2,860
Software	3		3,349		3,349
Furniture and fixtures	5		936		936
Leasehold improvements	Life of lease		410		443
Equipment	5		166		166
			<u>7,723</u>		<u>7,754</u>
Less accumulated depreciation and amortization			<u>(5,937)</u>		<u>(4,907)</u>
		\$	<u>1,786</u>	\$	<u>2,847</u>

6. Short Term Debt

Revolving debt was issued in connection with an amendment, dated March 14, 2003, to the Aventis Collaboration Agreement that established a line of credit related to the development, manufacturing and commercialization of Genasense® (Line of Credit). The Line of Credit was considered an advance against both past and future costs and the borrowing base was adjusted on a monthly basis. With the Aventis notice of termination, Genta could not borrow additional funds and the Line of Credit had to be repaid at the end of the termination period. All payments otherwise due to Genta were applied against the balance on the Line of Credit until the Line of Credit was repaid. On May 10, 2005, the Company announced that Genta and Aventis had finalized a termination agreement, providing for no future financial obligations by either party and the remaining balance on the Line of Credit was forgiven. During the six months ended June 30, 2005, \$6.0 million of reimbursement due from Aventis was applied to the balance of the Line of Credit and the remaining balance of \$1.3 million was recorded as Gain on forgiveness of debt.

7. Comprehensive Income/(Loss)

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

(\$ in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net income/(loss)	\$ 1,919	\$ (29,155)	\$ 15,944	\$ (41,687)
Change in market value on available-for-sale marketable securities	44	(73)	46	(57)
Total comprehensive income/(loss)	\$ 1,963	\$ (29,228)	\$ 15,990	\$ (41,744)

8. Net Income/(Loss) per Share

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

(\$ in thousands, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Numerator:				
Net income/(loss)	\$ 1,919	\$ (29,155)	\$ 15,944	\$ (41,687)
Denominator:				
Weighted average shares outstanding:				
Basic	95,358	79,016	95,358	77,945
Effect of dilutive stock options, warrants and convertible preferred stock	173	--	177	--
Diluted	95,531	79,016	95,535	77,945
Net income/(loss) per share:				
Basic	\$ 0.02	\$ (0.37)	\$ 0.17	\$ (0.53)

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

Diluted

\$ 0.02 \$ (0.37) \$ 0.17 \$ (0.53)

9. 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 were contractually applied against the balance of the Line of Credit until the Line of Credit was repaid. During the six months ended June 30, 2005, \$6.0 million of reimbursement due to Genta was applied to the balance of the Line of Credit. In addition, the Company recorded a gain on the forgiveness of debt of \$1.3 million.

No interest or income taxes were paid for the six months ended June 30, 2005 and 2004, respectively.

10. 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.

11. Recent Accounting Pronouncements

In May 2005, the Financial Accounting Standards Board (FASB) issued Statement (SFAS) No. 154, *Accounting Changes and Error Corrections*, effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. SFAS 154 requires voluntary changes in accounting principle be retrospectively applied to financial statements from previous periods unless such application is impracticable. Under the newly issued standard changes in depreciation, amortization, or depletion for long-lived, non-financial assets should be accounted for as a change in accounting estimate that is effected by a change in accounting principle. The Company believes that the adoption of this standard will not have a material impact on the Company's results of operations, financial position or cash flow.

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 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. 123(R) 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. The Company does 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, the adoption of this statement, effective June 2005, will not have a material impact on the Company's results of operations, financial position or cash flows.

12. Subsequent Event

On August 8, 2005, the Company announced that it had entered into a definitive agreement with institutional investors to sell approximately 19.1 million shares of its common stock for gross proceeds of approximately \$17.5 million, before fees and expenses. The closing is expected to take place on August 11, 2005, subject to the satisfaction of customary closing conditions. After deducting placement fees, the Company expects to receive net proceeds of approximately \$16.5 million, (before expenses).

