

GENTA INC DE/
Form 10-Q
November 07, 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 September 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

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

Yes No

As of October 31, 2005, the registrant had 114,417,093 shares of common stock outstanding.

Genta Incorporated
INDEX TO FORM 10-Q

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited):

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

Consolidated Statements of Operations for the Three
and Nine Months Ended September 30, 2005
and 2004 4

Consolidated Statements of Cash Flows for the Nine
Months Ended September 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 16

Item 3. Quantitative and Qualitative Disclosures about Market Risk 26

Item 4. Controls and Procedures 26

PART II. OTHER INFORMATION

Item 1. Legal Proceedings 27

Item 6. Exhibits 27

SIGNATURES 28

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements:

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

Consolidated Statements of Operations for the Three
and Nine Months Ended September 30, 2005
and 2004

Consolidated Statements of Cash Flows for the Nine
Months Ended September 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 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)

ASSETS	September 30, 2005	December 31, 2004
Current assets:		
Cash and cash equivalents	\$ 12,905	\$ 36,489
Marketable securities (Note 3)	15,909	5,758
Accounts receivable	44	--
Inventory (Note 4)	319	354
Prepaid expenses and other current assets	630	1,910
	29,807	44,511
Total current assets		
Property and equipment, net (Note 5)	1,428	2,847
Intangibles, net	--	286
Prepaid royalties	1,268	1,268
Other assets	1,635	1,620
	34,138	50,532
Total assets	\$ 34,138	\$ 50,532
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 7,810	\$ 14,424
Deferred revenues, current portion	--	26,228
Notes payable	130	816
Short term debt (Note 6)	--	7,312
	7,940	48,780
Total current liabilities and total liabilities		
Commitments and contingencies (Note 11)		
Stockholders' equity (Note 7):		
Preferred stock, 5,000 shares authorized		
Series A convertible preferred stock, \$.001 par value;		
10 shares issued and outstanding, liquidation value of \$485 at		
September 30, 2005 and December 31, 2004, respectively	--	--
Series G participating cumulative preferred stock, \$.001 par		
value, 0 shares issued and outstanding at September 30, 2005		
and December 31, 2004, respectively		
Common stock, \$.001 par value; 150,000 shares authorized,		
114,417 and 95,358 shares issued and outstanding at September 30, 2005		
and December 31, 2004, respectively	114	95
Additional paid-in capital	373,993	357,714
Accumulated deficit	(347,943)	(355,984)
Deferred compensation	(8)	(41)
Accumulated other comprehensive income/(loss)	42	(32)
	26,198	1,752
Total stockholders' equity		
Total liabilities and stockholders' equity	\$ 34,138	\$ 50,532

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

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
	(Unaudited)		(Unaudited)	
Revenues:				
License fees and royalties	\$ --	\$ 261	\$ 5,241	\$ 783
Development funding	--	1,049	20,988	3,145
Product sales - net	86	87	259	711
	86	1,397	26,488	4,639
Total revenues				
Cost of goods sold	22	19	56	165
Provision for excess inventory	--	693	(21)	693
	22	712	35	858
Total cost of goods sold				
Gross margin	64	685	26,453	3,781
Costs and expenses:				
Research and development (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of \$53 for the three months and \$158 for the nine months ended September 30, 2004)	4,619	20,643	14,040	61,940
Selling, general and administrative (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of \$11 for the three months ended September 30, 2005 and September 30, 2004, and \$34 and \$50 for the nine months ended September 30, 2005 and September 30, 2004 respectively)	3,495	4,721	12,116	24,228
Loss on disposition of property and equipment	1	1,254	4	1,254
	8,115	26,618	26,160	87,422
Total costs and expenses - gross				
Aventis reimbursement	--	(20,489)	(6,090)	(36,453)
	8,115	6,129	20,070	50,969
Total costs and expenses - net				
Gain on forgiveness of debt	--	--	1,297	--
Other income/(expense)	147	(136)	361	(79)
	(7,904)	(5,580)	8,041	(47,267)
Net income/(loss)				
Net income/(loss) per basic and diluted share (Note 9)	\$ (0.07)	\$ (0.07)	\$ 0.08	\$ (0.60)
Shares used in computing net income/(loss) per basic share	105,629	80,358	98,820	78,758
Shares used in computing net income/(loss) per diluted share	105,629	80,358	99,015	78,758

