

GENTA INC DE/
Form 10-Q
May 09, 2006

**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 March 31, 2006

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

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 April 30, 2006, the registrant had 133,669,156 shares of common stock outstanding.

**Genta Incorporated
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GENTA INCORPORATED
CONSOLIDATED BALANCE SHEETS
(Unaudited)

(In thousands, except par value data)	March 31, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 21,229	\$ 9,314
Marketable securities (Note 3)	25,931	11,968
Accounts receivable - net	18	59
Inventory (Note 4)	380	396
Prepaid expenses and other current assets	1,251	1,655
Total current assets	48,809	23,392
Property and equipment, net (Note 5)	752	1,077
Prepaid royalties (Note 6)	1,268	1,268
Other assets	1,656	1,649
Total assets	\$ 52,485	\$ 27,386
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,034	\$ 10,960
Notes payable	278	729
Total current liabilities	8,312	11,689
Commitments and contingencies (Note 12)		
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 March 31, 2006 and December 31, 2005, respectively	--	--
Series G participating cumulative preferred stock, \$.001 par value; 0 shares issued and outstanding at March 31, 2006 and December 31, 2005, respectively	--	--
Common stock, \$.001 par value; 150,000 shares authorized, 133,650 and 114,500 shares issued and outstanding at March 31, 2006 and December 31, 2005	134	115
Additional paid-in capital	412,121	373,709
Accumulated deficit	(368,082)	(358,187)
Accumulated other comprehensive income	--	60
Total stockholders' equity	44,173	15,697
Total liabilities and stockholders' equity	\$ 52,485	\$ 27,386

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

(In thousands, except per share data)	Three Months Ended March 31,	
	2006	2005
Revenues:		
License fees and royalties	\$ -	\$ 3,684
Development funding	--	14,754
Product sales - net	67	76
Total revenues	67	18,514
Cost of goods sold	16	15
Operating expenses:		
Research and development	4,750	3,870
Selling, general and administrative	5,456	3,986
Total operating expenses - gross	10,206	7,856
Aventis reimbursement	--	(3,252)
Total operating expenses - net	10,206	4,604
Other income	260	130
Net (loss)/income	(9,895)	14,025
Net (loss)/income per basic and diluted share (Note 10)	\$ (0.08)	\$ 0.15
Shares used in computing net (loss)/income per basic share	118,186	95,358
Shares used in computing net (loss)/income per diluted share	118,186	95,506

See accompanying notes to consolidated financial statements

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

(In thousands)	Three Months Ended March 31,	
	2006	2005
	<u> </u>	<u> </u>
Operating activities:		
Net (loss)/income	\$ (9,895)	\$ 14,025
Items reflected in net (loss)/income not requiring cash:		
Depreciation and amortization	334	663
Stock-based compensation (Note 8)	597	--
Realized gain on maturity of marketable securities	(92)	--
Compensation expense related to certain stock options issued in 1999 and 2000	--	11
Non-cash reimbursement of research & development expense	--	(3,252)
Amortization of deferred revenues	--	(18,438)
Changes in operating assets and liabilities:		
Accounts receivable	41	--
Inventory (Note 4)	16	15
Prepaid expenses and other current assets	404	584
Accounts payable and accrued expenses	(2,926)	(4,093)
Other assets	(7)	(6)
	<u> </u>	<u> </u>
Net cash used in operating activities	(11,528)	(10,491)
	<u> </u>	<u> </u>
Investing activities:		
Purchase of marketable securities (Note 3)	(25,931)	(9,942)
Maturities and sales of marketable securities (Note 3)	12,000	--
Purchase of property and equipment	(9)	(7)
	<u> </u>	<u> </u>
Net cash used in investing activities	(13,940)	(9,949)
	<u> </u>	<u> </u>
Financing activities:		
Repayments of note payable	(451)	(527)
Issuance of common stock, net (Note 7)	37,736	--
Issuance of common stock upon exercise of stock options	98	--
	<u> </u>	<u> </u>
Net cash provided by/(used in) financing activities	37,383	(527)
	<u> </u>	<u> </u>
Increase/(decrease) in cash and cash equivalents	11,915	(20,967)
Cash and cash equivalents at beginning of period	9,314	36,489
	<u> </u>	<u> </u>
Cash and cash equivalents at end of period	\$ 21,229	\$ 15,522
	<u> </u>	<u> </u>

See accompanying notes to consolidated financial statements

GENTA INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2006
(Unaudited)

1. Organization and Business

Genta Incorporated (Genta or the Company) is a biopharmaceutical company engaged in 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 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. Any adverse events with respect to approvals by the U.S. Food and Drug Administration (FDA) and/or European Medicines Agency (EMEA) could negatively impact our ability to obtain additional funding or identify potential partners.

The Company has prepared its financial statements under the assumption that it is a going concern. The Company's recurring losses and negative cash flows from operations raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company had \$47.2 million of cash, cash equivalents and marketable securities on hand at March 31, 2006. On March 13, 2006, the Company sold 19.0 million shares of its common stock at a price of \$2.15 per share for gross proceeds of \$40.8 million, before fees and expenses. After deducting fees and expenses the Company received net proceeds of \$37.7 million. During the first three months of 2006, cash used in operating activities was \$11.5 million.