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 for Genasens® from the U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMEA);
- 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 had recurring annual operating losses since its inception 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 six months ended June 30, 2005, Genta reported total revenues of \$26.4 million and net income of \$15.9 million or \$0.17 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[®]. On May 10, 2005, the Company announced that Genta and Aventis had signed an agreement to finalize the termination of their development and commercialization collaboration for Genasense[®]. The termination agreement provided for no future financial obligations by either party. There will be no further revenues recognized associated with this agreement subsequent to May 8, 2005. As of June 30, 2005, the Company had cash, cash equivalents and marketable securities totaling \$20.2 million. Management continues to anticipate that total average monthly cash outflow will be in the \$3.0 million to \$4.0 million range. On August 8, 2005, the Company announced that it had entered into a definitive agreement with institutional investors to sell approximately 19.1 million shares of its common stock for gross proceeds of approximately \$17.5 million, before fees and expenses. The closing is expected to take place on August 11, 2005, subject to the satisfaction of customary closing conditions. After deducting placement fees, the Company expects to receive net proceeds of approximately \$16.5 million, (before expenses).

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.

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 advanced malignant melanoma. The FDA Oncology Drugs Advisory Committee voted not to recommend Genasense[®] for marketing approval. 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 has continued long-term follow-up of patients who were enrolled in the malignant melanoma trial. In May 2005, we announced that updated data from extended follow-up for a minimum of 24 months continued to show statistical significance for overall response, complete response and progression free survival. Statistical significance was achieved for durable response, (P=0.02). However, overall survival by intent to treat analysis did not show a statistically significant improvement for patients treated with Genasense[®], (P=0.077).

On June 30, 2005, the Company announced that it had filed a formal Letter of Intent with the European Medicines Agency (EMEA) as the initial step for submission of a Marketing Authorization Application (MAA) for Genasense[®]. In the submission, we will seek approval for use of Genasense[®] plus dacarbazine for the treatment of patients with metastatic melanoma who have not previously received chemotherapy. The letter, which is required under centralized registration procedures when marketing authorization is requested concurrently in all member states of the European Union, initiates a six-month process that concludes with filing the completed application. The marketing application for Genasense[®] is supported by extended follow-up of patients from a Phase 3 trial of dacarbazine with or without Genasense[®] in previously untreated patients with metastatic melanoma. The study included 771 patients at 139 sites in nine countries. The MAA will include data from 24 months of minimum follow-up on all patients. Subsequent to filing the letter of intent, the Company was notified that the EMEA has assigned Spain and France as Rapporteur and Co-Rapporteur, respectively, for review of the melanoma MAA.

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 (CR) or a nodular partial remission (nPR)), as determined by review of clinical data and bone marrow biopsies using experts who were blinded as to treatment assignment. Analysis of study results showed 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. No significant 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[®]. Treatment-emergent adverse events (irrespective of relation to study drugs) during treatment or within thirty days from last dose of treatment that resulted in death occurred in nine patients treated with Genasense[®] plus chemotherapy compared with five 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. In May 2005, we announced that additional follow-up had shown that the duration of major responses (CR/nPR) was significantly superior for patients in the Genasense[®] treatment group.

On June 30, 2005, the Company announced that it had initiated submission of an NDA with the FDA seeking marketing approval of Genasense[®]. The NDA seeks accelerated approval for the use of Genasense[®] in combination with fludarabine plus cyclophosphamide for the treatment of patients with chronic lymphocytic leukemia (CLL) who have previously received fludarabine. Genasense[®] has received Fast Track designation by the FDA in CLL, meaning that the indication represents an unmet medical need. Upon agreement with the FDA, Fast Track designation enables the Company to submit the NDA on a "rolling" basis as specific sections are completed. Genta has submitted the initial section and the Company anticipates that the NDA will be completed by the end of the fourth quarter of 2005. Genasense[®] has also received designation as an Orphan Drug in CLL, which provides for a period of marketing exclusivity if the product is approved, certain tax benefits and exemption from certain fees at the time of NDA submission. If accelerated approval is granted, it would require us to conduct a confirmatory study and we plan to discuss the design of that study with the FDA. Although Fast Track designation, orphan drug designation and accelerated approval provisions are beneficial, there can be no assurance that the NDA will be reviewed faster by the FDA or that the NDA will be approved.