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

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Nine Months Ended September 30,	
	2005	2004
	(Unaudited)	
Operating activities:		
Net income/(loss)	\$ 8,041	\$ (47,267)
Items reflected in net income/(loss) not requiring cash:		
Depreciation and amortization	1,723	2,323
Loss on disposition of property and equipment	4	1,254
Non-cash reimbursement of research & development expense	(6,090)	(15,541)
Provision for excess inventory	(21)	693
Gain on forgiveness of debt	(1,297)	--
Amortization of deferred revenues	(26,228)	(3,928)
Compensation expense related to certain stock options issued in 1999 and 2000	34	208
Changes in operating assets and liabilities:		
Accounts receivable	(44)	10,558
Inventory	55	(1,191)
Notes receivable	--	3,542
Prepaid expenses and other current assets	1,280	1,500
Accounts payable and accrued expenses	(6,538)	3,463
Other assets	(15)	(22)
	(29,096)	(44,408)
Investing activities:		
Purchase of marketable securities	(21,839)	(7,281)
Maturities and sales of marketable securities	11,763	59,242
Deposit to restricted cash account	--	(294)
Redemption of restricted cash account	--	165
Purchase of property and equipment	(56)	(1,767)
Proceeds from sale of property and equipment	34	157
	(10,098)	50,222
Financing activities:		
Issuance of common stock, net	16,297	--
Borrowings under note payable	--	419
Repayments of note payable	(687)	(888)
Deferred financing costs	--	(48)
Issuance of common stock upon exercise of warrants and options	--	480
	15,610	(37)
(Decrease)/increase in cash and cash equivalents	(23,584)	5,777
Cash and cash equivalents at beginning of period	36,489	25,153
	\$ 12,905	\$ 30,930

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

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
September 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.

The Company has \$28.8 million of cash and cash equivalents and marketable securities on hand at September 30, 2005. On August 11, 2005, the Company sold 19.1 million shares of its common stock at a price of \$0.92 per share for gross proceeds of \$17.5 million, before fees and expenses. After deducting fees and expenses the Company received net proceeds of \$16.3 million. 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 into the middle of 2006.

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.

Additional alternatives available to the Company to subsequently sustain its operations include 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.

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 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. 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.

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®. The termination agreement provided for no future financial obligations by either party.

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. 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 September 30, 2005, the Company's remaining 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 Statements 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 using 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 evaluation, 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 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.

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 September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net income/(loss) applicable to common shares, as reported	\$ (7,904)	\$ (5,580)	\$ 8,041	\$ (47,267)
Add: Equity related employee compensation expense included in reported net income, net of related tax effects	11	65	34	208
Deduct: Total stock-based employee compensation expense determined under fair- value based method for all awards, net of related tax effects	(1,291)	(2,455)	(4,248)	(7,254)
Pro forma net income/(loss)	\$ (9,184)	\$ (7,970)	\$ 3,827	\$ (54,313)
Net income/(loss) per share attributable to common shareholders:				
As reported: Basic and diluted	\$ (0.07)	\$ (0.07)	\$ 0.08	\$ (0.60)
Pro forma: Basic and diluted	\$ (0.09)	\$ (0.10)	\$ 0.04	\$ (0.69)

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

	Three Months Ended September 30,	
	2005	2004
Risk-free interest rate	4.1%	3.5%
Dividend yield	--	--
Expected life (years)	6.2	4.0
Expected volatility	118%	77%

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):

	September 30, 2005	December 31, 2004
Cost	\$ 15,867	\$ 5,790
Gross unrealized gains	42	10
Gross unrealized losses	--	(42)
Fair value	\$ 15,909	\$ 5,758

The estimated fair value of each marketable security has been compared with its cost, and therefore, an unrealized gain of approximately \$42 thousand and a net unrealized loss of approximately \$32 thousand have been recognized in Accumulated other comprehensive income/(loss) at September 30, 2005 and December 31, 2004, respectively.