Management plans to increase its spending from April through September to an average rate of approximately \$5 million per month. The Company anticipates that it will have sufficient cash funds to maintain its present operations into the first quarter of 2007.

If the NDA for Genasense® is approved, the Company anticipates that it will require additional cash if it undertakes to launch the product in the U.S. in the fourth quarter of 2006 in order to maximize the commercial opportunity. The Company has commenced discussions with several companies regarding partnerships for the further development and global commercialization of Genasense®. Those discussions are currently ongoing. Additional alternatives available to the Company to subsequently sustain its operations include financing arrangements with potential corporate partners, debt financing, asset-based loans, royalty-based financings, equity financing 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.

If the Company is unable to raise additional funds, management will need to do one or more of the following:

- o delay, scale back or eliminate some or all of our research and product development programs and sales and marketing activity;
- o license third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;
- o attempt to sell the Company;
- o cease operations; or
- o declare bankruptcy.

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 that are effective as of March 31, 2006 have been considered in preparing the consolidated financial statements. 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. 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, 2005. 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

Genta recognizes revenue from product sales when title to product and associated risk of loss has passed to the customer and the Company is reasonably assured of collecting payment for the sale. All revenue from product sales are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances. The Company allows return of its product for up to twelve months after product expiration. In December 2004, a wholesaler contacted the Company to return a significant portion of its inventory of Ganite®. The Company agreed to the return of this product and recorded a provision for sales returns, as well as provided for potential returns from other wholesalers. In January 2005, the wholesaler returned \$0.5 million of Ganite®. At March 31, 2006, the Company's remaining provision for sales returns was \$0.8 million.

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.

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, which terminated in May 2005, have been recorded as a reduction to expenses in the Consolidated Statements of Operations.

On March 23, 2006, the Company entered into an exclusive, worldwide licensing agreement with Emisphere Technologies, Inc. to develop an oral formulation of a gallium-containing compound. Under the terms of the new agreement, Genta will pay Emisphere up to \$24 million only upon the achievement of certain milestones during the course of product development and royalties based upon sales.

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.

Inventories

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

Income Taxes

The Company uses the liability method of accounting for income taxes. Deferred income taxes are determined based on the estimated future tax effects of differences between the financial statement and tax bases of assets and liabilities given the provisions of the enacted tax laws. Management records valuation allowances against net deferred tax assets, if based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

Stock Options

Effective January 1, 2006, Genta adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment, (SFAS 123R), using the modified prospective transition method and therefore has not restated results for prior periods. Under the new standard, all share-based payments including grants of employee stock options are recognized in the Consolidated Statement of Operations based on their fair values, as pro-forma disclosure is no longer an alternative. The amount of compensation cost is measured based on the grant-date fair value of the equity instrument issued. The Company utilizes a Black-Scholes option-pricing model to measure the fair value of stock options granted to employees. See Note 8 to our Consolidated Financial Statements for a further discussion on stock-based compensation.

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):

	<u>March 31, 2006</u>	<u>December 31, 2005</u>
Cost	\$ 25,931	\$ 11,908
Gross unrealized gains	5	60
Gross unrealized losses	(5)	--
Fair value	<u>\$ 25,931</u>	<u>\$ 11,968</u>

During the three months ended March 31, 2006, the Company realized \$92 thousand on realized gains on the maturity of marketable securities.

The estimated fair value of each marketable security has been compared with its cost, and therefore, an unrealized gain of \$60 thousand has been recognized in Accumulated other comprehensive income at December 31, 2005.

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):

	March 31, 2006	December 31, 2005
Raw materials	\$ 191	\$ 191
Work in process	--	--
Finished goods	189	205
	<u>\$ 380</u>	<u>\$ 396</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 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	March 31, 2006	December 31, 2005
Computer equipment	3	\$ 2,880	\$ 2,871
Software	3	3,349	3,349
Furniture and fixtures	5	936	936
Leasehold improvements	Life of lease	410	410
Equipment	5	182	182
		<u>7,757</u>	<u>7,748</u>
Less accumulated depreciation and amortization		(7,005)	(6,671)
		<u>\$ 752</u>	<u>\$ 1,077</u>

6. Prepaid Royalties

In December 2000, the Company recorded \$1.3 million as the fair value for its commitment to issue 162,338 shares of common stock to a major university as consideration for an amendment to a license agreement initially executed on August 1, 1991 related to antisense technology licensed from the university. The amendment provided for a reduction in the royalty percentage rate to be paid to the university based on the volume of sales of the Company's products containing the antisense technology licensed from such university. These shares were issued in the first quarter of 2001. The Company will amortize the prepaid royalties upon the commercialization of Genasense® through the term of the arrangement, which expires twelve years from the date of first commercial sale.

7. Stockholders' Equity*Common Stock*

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In March 2006, the Board of Directors approved an amendment to increase the number of shares of authorized common stock to 250.0 million shares from 150.0 million shares. This amendment has been submitted to the Company's stockholders for approval at the Company's Annual Meeting of Stockholders in June 2006.