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 hormone refractory prostate cancer (HRPC). We are also conducting a number of non-randomized clinical trials in patients with various types of cancer, either under our own sponsorship or in collaboration with the National Cancer Institute (NCI).

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

In April 2002, we entered into a series of agreements 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 continued to support the development of Genasense[®] for a six-month termination period.

On May 10, 2005, the Company announced that Genta and Aventis had signed an agreement to finalize the termination of their development and commercialization collaboration for Genasense[®]. The termination agreement provided for no future financial obligations by either party and the retirement of the Line of Credit established by Aventis to Genta. Aventis returned its current inventory of Genasense[®] drug supply to Genta. In addition, Genta assumed 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 were not terminated at that time.

Results of Operations for the Three Months Ended June 30, 2005 and 2004

(\$ in thousands)	Summary Operating Results For the three months ended June 30,			
	2005	Increase (Decrease)		2004
		\$	%	
Revenues:				
License fees and royalties	\$ 1,556	\$ 1,295	496%	\$ 261
Development funding	6,234	5,185	494%	1,049
Product sales - net	97	(154)	(61)%	251
Total revenues	7,887	6,326	405%	1,561
Cost of goods sold	18	(34)	(65)%	52
Provision for excess inventory	(21)	(21)	(100)%	--
Total cost of goods sold	(3)	(55)	(106)%	52
Gross margin	7,890	6,381	423%	1,509
Costs and expenses:				
Research and development (including non-cash compensation expense of \$52 for the three months ended June 30, 2004)	5,551	(23,394)	(81)%	28,945
Selling, general and administrative (including non-cash compensation expense of \$11 and \$22 for the three months ended June 30, 2005 and June 30, 2004, respectively)	4,635	(5,649)	(55)%	10,284
Total costs and expenses - gross	10,186	(29,043)	(74)%	39,229
Less: Aventis reimbursement	(2,838)	5,693	67%	(8,531)
Total costs and expenses - net	7,348	(23,350)	(76)%	30,698
Gain on forgiveness of debt	1,297	1,297	100%	--
Other income	80	46	135%	34
Net income/(loss)	\$ 1,919	\$ 31,074	107%	\$ (29,155)

Total Revenues

Total revenues, consisting of license fees and royalties, development funding and net product sales were \$7.9 million for the three months ended June 30, 2005 compared to \$1.6 million for the three months ended June 30, 2004. License fees and development funding revenues are generated by the recognition of 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-months 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, we determined that the remaining deferred revenue should be recognized over the termination period. On November 9, 2004, we began to recognize the remaining deferred revenue over the six-month period, resulting in increased revenue of \$6.5 million for the three months ended June 30, 2005 compared to the three months ended June 30, 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 three months ended June 30, 2005 were significantly below the prior-year period.

Cost of Goods Sold

In 2004, we recorded provisions for excess inventory of Ganite[®] of \$1.4 million based on the significant decline of sales of the product. During the three months ended June 30, 2005, sales of Ganite[®] have slightly increased above both sales during the first three months of 2005 and previously forecasted sales. Accordingly, we have lowered the reserve for excess inventory of Ganite[®] by \$21 thousand.