4. Inventory

Inventory is stated at the lower of cost or market with cost being determined using the first-in, first-out (FIFO) method. Inventory consisted of the following (\$ thousands):

	September 30, 2005	December 31, 2004
Raw materials	\$ 308	\$ 333
Work in process	--	--
Finished goods	11	21
	\$ 319	\$ 354

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 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	September 30, 2005	December 31, 2004
Computer equipment	3	\$ 2,871	\$ 2,860
Software	3	3,349	3,349
Furniture and fixtures	5	936	936
Leasehold improvements	Life of lease	410	443
Equipment	5	182	166
		7,748	7,754
Less accumulated depreciation and amortization		(6,320)	(4,907)
		\$ 1,428	\$ 2,847

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, resulting in a gain on forgiveness of debt of \$1.3 million.

7. Stockholders Equity

Common Stock

In March 2004, the Board of Directors approved an amendment to increase the authorized common stock to 150.0 million shares from 120.0 million shares. In June 2004, shareholders approved this amendment at the Annual Meeting of Stockholders.

In December 2004, the Company issued 15.0 million shares of its common stock through a direct placement with two institutions and received net proceeds of approximately \$21.6 million.

In August 2005, the Company issued 19.1 million shares of its common stock and received net proceeds of approximately \$16.3 million.

In September 2005, the Board of Directors adopted a Stockholder Rights Plan and declared a dividend of one preferred stock purchase right (a Right) for each outstanding share of common stock of the Company, payable to holders of record as of the close of business on September 27, 2005. Generally, the rights become exercisable upon the earlier of the close of business on the tenth business day following the first public announcement that any person or group has become a beneficial owner of 15% or more of the Company's Common Stock and the close of business on the tenth business day after the date of the commencement of a tender or exchange offer by any person which would, if consummated, result in such person becoming a beneficial owner of 15% or more of the Company's common stock. Each Right shall be exercisable to purchase, for \$25.00, subject to adjustment, one one-hundredth of a newly registered share of Series G Participating Cumulative Preferred Stock, par value \$0.001 per share of the Company. The terms and conditions of the Rights are set forth in a Rights Agreement dated

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

September 20, 2005 between the Company and Mellon Investor Services, LLC, as Rights Agent.

Series A Preferred Stock

Each share of Series A Preferred Stock is immediately convertible into shares of the Company's common stock, at a rate determined by dividing the aggregate liquidation preference of the Series A Preferred Stock by the conversion price. The conversion price is subject to adjustment for antidilution. As of September 30, 2005 and December 31, 2004, each share of Series A Preferred Stock was convertible into 9.8067 and 8.4274 shares of common stock, respectively.

At September 30, 2005 and December 31, 2004, the Company had 9,700 shares of Series A Convertible Preferred Stock issued and outstanding.

Series G Preferred Stock

The Company has authorized 5.0 million shares of preferred stock of which 2.0 million shares has been designated Series G Participating Cumulative Preferred.

8. Comprehensive Income/(Loss)

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

(\$ in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net income/(loss)	\$ (7,904)	\$ (5,580)	\$ 8,041	\$ (47,267)
Change in market value on available-for-sale marketable securities	38	15	74	(42)
Total comprehensive income/(loss)	\$ (7,866)	\$ (5,565)	\$ 8,115	\$ (47,309)

9. 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 September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Numerator:				
Net income/(loss)	\$ (7,904)	\$ (5,580)	\$ 8,041	\$ (47,267)
Denominator:				
Weighted average shares outstanding:				
Basic	105,629	80,358	98,820	78,758
Effect of dilutive stock options, warrants and convertible preferred stock	--	--	195	--
Diluted	105,629	80,358	99,015	78,758

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

Net income/(loss) per share:

Basic	\$	(0.07)	\$	(0.07)	\$	0.08	\$	(0.60)
Diluted	\$	(0.07)	\$	(0.07)	\$	0.08	\$	(0.60)

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 were contractually applied against the balance of the Line of Credit until the Line of Credit was repaid. During the nine months ended September 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 nine months ended September 30, 2005 and 2004, respectively.

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 its principal officers on behalf of purported classes of the Company's shareholders who purchased its 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. On September 30, 2005, the court granted in part and denied in part the Company's motion to dismiss the plaintiffs' complaint. The court dismissed plaintiffs' claim that the defendants engaged in a scheme or artifice to defraud plaintiffs, but allowed plaintiffs' claims to proceed with respect to their allegations that defendants issued false and misleading public statements about Genasense®. On October 17, 2005 defendants filed an answer to the complaint and will soon commence pre-trial discovery.