In March 2006, the Company issued 19.0 million shares of its common stock at a price of \$2.15 per share, raising approximately \$37.7 million, net of estimated fees and expenses.

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.

In August 2005, the Company issued 19.1 million shares of its common stock and received net proceeds of approximately \$16.0 million.

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 March 31, 2006 and December 31, 2005, each share of Series A Preferred Stock was convertible into 10.6853 and 9.8067 shares of common stock, respectively. At March 31, 2006 and December 31, 2005, 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. At March 31, 2006 the Company had no issued or outstanding shares of Series G Participating Cumulative Preferred Stock.

Common Stock Reserved

At March 31, 2006, the Company had 133.7 million shares of common stock outstanding, 12.7 million additional shares reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants and 3.3 million additional shares of common stock authorized for issuance and remaining to be granted under the Company's stock option plans.

8. Stock-Based Compensation

Effective January 1, 2006, the Company adopted SFAS 123R, which requires the Company to measure the cost of employee services received in exchange for all equity awards granted based on the fair value of the award as of the grant date. SFAS 123R supersedes Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123), and Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). The Company adopted SFAS 123R using the modified prospective transition method, which requires the Company to record compensation cost related to unvested stock awards as of December 31, 2005 by recognizing the unamortized grant date fair value of these awards over the remaining requisite service periods of those awards, with no change in historical reported earnings. Awards granted after December 31, 2005 are valued at fair value in accordance with the provisions of SFAS 123R and are recognized on a straight-line basis over the requisite service periods of each award. The new standard also requires the Company to estimate forfeiture rates for all unvested awards, which it has done for 2006 based on its historical experience.

The Company estimates the fair value of each option award on the date of the grant using the Black-Scholes option valuation model. Expected volatilities are based on the historical volatility of the Company's common stock over a period commensurate with the options' expected term. The expected term represents the period of time that options granted are expected to be outstanding and is calculated in accordance with the Securities and Exchange Commission (SEC) guidance provided in the SEC's Staff Accounting Bulletin 107, (SAB 107), using a simplified method. The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of the Company's stock options. The following table summarizes the weighted-average assumptions used in the Black-Scholes model for options granted during the first three months of 2006 and 2005.

	Three Months Ended March 31,	
	2006	2005
Expected volatility	98%	119%
Expected dividends	--	--
Expected term (in years)	6.25	6.25
Risk-free rate	4.6%	4.1%

Prior to 2006, the Company accounted for stock-based compensation in accordance with APB 25 using the intrinsic value method, which did not require that compensation cost be recognized for the Company's stock options, provided the option exercise price was not less than the common stock's fair market value on the date of the grant. The Company provided pro-forma disclosure amounts in accordance with SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, as if the fair value method defined by SFAS No. 123 had been applied to its stock-based compensation. The Company's net income and net income per share for the three months ended March 31, 2005 would have been reduced if compensation cost related to stock options had been recorded in the financial statements based on fair value at the grant dates.

The following table sets forth the pro-forma net income as if the fair value method had been applied to all awards:

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

As a result of adopting SFAS 123R, the impact to the Consolidated Statement of Operations was to increase expenses and net loss by approximately \$0.6 million for the three months ended March 31, 2006. The impact on both basic and diluted earnings per share for the three months ended March 31, 2006 was \$0.01 per share. The estimated share-based compensation expense, related to all of the Company's share-based awards, recognized for the three months ended March 31, 2006 was comprised as follows:

(\$ thousands, except per share data)	Three Months Ended March 31, 2006
Research and development expenses	\$ 207
Selling, general and administrative expenses	390
Total share-based compensation expense	\$ 597
Net share-based compensation expense, per common share:	
Basic	\$ 0.01
Diluted	\$ 0.01

For the three months ended March 31, 2005, selling, general and administrative expenses include \$11 thousand of non-cash compensation expense related to certain stock options issued in 1999 and 2000.

As of March 31, 2006, the Company has two share-based compensation plans, which are described below.

1998 Stock Incentive Plan

Pursuant to the Company's 1998 Stock Incentive Plan as amended (the "1998 Plan"), 18.5 million shares have been provided for the grant of stock options to employees, directors, consultants and advisors of the Company. In March 2006, the Board of Directors approved an amendment to increase the total number of shares of common stock authorized for issuance under the 1998 Plan to 20.5 million shares from 18.5 million shares. This amendment has been submitted to the Company's stockholders for approval at the Company's Annual Meeting of Stockholders in June 2006. Option awards must be granted with an exercise price at not less than the fair market price of the Company's common stock on the date of the grant; those option awards generally vest over a four-year period in equal increments of 25%, beginning on the first anniversary of the date of the grant. All options granted have contractual terms of ten years from the date of the grant.