Research and Development Expenses

Research and development expenses before reimbursement were \$5.6 million for the three months ended June 30, 2005 compared to \$28.9 million for the three months ended June 30, 2004. During the three months ended June 30, 2005, approximately \$5.3 million or 96% of research and development expenses before reimbursement were incurred on the Genasense[®] project. In the prior-year period, research and development expenses before reimbursement incurred on the Genasense[®] project of approximately \$27.4 million included the expensing of \$7.0 million of vialled Genasense[®] product, which had been produced to be commercial inventory, as the vials were to be used in clinical trials. Also, \$11.7 million of Genasense[®] bulk drug substance was expensed. Research and development expenses in 2005 also declined from the prior-year period due to our decision in May 2004 to reduce staff and reduce most non-Genasense[®] related programs. Of the \$5.6 million in research and development expenses for the three months ended June 30, 2005, \$2.8 million was reimbursable pursuant to our Collaborative Agreement with Aventis. With the Aventis notice of termination, payments of \$2.8 million otherwise due to Genta were applied against the balance of the Line of Credit (see Note 6 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 \$4.6 million for the three months ended June 30, 2005 compared to \$10.3 million for the three months ended June 30, 2004. 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[®]. Expenses in 2004 were at a substantially higher rate of spending in anticipation of approval and launch of Genasense[®]. In addition, in the 2004 period, we recorded \$1.0 million of legal expenses related to certain class action lawsuits (see Note 10 to our Financial Statements).

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 was required to reimburse under our Collaborative Agreement with Aventis, follows:

(\$ in thousands)	Three months ended June 30,	
	2005	2004
Reimbursement to Genta		
Third-party costs	\$ 1,559	\$ 4,589
Drug supply costs	899	2,837
FTE s	425	1,604
	<hr/>	<hr/>
Amount due to Genta	2,883	9,030
Reimbursement to Aventis	(45)	(499)
	<hr/>	<hr/>
Net reimbursement to Genta	\$ 2,838	\$ 8,531
	<hr/>	<hr/>

Net expense reimbursement from Aventis of \$2.8 million for the three months ended June 30, 2005 declined from \$8.5 million for the prior-year period due to lower expenses incurred on the Genasense® project and the Collaborative Agreement coming to an end in May 10, 2005.

Once Aventis provided notice of termination of the Collaborative Agreement, all payments otherwise due from Aventis were applied against the balance on the Line of Credit until the Line of Credit was repaid. During the three months ended June 30, 2005, \$2.8 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.

Gain on Forgiveness of Debt

On May 10, 2005, the Company announced that Aventis and Genta had finalized the termination of the Collaborative Agreement. Pursuant to the terms of the Collaborative Agreement, \$2.8 million of reimbursable costs accrued and owed to the Company by Aventis were applied against the Line of Credit with Aventis and the remaining balance of \$1.3 million was forgiven.

Net Income/(Loss)

The Company recorded net income of \$1.9 million, or \$0.02 per share, for the three months ended June 30, 2005, compared to a net loss of \$29.2 million, or \$0.37 per share, for the three months ended June 30, 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, lower research and development expenses, lower selling, general and administrative expenses, along with a gain on the forgiveness of debt.

Results of Operations for the Six Months Ended June 30, 2005 and 2004**Summary Operating Results
For the six months ended June 30,**

(\$ in thousands)	Increase (Decrease)			2004
	2005	\$	%	
Revenues:				
License fees and royalties	\$ 5,241	\$ 4,719	904%	\$ 522
Development funding	20,988	18,891	901%	2,097
Product sales - net	172	(452)	(72)%	624
Total revenues	26,401	23,158	714%	3,243
Cost of goods sold				
Cost of goods sold	33	(113)	(77)%	146
Provision for excess inventory	(21)	(21)	(100)%	--
Total cost of goods sold	12	(134)	(92)%	146
Gross margin	26,389	23,292	752%	3,097
Costs and expenses:				
Research and development (including non-cash compensation expense of \$104 for the six months ended June 30, 2004)	9,421	(31,876)	(77)%	41,297
Selling, general and administrative (including non-cash compensation expense of \$22 and \$39 for the six months ended June 30, 2005 and June 30, 2004, respectively)	8,621	(10,886)	(56)%	19,507
Total costs and expenses - gross	18,042	(42,762)	(70)%	60,804
Less: Aventis reimbursement	(6,090)	9,874	62%	(15,964)
Total costs and expenses - net	11,952	(32,888)	(73)%	44,840
Gain on forgiveness of debt	1,297	1,297	100%	--
Other income	210	154	275%	56
Net income/(loss)	\$ 15,944	\$ 57,631	138%	\$ (41,687)