In addition, two separate 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 continue to 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. 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. 153, *Exchanges of Non-monetary Assets*, an amendment of APB Opinion No. 29. The adoption of this statement, effective June 2005, did not 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, did not have a material impact on the Company's results of operations, financial position or cash flows.

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 nine months ended September 30, 2005, Genta reported total revenues of \$26.5 million and net income of \$8.0 million or \$0.08 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 September 30, 2005, the Company had cash, cash equivalents and marketable securities totaling \$28.8 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 11, 2005, the Company sold 19.1 million shares of its common stock at a price of \$0.92 per share for gross proceeds of \$17.5 million, before fees and expenses. After deducting fees and expenses the Company received net proceeds of \$16.3 million.

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.

On September 19, 2005, the Company announced the presentation of results from extended follow-up of patients enrolled in the Phase 3 randomized trial of Genasense® plus chemotherapy for patients with relapsed or refractory CLL. In the Phase 3 trial, 241 patients with relapsed or refractory CLL were randomly assigned to receive fludarabine plus cyclophosphamide (Flu/Cy) chemotherapy with or without Genasense®. The trial achieved its primary endpoint, which was a statistically significant increase in the proportion of patients who achieved a complete or nodular partial response (CR/nPR) (17% vs. 7%, respectively; P=0.025). To date, six of the eight patients (75%) who achieved CR/nPR with chemotherapy alone have relapsed compared with five of twenty patients (25%) in the Genasense® treatment group. The median duration of CR/nPR was 22 months in the chemotherapy-alone group; the median has not been reached in the Genasense® group (P=0.03). All CR/nPR responses have been durable (i.e., exceeding six months duration).

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. The Company has requested a meeting with the FDA to discuss plans for a confirmatory post-approval study.

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

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 regulatory applications 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).

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. 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 September 30, 2005 and 2004

(\$ in thousands)	Summary Operating Results			
	For the three months ended September 30,			
		Increase (Decrease)		
	2005	\$	%	2004
Revenues:				
License fees and royalties	\$ -	\$ (261)	(100)%	\$ 261
Development funding	--	(1,049)	(100)%	1,049
Product sales - net	86	(1)	(1)%	87
Total revenues	86	(1,311)	(94)%	1,397
Cost of goods sold	22	3	16%	19
Provision for excess inventory	--	(693)	(100)%	693
Total cost of goods sold	22	(690)	(97)%	712
Gross margin	64	(621)	(91)%	685
Costs and expenses:				
Research and development (including non-cash compensation expense of \$53 for the three months ended September 30, 2004)	4,619	(16,024)	(78)%	20,643
Selling, general and administrative (including non-cash compensation expense of \$11 for the three months ended September 30, 2005 and September 30, 2004)	3,495	(1,226)	(26)%	4,721
Loss on disposition of property and equipment	1	(1,253)	(100)%	1,254
Total costs and expenses - gross	8,115	(18,503)	(70)%	26,618
Less: Aventis reimbursement	--	20,489	100%	(20,489)

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

Total costs and expenses - net	<u>8,115</u>	<u>1,986</u>	<u>32%</u>	<u>6,129</u>
Other income/(expense)	<u>147</u>	<u>283</u>	<u>208%</u>	<u>(136)</u>
Net loss	<u>\$ (7,904)</u>	<u>\$ (2,324)</u>	<u>(42)%</u>	<u>\$ (5,580)</u>

Total Revenues

Total revenues were \$0.1 million for the three months ended September 30, 2005 compared with \$1.4 million for the three months ended September 30, 2004. License fees and development funding revenues of \$1.3 million for the three months ended September 30, 2004 were 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. 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, ended May 8, 2005.

Product sales-net are generated from sales of Ganite®, the Company's commercial product for the treatment of cancer-related hypercalcemia. Product sales-net for the three months ended September 30, 2005 were virtually unchanged compared with the prior-year period.

Cost of Goods Sold

Cost of goods sold for the prior-year period includes a provision for excess inventory of Ganite® of \$0.7 million. Excluding the provision for excess inventory, cost of goods sold for the three months ended September 30, 2005 were virtually unchanged from the prior-year period, consistent with product sales.