The following table summarizes the option activity under the 1998 Plan as of March 31, 2006 and changes during the quarter then ended:

Stock Options	Number of Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2006	9,418	\$ 5.04		
Granted	1,851	\$ 2.10		
Exercised	--	--		
Forfeited or expired	31	\$ 8.36		
Outstanding at March 31, 2006	11,238	\$ 4.55	6.1	\$ 1,006
Exercisable at March 31, 2006	6,727	\$ 4.29	4.4	\$ 103

The weighted-average grant-date fair value of options granted during the quarter ended March 31, 2006 was \$1.69. The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between Genta's closing stock price on the last trading day of the first quarter of 2006 and the exercise price, multiplied by the number of in-the money options) that would have been received by the option holders had all option holders exercised their options on March 31, 2006. The amount of aggregate intrinsic value will change based on the fair market value of the Company's stock.

As of March 31, 2006, there was approximately \$4.1 million of total unrecognized compensation cost related to non-vested share-based compensation granted under the 1998 Plan, which is expected to be recognized over a weighted-average period of 1.7 years.

1998 Non-Employee Directors' Plan

Pursuant to the Company's 1998 Non-Employee Director's Plan as amended (the Directors' Plan), 3.8 million shares have been provided for the grant of non-qualified stock options to the Company's non-employee members of the Board of Directors. Option awards must be granted with an exercise price at not less than the fair market price of the Company's common stock on the date of the grant. Initial option grants vest over a three-year period in equal increments, beginning on the first anniversary of the date of the grant. Subsequent grants, generally vest on the date of the grant. All options granted have contractual terms of ten years from the date of the grant.

The fair value of each option award is estimated on the date using the same valuation model used for options granted under the 1998 Plan.

The following table summarizes the option activity under the Directors' Plan as of March 31, 2006 and changes during the quarter then ended:

Stock Options	Number of Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2006	1,158	\$ 6.26		
Granted	--	--		
Exercised	100	\$ 0.98		
Forfeited or expired	--	--		
Outstanding at March 31, 2006	1,058	\$ 6.76	5.9	\$ 249
Exercisable at March 31, 2006	1,010	\$ 7.02	5.7	\$ 204

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between Genta's closing stock price on the last trading day of the first quarter of 2006 and the exercise price, multiplied by the number of in-the money options) that would have been received by the option holders had all option holders exercised their options on March 31, 2006. The amount of aggregate intrinsic value will change based on the fair market value of the Company's stock. The intrinsic value of stock options exercised during the three months ended March 31, 2006 was \$.2 million.

9. Comprehensive Income

An analysis of comprehensive income is presented below:

(\$ in thousands)	Three Months Ended March 31,	
	2006	2005
Net (loss)/income	\$ (9,895)	\$ 14,025
Change in market value on available-for-sale marketable Securities	--	3
Total comprehensive (loss)/income	\$ (9,895)	\$ 14,028

10. Net (Loss)/Income per Share

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

(\$ in thousands, except share and per share amounts)	Three Months Ended March 31,	
	2006	2005
Numerator:		
Net (loss)/income	\$ (9,895)	\$ 14,025
Denominator:		
Weighted average shares outstanding:		
Basic	118,186	95,358
Effect of dilutive stock options, warrants and convertible preferred stock	--	148
Diluted	118,186	95,506
Net (loss)/income per share:		
Basic	\$ (0.08)	\$ 0.15
Diluted	\$ (0.08)	\$ 0.15

For the three months ended March 31, 2006 and 2005, 12.3 million and 11.3 million, respectively, of equivalent common shares issuable under the Company's stock incentive plans were excluded from the computation of diluted (loss)/income per share because the effect would have been antidilutive. Also, for the three months ended March 31, 2006 and 2005, 0.4 million and 0.2 million, respectively, of equivalent common shares obtainable upon conversion of the Company's Series A preferred stock and exercise of warrants were excluded from the computation of diluted (loss)/income per share because the effect would have been antidilutive.

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

No interest or income taxes were paid for the three months ended March 31, 2006 and 2005, respectively.

12. 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®. As of March 2006, nonbinding mediation has not produced a settlement and the case is proceeding to 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. The Federal shareholder derivative action was consolidated with the securities action. The Federal derivative plaintiffs have not yet filed a consolidated amended complaint asserting their claims. Instead, the Federal shareholder derivative action has been stayed, pending developments in the Federal securities action.

Based on facts substantially similar to those asserted in the shareholder class actions, the State derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and committed other violations of New Jersey law. On February 9, 2006, the Superior Court of New Jersey dismissed the plaintiffs' derivative complaint in the New Jersey State case based in part on plaintiffs' failure to make a pre-suit demand on Genta's Board of Directors and in part based on plaintiffs' failure to state a cause of action. Plaintiffs served a motion for reconsideration on February 27, 2006.

The Company believes these litigations are without merit and will continue to vigorously defend against these suits.

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:

- o the Company's financial projections;
- o the Company's projected cash flow requirements and estimated timing of sufficient cash flow;
- o the Company's current and future license agreements, collaboration agreements, and other strategic alliances;
- o the Company's ability to obtain necessary regulatory approval for Genasense® (oblimersen sodium) Injection from the U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMEA);
- o the safety and efficacy of the Company's products;
- o the commencement and completion of clinical trials;
- o the Company's ability to develop, manufacture and sell its products;
- o the adequacy of the Company's capital resources and the Company's ability to obtain sufficient financing to maintain the Company's planned operations;
- o the adequacy of the Company's patents and proprietary rights;
- o the impact of litigation that has been brought against the Company and its officers and directors;
- o the other risks described under Risk Factors in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2005 and in this Form 10-Q.