Total Revenues

Total revenues, consisting of license fees and royalties, development funding and net product sales were \$26.4 million for the six months ended June 30, 2005 compared to \$3.2 million in for the six months ended June 30, 2004. License fees and development funding revenues are generated by the recognition of 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 notice to Genta that it was terminating its Collaborative Agreement with the Company regarding the development and commercialization of Genasense®. On November 9, 2004, we began to recognize the remaining deferred revenue over the six-month termination notice period, resulting in increased revenue of \$23.6 million for the six months ended June 30, 2005 compared to the six months ended June 30, 2004.

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

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 six months ended June 30, 2005 are significantly below the prior-year period.

Research and Development Expenses

Research and development expenses before reimbursement were \$9.4 million for the six months ended June 30, 2005 compared to \$41.3 million for the six months ended June 30, 2004. During the six months ended June 30, 2005, approximately \$9.0 million or 96% of research and development expenses before reimbursement were incurred on the Genasense[®] project. In the prior-year period, research and development expenses before reimbursement incurred on the Genasense[®] project of approximately \$38.2 million included the expensing of approximately \$7.0 million of vialled Genasense[®] product and \$11.7 million of Genasense[®] bulk drug substance. Research and development expenses in 2005 also decreased due to our decision in May 2004 to reduce staff and reduce most non-Genasense[®] related programs. Of the \$9.4 million in research and development expenses for the six months ended June 30, 2005, \$6.1 million was reimbursable pursuant to our Collaborative Agreement with Aventis. With the Aventis notice of termination, payments of \$6.0 million otherwise due to Genta were applied against the balance of the Line of Credit (see Note 6 to our Financial Statements).

Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$8.6 million for the six months ended June 30, 2005 compared to \$19.5 million for the six months ended June 30, 2004. 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[®]. Expenses in 2004 were at a substantially higher rate of spending in anticipation of approval and launch of Genasense[®]. In addition, in the 2004 period, we recorded \$1.0 million of legal expenses related to certain class action lawsuits (see Note 10 to our Financial Statements).

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 was required to reimburse under our Collaborative agreement with Aventis, follows:

(\$ in thousands)	Six months ended June 30,	
	2005	2004
Reimbursement to Genta		
Third-party costs	\$ 2,917	\$ 10,953
Drug supply costs	1,807	2,593
FTE s	1,513	3,334
	6,237	16,880
Reimbursement to Aventis	(147)	(916)
Net reimbursement to Genta	\$ 6,090	\$ 15,964

Net expense reimbursement from Aventis of \$6.1 million for the six months ended June 30, 2005 declined from \$16.0 million for the six months ended June 30, 2004 due to lower expenses incurred on the Genasense[®] project and the Collaborative Agreement coming to an end in May 2005.

Once Aventis provided notice of termination of the Collaborative Agreement, all payments otherwise due from Aventis were applied against the balance on the Line of Credit until the Line of Credit was repaid. During the six months ended June 30, 2005, \$6.0 million of reimbursement due to Genta was applied to the balance of the Line of Credit.

Other Income

Net other income for the six months ended June 30, 2005 increased by \$0.2 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 \$15.9 million, or \$0.17 per share, for the six months ended June 30, 2005, compared to a net loss of \$41.7 million, or \$0.53 per share, for the six months ended June 30, 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, lower research and development expenses, lower selling, general and administrative expenses, along with a gain on the forgiveness of debt.

Liquidity and Capital Resources

At June 30, 2005, the Company had cash, cash equivalents and marketable securities totaling \$20.2 million compared to \$42.2 million at December 31, 2004. Cash flow used in operating activities was \$21.6 million for the six months ended June 30, 2005 compared to \$31.4 million for the six months ended June 30, 2004. This decline reflects our smaller organization and focus on Genasense[®]. Management continues to anticipate that total average monthly cash outflow will be in the \$3.0 million to \$4.0 million range.