Research and Development Expenses

Research and development expenses before reimbursement were \$4.6 million for the three months ended September 30, 2005 compared with \$20.6 million for the three months ended September 30, 2004. During the three months ended September 30, 2005, approximately \$4.3 million or 93% of research and development expenses were incurred on the Genasense® project. In the prior-year period, research and development expenses before reimbursement incurred on the Genasense® project of approximately \$20.1 million included \$13.3 million related to purchases of Genasense® bulk drug substance.

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 \$3.5 million for the three months ended September 30, 2005 compared with \$4.7 million for the three months ended September 30, 2004. The decline is primarily due to lower headcount and resultant payroll expenses in 2005 combined with lower depreciation expense resulting from limited purchases of equipment since mid-2004.

Aventis Reimbursement

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, for the three months ended September 30, 2004, follows:

(\$ in thousands)	Three months ended September 30, 2004
Reimbursement to Genta	
Third-party costs	\$ 3,982
Drug supply costs	15,620
FTE s	1,333
	<hr/>
Amount due to Genta	20,935
Reimbursement to Aventis	(446)
	<hr/>
Net reimbursement to Genta	\$ 20,489
	<hr/>

In September 2004, the Company transferred \$15.5 million of vialled Genasense[®] drug product and Genasense[®] bulk drug substance to Aventis. This amount is included in Drug supply costs in the above table.

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. Consequently, none of the research and development expenses incurred by the Company during the three-month period ended September 30, 2005 were reimbursable.

Loss on disposition of property and equipment

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

Net Loss

The Company recorded a net loss of \$7.9 million, or \$0.07 per share, for the three months ended September 30, 2005, compared with a net loss of \$5.6 million, or \$0.07 per share, for the three months ended September 30, 2004. As described above, the prior-year period included revenues of \$1.3 million from the continued recognition of the license fee and development funding received in 2002 from Aventis, expenses of \$13.3 million related to purchases of Genasense[®] bulk drug substance and a loss of \$1.3 million from the disposition of property and equipment; more than offset by \$20.5 million of reimbursement from Aventis, including the transfer of \$15.5 million of vialled Genasense[®] drug product and bulk drug substance to Aventis. The absence of these items in this year s three-month period was primarily offset by lower research and development and selling, general and administrative expenses.

Results of Operations for the Nine Months Ended September 30, 2005 and 2004

(\$ in thousands)	Summary Operating Results			
	For the nine months ended September 30,			
	2005	Increase (Decrease)		2004
	\$	%		
Revenues:				
License fees and royalties	\$ 5,241	\$ 4,458	569%	\$ 783
Development funding	20,988	17,843	567%	3,145
Product sales - net	259	(452)	(64)%	711
Total revenues	26,488	21,849	471%	4,639
Cost of goods sold	56	(111)	(68)%	165
Provision for excess inventory	(21)	(712)	(103)%	693
Total cost of goods sold	35	(823)	(96)%	858
Gross margin	26,453	22,672	600%	3,781
Costs and expenses:				
Research and development (including non-cash compensation expense of \$158 for the nine months ended September 30, 2004)	14,040	(47,900)	(77)%	61,940
Selling, general and administrative (including non-cash compensation expense of \$34 and \$50 for the nine months ended September 30, 2005 and September 30, 2004, respectively)	12,116	(12,112)	(50)%	24,228
Loss on disposition of property and equipment	4	(1,250)	(100)%	1,254
Total costs and expenses - gross	26,160	(61,262)	(70)%	87,422
Less: Aventis reimbursement	(6,090)	(30,363)	(83)%	(36,453)
Total costs and expenses - net	20,070	(30,899)	(61)%	50,969
Gain on forgiveness of debt	1,297	1,297	100%	--
Other income/(expense)	361	440	557%	(79)
Net income/(loss)	\$ 8,041	\$ 55,308	117%	\$ (47,267)

Total Revenues

Total revenues, consisting of license fees and royalties, development funding and net product sales were \$26.5 million for the nine months ended September 30, 2005 compared with \$4.6 million for the nine months ended September 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.

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

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

six-month termination notice period; resulting in increased revenue of \$22.3 million for the nine months ended September 30, 2005 compared with the nine months ended September 30, 2004.

Product sales of Ganite[®] during the nine months ended September 30, 2005 are below the prior-year period. In May 2004, the Company eliminated its sales force and significantly reduced its marketing support for Ganite[®].