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. The Company has had recurring annual operating losses since its inception and we expect to incur substantial operating losses due to continued requirements for ongoing and planned research and development activities, pre-clinical and clinical testing, manufacturing activities, regulatory activities and establishment of a sales and marketing organization. From our inception to March 31, 2006, we have incurred a cumulative net loss of \$368.1 million. Management expects that such losses will continue at least until our lead product, Genasense® receives approval from the FDA for commercial sale in one or more indications. Achievement of profitability is dependent on the timing of Genasense® regulatory approvals in the U.S. and outside the U.S. We have experienced significant quarterly fluctuations in operating results and we expect that these fluctuations in revenues, expenses and losses will continue.

We have prepared our financial statements under the assumption that the Company is a going concern. The Company's recurring losses and negative cash flows from operations raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company has \$47.2 million of cash and cash equivalents and marketable securities on hand at March 31, 2006. On March 13, 2006, the Company sold 19.0 million shares of our common stock at a price of \$2.15 per share raising approximately \$37.7 million, net of estimated fees and expenses. During the first three months of 2006, cash used in operating activities was \$11.5 million.

Management plans to increase its spending from April through September to an average rate of approximately \$5 million per month. Management anticipates that it will have sufficient cash funds to maintain its present operations into the first quarter of 2007.

If the NDA for Genasense® is approved, management anticipates that it will require additional cash if it undertakes to launch the product in the U.S. in the fourth quarter of 2006 in order to maximize the commercial opportunity. We have commenced discussions with several companies regarding partnerships for the further development and global commercialization of Genasense®. Those discussions are currently ongoing. Additional alternatives available to the Company to subsequently sustain its operations include financing arrangements with potential corporate partners, debt financing, asset-based loans, royalty-based financings, equity financing 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.

We have 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 our first New Drug Application (NDA) with the FDA for Genasense® as a treatment combined with chemotherapy for patients with advanced malignant melanoma. In May 2004, the application failed to gain a majority vote for marketing approval from FDA's Oncology Drug Advisory Committee (ODAC). As a consequence, we withdrew the NDA, which allows the Company to potentially resubmit the application. However, we continued long-term follow-up of patients who were enrolled in the advanced malignant melanoma trial. On May 16, 2005, we announced updated data from this trial. The updated data continued to show statistical significance for overall response, complete response and progression free survival. Statistical significance was also achieved for durable response (P=0.02). We commissioned a new, independent review of the X-rays that documented the major responses, which confirmed the originally reported responses with high concordance. Overall survival by intent-to-treat analysis had improved from the time of the FDA filing but did not yield a statistically significant improvement at a significance level (i.e., P less than 0.05). The P value at the time of the FDA filing was 0.18, whereas the P value with the most recent analysis was 0.077. Our analysis also identified a statistically significant treatment interaction effect for blood levels of an enzyme known as LDH, which was a prospectively specified stratification factor. When this effect was analyzed by treatment arm, survival (and all other efficacy endpoints) was significantly superior for patients who had received Genasense® (P=0.018) who did not have an elevation in LDH at study entry (n=508).

On January 3, 2006, the Company announced that it had completed a Marketing Authorization Application (MAA) to the EMEA, which seeks approval for use of Genasense® plus dacarbazine for the treatment of patients with advanced melanoma who have not previously received chemotherapy. On February 1, 2006, the Company announced that it had received notice from the EMEA that its MAA had been validated for review by the Agency, which signals the start of formal scientific assessment. As part of this process, we anticipate receiving scientific questions from EMEA in June 2006 and then expect to make a formal response thereafter.

In December 2004, we presented results from its randomized trial which was conducted in patients with relapsed or refractory CLL. In this trial, 241 patients who had relapsed or had not responded to prior therapy were treated with standard chemotherapy using fludarabine and cyclophosphamide (Flu/Cy). After stratifying patients using conventional criteria, they were randomly assigned to receive Genasense® or no additional treatment. Initial results showed that the trial achieved its primary endpoint: the proportion of patients who achieved a complete or nodular partial response (CR/nPR) was significantly improved with the addition of Genasense® to Flu/Cy chemotherapy (17% vs. 7%; P=0.025). The response required independent confirmation by an external clinical reviewer who was blinded to treatment assignment and who reviewed clinical, laboratory and radiologic data. A second independent reviewer evaluated bone marrow biopsies. Agreement between the clinical and bone marrow reviews was required in order to determine response in this study.

Extended patient follow-up in the CLL trial also showed that the duration of CR/nPR was significantly superior for patients treated with Genasense® plus chemotherapy. As of June 2005, 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 had not been reached in the Genasense® group (P=0.03). All CR/nPR responses were durable (i.e., exceeding six months duration). Additional analysis showed that patients who achieved CR/nPR also experienced substantial clinical benefit, especially with respect to improvement of disease-related symptoms. Several secondary endpoints were not improved by the addition of Genasense®. For example, no difference was observed in overall response rate (i.e., the percentage of patients who achieved CR/nPR plus partial response (PR), or in time-to-disease progression. Overall survival will be formally evaluated in mid-2006 after all patients have completed a minimum of two years of follow-up. Adverse events (irrespective of relation to study drugs) during treatment or within 30 days from last dose of treatment that resulted in death occurred in 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. 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®.