At June 30, 2005, Genta had no outstanding balance on the Line of Credit with Aventis (compared to \$7.3 million as of December 31, 2004). With the Aventis notice of termination, Genta could not borrow additional funds and the Line of Credit had to be repaid at the end of the termination period. All payments otherwise due to Genta were applied against the balance on the Line of Credit until the Line of Credit was repaid. On May 10, 2005, the Company announced that Genta and Aventis had finalized a termination agreement, providing for no future financial obligations by either party and the remaining balance on the Line of Credit was forgiven. During the six-month period ended June 30, 2005, \$6.0 million of reimbursement due from Aventis was applied to the balance of the Line of Credit and the remaining balance of \$1.3 million was recorded as Gain on forgiveness of debt.

On August 8, 2005, the Company announced that it had entered into a definitive agreement with institutional investors to sell approximately 19.1 million shares of its common stock for gross proceeds of approximately \$17.5 million, before fees and expenses. The closing is expected to take place on August 11, 2005, subject to the satisfaction of customary closing conditions. After deducting placement fees, the Company expects to receive net proceeds of approximately \$16.5 million, (before expenses). With the completion of this financing, 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 well into 2006. There are a number of alternatives available to the Company to sustain its operations beyond 2006 should there be a delay in approval of Genasense[®].

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 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[®] for one or more applications, 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 May 2005, the Financial Accounting Standards Board (FASB) issued Statement (SFAS) No. 154, *Accounting Changes and Error Corrections*, effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. SFAS 154 requires voluntary changes in accounting principle be retrospectively applied to financial statements from previous periods unless such application is impracticable. Under the newly issued standard changes in depreciation, amortization, or depletion for long-lived, non-financial assets should be accounted for as a change in accounting estimate that is effected by a change in accounting principle. We believe that the adoption of this standard will not have a material impact on the Company's results of operations, financial position or cash flow.

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 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. 123(R) 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, the adoption of this statement, effective June 2005, will not 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 June 30, 2005.

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 4. Submission of Matters to a Vote of Security Holders

(a) The Company held its Annual Meeting of Stockholders (the "Annual Meeting") on June 23, 2005.

(b) Proxies for the meeting were solicited pursuant to Regulation 14A of the Exchange Act. There was no solicitation in opposition to the Board of Directors' nominees for directors listed in the definitive proxy statement of the Company dated as of April 30, 2005. All of the Board of Directors' nominees were elected.

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

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

Directors	Votes For	Withheld
Raymond P. Warrell, Jr., M.D	80,960,490	2,762,275
Jerome E. Groopman, M.D	81,022,429	2,700,336
Betsy McCaughey, Ph.D	81,059,563	2,663,202
Peter T. Tattle	81,059,091	2,663,674
Daniel D. Von Hoff, M.D	80,976,757	2,746,008
Harlan J. Wakoff	80,987,658	2,735,107
Douglas G. Watson	80,859,724	2,863,041
Michael S. Weiss	80,775,392	2,947,373

(ii) Approval of an amendment to the Company's Non-Employee Director's 1998 Stock Option Plan with respect to the number of options authorized for issuance under the plan. The result of the voting was as follows:

For:	14,381,183 votes
Against:	4,883,269 votes
Abstain:	6,917,492 votes

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

(iii) Ratification of the selection of Deloitte & Touche LLP as the Company's independent auditors for the fiscal year ending December 31, 2005. The result of the voting was as follows:

For:	76,429,783 votes
Against:	388,140 votes
Abstain:	6,904,842 votes

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)
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

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

- 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: August 9, 2005

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

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

Date: August 9, 2005

/s/ WILLIAM P.
KEANE

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

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

Exhibit Index	Sequentially
Exhibit	Numbered
Number	Pages
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)
3.2	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