Cost of Goods Sold

Cost of goods sold for the prior-year period includes a provision for excess inventory of Ganite[®] of \$0.7 million. Excluding the provision for excess inventory, cost of goods sold for the three months ended September 30, 2005 decreased from the prior-year period, consistent with the decline in product sales.

Research and Development Expenses

Research and development expenses before reimbursement were \$14.0 million for the nine months ended September 30, 2005 compared with \$61.9 million for the nine months ended September 30, 2004. During the nine months ended September 30, 2005, approximately \$13.3 million or 95% 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 \$58.0 million included \$32.2 million related to the expensing of vialled Genasense® drug product and 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 \$14.0 million in research and development expenses for the nine months ended September 30, 2005, \$6.1 million were 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 until it was repaid in May 2005 (see Note 6 to our Financial Statements).

Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$12.1 million for the nine months ended September 30, 2005 compared with \$24.2 million for the nine months ended September 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®. In addition, in the 2004 period, we recorded \$1.0 million of legal expenses related to certain class action lawsuits (see Note 11 to our Financial Statements).

Aventis Reimbursement

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)	Nine months ended	
	September 30,	
	2005	2004
Reimbursement to Genta		
Third-party costs	\$ 2,917	\$ 14,936
Drug supply costs	1,807	18,211
FTE s	1,513	4,668
Amount due to Genta	6,237	37,815
Reimbursement to Aventis	(147)	(1,362)
Net reimbursement to Genta	\$ 6,090	\$ 36,453

Net expense reimbursement from Aventis of \$6.1 million for the nine months ended September 30, 2005 declined from \$36.5 million for the nine months ended September 30, 2004 due to the termination of the Collaborative Agreement in May 2005 and lower expenses incurred on the Genasense® project. In addition, in September 2004, the Company transferred \$15.5 million of vialled Genasense® drug product and Genasense® bulk drug substance to Aventis. This amount is included in Drug supply costs in the above table.

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 in May 2005. Reimbursement of \$6.0 million due to Genta was applied to the balance of the Line of Credit.

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.

Other Income/(Expense)

Net other income for the nine months ended September 30, 2005 of \$0.4 million favorably compared with net other expense of \$0.1 million for the prior year period. This was the result of lower interest expense, due to lower borrowings from Aventis, partially offset by lower interest income, resulting from lower investment balances.

Net Income/(Loss)

The Company recorded net income of \$8.0 million, or \$0.08 per share, for the nine months ended September 30, 2005, compared with a net loss of \$42.3 million, or \$0.60 per share, for the nine months ended September 30, 2004. The increase in net income and net income per share was primarily due to accelerated recognition through May 2005 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 forgiveness of debt.

Liquidity and Capital Resources

At September 30, 2005, the Company had cash, cash equivalents and marketable securities totaling \$28.8 million compared with \$42.2 million at December 31, 2004. Cash used in operating activities was \$29.1 million for the nine months ended September 30, 2005 compared with \$44.4 million for the nine months ended September 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 September 30, 2005, Genta had no outstanding short-term debt compared with the outstanding balance of \$7.3 million on the Line of Credit with Aventis as of December 31, 2004.

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.

The Company has \$28.8 million of cash and cash equivalents and marketable securities on hand at September 30, 2005. On August 11, 2005, the Company sold 19.1 million shares of its common stock at a price of \$0.92 per share for gross proceeds of \$17.5 million, before fees and expenses. After deducting fees and expenses, the Company received net proceeds of \$16.3 million. 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 into the middle of 2006.

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.

Additional alternatives available to the Company to subsequently sustain its operations include 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.

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. The adoption of this statement, effective June 2005, did not 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, did 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 September 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. On September 30, 2005, the court granted in part and denied in part our motion to dismiss the plaintiffs' complaint. The court dismissed plaintiffs' claim that the defendants engaged in a scheme or artifice to defraud plaintiffs, but allowed plaintiffs' claims to proceed with respect to their allegations that defendants issued false and misleading public statements about Genasense®. On October 17, 2005 defendants filed an answer to the complaint and will soon commence pre-trial discovery.

In addition, two separate 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 continue to 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) |

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

Exhibit Number	Description of Document
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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized

Genta Incorporated

Date: November 7, 2005

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

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

Date: November 7, 2005

/s/ RICHARD J.
MORAN

Richard J. Moran
Senior Vice President,
Chief Financial
Officer and Corporate
Secretary

Exhibit Index

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
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