On December 28, 2005, the Company completed submission of an NDA to the FDA that seeks accelerated approval for the use of Genasense® in combination with fludarabine plus cyclophosphamide for the treatment of patients with relapsed or refractory CLL who have previously received fludarabine. Genasense® had received Fast Track designation by the FDA in CLL, meaning that the indication represents an unmet medical need. Genasense® has been granted designation as an Orphan Drug by the FDA. On March 1, 2006, the Company announced that the NDA had been accepted for review by the FDA and set a target Prescription Drug User Fee Act (PDUFA) action date of October 28, 2006. However, acceptance of this NDA does not necessarily lead to FDA approval. Following its review of all the Company's information concerning Genasense® the FDA may refuse to approve altogether, or the Agency may ask for more data to be obtained before approval can be reconsidered. Either of these two decisions by the FDA would have a material adverse effect on our business. One of the requirements for Accelerated Approval is that the Company will be required to conduct a confirmatory trial. The Company has formulated a design for such a trial and has submitted a proposal to the FDA for review as a Special Protocol Assessment (SPA). The submitted proposal incorporated initial comments received from the FDA. Final comments on the SPA request are expected during the first half of 2006. Formal initiation of the trial will depend upon resolution of trial design issues with the FDA, among other factors. Although Fast Track designation, Orphan Drug designation and Accelerated Approval provisions are beneficial, we cannot assure you that the NDA will be approved. In particular, the FDA may not be satisfied that achievement of the primary endpoint used in the Company's recent clinical trial being an increased proportion of CR/nPRs compared to patients treated with standard chemotherapy is sufficient basis for approval.

In November 2004, the Company reported that its 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 previously had received extensive therapy. Based on the results of the Phase 3 trial, we have no plans to submit an NDA in this indication at the current time. We have not yet determined what additional clinical trials, if any, may be undertaken in patients with multiple myeloma.

In addition, we are conducting (under our 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).

On March 23, 2006, the Company entered into an exclusive, worldwide licensing agreement with Emisphere Technologies, Inc. to develop an oral formulation of a gallium-containing compound. Ganite® (gallium nitrate injection), Genta's only commercialized product, is derived from this class of compounds. Under the terms of the new agreement, we will pay Emisphere up to \$24 million only upon the achievement of certain milestones during the course of product development and royalties based upon sales. Emisphere will utilize its proprietary oral delivery technology, eligen®, to supply a finished oral dosage form to Genta. We will reimburse Emisphere for time and expenses, as incurred, to create the oral dosage formulation. We will be responsible for toxicology, clinical development, regulatory submissions, and worldwide commercialization. The agreement is in effect until the later of (a) receipt of initial regulatory approval or (b) expiration of all royalty and payment obligations.

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®. 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 March 31, 2006 and 2005

(\$ in thousands)	Summary Operating Results For the three months ended March 31,			2005
	2006	Increase (Decrease) \$	%	
Revenues:				
License fees and royalties	\$ -	\$ (3,684)	(100%)	\$ 3,684
Development funding	--	(14,754)	(100%)	14,754
Product sales - net	67	(9)	(12%)	76
Total revenues	67	(18,447)	(100%)	18,514
Cost of goods sold	16	1	7%	15
Operating expenses:				
Research and development	4,750	880	23%	3,870
Selling, general and administrative	5,456	1,470	37%	3,986
Total operating expenses - gross	10,206	2,350	30%	7,856
Less: Aventis reimbursement	--	3,252	100%	(3,252)
Total operating expenses - net	10,206	5,602	122%	4,604
Other income	260	130	100%	130
Net (loss)/income	(9,895)	(23,920)	(171)%	\$ 14,025

Total revenues

Total revenues were \$0.1 million for the three months ended March 31, 2006 compared with \$18.5 million for the three months ended March 31, 2005. License fees and development funding revenues of \$18.4 million for the three months ended March 31, 2005 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®. We 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 March 31, 2006 were \$67 thousand compared to \$76 thousand in the prior-year period.

Research and development expenses

Research and development expenses before reimbursement were \$4.8 million for the three months ended March 31, 2006 compared with \$3.9 million for the three months ended March 31, 2005. Expenses in 2006 include the recognition of \$0.2 million of stock option expense, resulting from the adoption of SFAS 123R. In addition, during 2006, we increased spending on manufacturing, including expenses to prepare for the production of Genasense®. During the three months ended March 31, 2006, approximately \$4.3 million or 93% of research and development expenses were incurred on the Genasense® project.

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 subject to wide variability. 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 that review 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 \$5.5 million for the three months ended March 31, 2006 compared with \$4.0 million for the three months ended March 31, 2005. Expenses in 2006 include the recognition of \$0.4 million of stock option expense, resulting from the adoption of SFAS 123R. In addition, during 2006, we increased sales and marketing expenses in preparation for the anticipated product launch of Genasense®.

Aventis reimbursement

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 us during the three-month period ended March 31, 2006 were reimbursable.

Other income

Net other income of \$0.3 million for the three months ended March 31, 2006 increased from net other income of \$0.1 million for the three months ended March 31, 2005 as a result of realized gains on the maturity of marketable securities in the first quarter of 2006 and lower interest expense, due to the Company having no debt since May 2005.

Net (loss)/income

We recorded a net loss of \$9.9 million, or \$0.08 per share, for the three months ended March 31, 2006, compared with net income of \$14.0 million, or \$0.15 per share, for the three months ended March 31, 2005. The decrease is primarily due to the fact that the prior-year period included revenues of \$18.4 million from the continued recognition of the license fee and development funding and \$3.3 million from the reimbursement for research and development expenses, as described above.

Liquidity and capital resources

At March 31, 2006, the Company had cash, cash equivalents and marketable securities totaling \$47.2 million compared with \$21.3 million at December 31, 2005. Cash used in operating activities was \$11.5 million for the three months ended March 31, 2006, which represents a small increase compared with \$10.5 million for the three months ended March 31, 2005.

We have prepared our financial statements under the assumption that the Company is a going concern. The Company's recurring losses and negative cash flows from operations raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty, (see Item 1A, Risk Factors).

On March 13, 2006, the Company sold 19.0 million shares of its common stock at a price of \$2.15 per share for gross proceeds of \$40.9 million, before fees and expenses. After deducting fees and expenses, the Company received net proceeds of \$37.7 million.

Management plans to increase its spending from April through September to an average rate of approximately \$5 million per month. Management anticipates that it will have sufficient cash funds to maintain its present operations into the first quarter of 2007.

If the NDA for Genasense® is approved, management anticipates that it will require additional cash if we undertake to launch the product in the U.S. in the fourth quarter of 2006 in order to maximize the commercial opportunity. We have commenced discussions with several companies regarding partnerships for the further development and commercialization of Genasense®. Those discussions are currently ongoing. Additional alternatives available to the Company to subsequently sustain its operations include financing arrangements with potential corporate partners, debt financing, asset-based loans, royalty-based financing, equity financing 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.

Our principal expenditures relate to our research and development activities, primarily focused on Genasense®, which include our ongoing and future clinical trials. We expect these expenditures to continue.

If we obtain NDA approval of Genasense® 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

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS 123R, Share-Based Payment, using the modified prospective transition method and therefore did not restate results for prior periods. Prior to January 1, 2006 we accounted for share-based compensation arrangements in accordance with APB Opinion No. 25, *Accounting for Stock Issued to Employees* and complied with the disclosure provisions of SFAS 123, *Accounting for Stock-Based Compensation*. SFAS 123R requires all public entities that used the fair-value method for either recognition or disclosure under SFAS 123 to apply the modified prospective transition method as of the required effective date. As a result, we adopted the provisions of SFAS 123R using this method, effective January 1, 2006. Under the modified prospective method, new awards are valued and accounted for prospectively upon adoption. Outstanding prior awards that are unvested as of January 1, 2006 are recognized as compensation cost over the remaining requisite service periods, as prior periods may not be restated. The adoption of SFAS 123R increased our expenses and reported net loss for the three months ended March 31, 2006 by \$0.6 million.

Management forecasts that the impact of adopting SFAS 123R for the twelve months ending December 31, 2006 will be between \$2.0 million and \$3.0 million, taking into account options granted in January 2006. This forecast is based on the Black-Scholes option-pricing model and includes estimates on the additional number of options to be granted during 2006, the price of our stock at the time of grants, the volatility of our stock price and the expected forfeiture rates. As such, our actual stock option expense may differ from this estimate.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our carrying values of cash, marketable securities, accounts payable and accrued expenses 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 Consolidated Financial Statements). We have not entered into and do not expect to enter into, financial instruments for trading or hedging purposes. We do not currently anticipate entering into interest rate swaps and/or similar instruments.

Genta's primary market risk exposure with regard to financial instruments is to changes in interest rates, which would impact interest income earned on such instruments. We have no material currency exchange or interest rate risk exposure as of March 31, 2006.

Item 4. Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As required by Rule 13a-15(b), Genta's 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 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®. As of March 2006, nonbinding mediation has not produced a settlement and the case is proceeding to 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. The Federal shareholder derivative action was consolidated with the securities action. The Federal derivative plaintiffs have not yet filed a consolidated amended complaint asserting their claims. Instead, the Federal shareholder derivative action has been stayed, pending developments in the Federal securities action.

Based on facts substantially similar to those asserted in the shareholder class actions, the State derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and committed other violations of New Jersey law. On February 9, 2006, the Superior Court of New Jersey dismissed the plaintiffs' derivative complaint in the New Jersey State case based in part on plaintiffs' failure to make a pre-suit demand on Genta's Board of Directors and in part based on plaintiffs' failure to state a cause of action. Plaintiffs served a motion for reconsideration on February 27, 2006.

The Company believes these litigations are without merit and will continue to vigorously defend against these suits.

Item 1A. Risk Factors

You should carefully consider the following risks and all of the other information set forth in this Form 10Q and Form 10-K for the year ended December 31, 2005 before deciding to invest in shares of our common stock. The risks described below are not the only ones facing our Company. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

Risk Related to Our Business

We may be unsuccessful in our efforts to obtain approval from the FDA or EMEA and commercialize Genasense®; or our other pharmaceutical products.

The commercialization of our pharmaceutical products involves a number of significant challenges. In particular, our ability to commercialize products, such as Ganite® and Genasense®, depends, in large part, on the success of our clinical development programs, our efforts to obtain regulatory approvals and our sales and marketing efforts directed at physicians, patients and third-party payors. A number of factors could affect these efforts, including:

- our ability to demonstrate clinically that our products are useful and safe in particular indications;
- delays or refusals by regulatory authorities in granting marketing approvals;
- our limited financial resources and sales and marketing experience relative to our competitors;
- actual and perceived differences between our products and those of our competitors;
- the availability and level of reimbursement for our products by third-party payors;
- incidents of adverse reactions to our products;
- side effects or misuse of our products and the unfavorable publicity that could result; and
- the occurrence of manufacturing, supply or distribution disruptions.

We cannot assure you that Genasense® will receive FDA or EMEA approval. Our financial condition and results of operations have been and will continue to be significantly affected by FDA and EMEA action with respect to Genasense®. Any adverse events with respect to FDA and/or EMEA approvals could negatively impact our ability to obtain additional funding or identify potential partners.

For example, on January 3, 2006, we announced that we had completed a Marketing Authorization Application, or MAA, to the EMEA that seeks approval for use of Genasense® plus dacarbazine for the treatment of patients with advanced melanoma who have not previously received chemotherapy. On February 1, 2006, we announced that we had received notice from the EMEA that our MAA was validated for review by the EMEA. We anticipate receiving consolidated questions from the EMEA approximately 120 days from the date of the MAA's validation. The centralized licensing procedure provides a single marketing authorization that is valid in all 25-member states of the European Community. Review of the application is coordinated by the EMEA, and Spain and France have been appointed as rapporteur and co-rapporteur countries, respectively.

On December 28, 2005, we completed submission of an NDA to the FDA that sought accelerated approval for the use of Genasense® in combination with fludarabine plus cyclophosphamide for the treatment of patients with relapsed or refractory 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. Genasense® has also been granted designation as an Orphan Drug by the FDA. On March 1, 2006, we announced that the NDA had been accepted for review by the FDA with a target action date of October 28, 2006. However, acceptance of this NDA does not necessarily lead to FDA approval. After reviewing in May 2005 a summary of our preliminary clinical data that were released in November 2004 from our CLL trial, the FDA expressed concern that simply achieving statistical significance in the primary endpoint (complete plus nodular partial responses [CR/nPR]) may not be likely to convey or predict clinical benefit, particularly absent improvement in time-to-progression. Subsequent to preparation of the preliminary data summary, the Company compiled additional information to support its claims of clinical benefit. First, the proportion of patients who relapsed from CR/nPR increased substantially over time from 25% to 75% in the patient group treated with chemotherapy alone. By contrast, the comparable increase in the Genasense group was 16% to 25%, which indicated lower risk of relapse. Second, the preliminary clinical data indicated that the median duration of CR/nPR had not been reached in either treatment group. Further follow-up showed that CR/nPRs achieved with the addition of Genasense® to chemotherapy were significantly longer when compared with those responses achieved with chemotherapy alone. For example, the median CR/nPR duration in the chemotherapy alone group was reached at 22 months, whereas the median has still not been reached in the Genasense group [P=0.03]. Third, the Company had prospectively collected data regarding specific parameters of disease-related morbidity, including but not limited to symptoms. Subsequent analysis of these data showed that patients in the Genasense treatment group who achieved CR/nPR also attained substantial improvement in these disease parameters. The NDA that was submitted by the Company in December 2005, which includes these data, was subsequently accepted for review by the FDA in February 2006.

Following its review of all our information concerning Genasense®, the FDA may refuse to approve altogether, or may ask for more data to be obtained, so that approval can be reconsidered. Any of these decisions by the FDA would have a material adverse effect on our business. One requirement for Accelerated Approval is that we will be required to conduct a confirmatory trial. We have formulated a design for such a trial and have submitted a proposal to the FDA for review as a Special Protocol Assessment, or SPA. The submitted proposal incorporated initial comments received from the FDA. Final comments on the submission are expected during the first half of 2006. Formal initiation of the trial will depend upon resolution of trial design issues with the FDA, among other factors. Although Fast Track designation, Orphan Drug designation and Accelerated Approval provisions are beneficial, we cannot assure you that the NDA will be approved. In particular, the FDA may not be satisfied that achievement of the primary endpoint used in our recent clinical trial, which was an increased proportion of complete responses/nodular partial responses compared to patients treated with standard chemotherapy, is a sufficient basis for approval. Further, increased symptom-free time may not be considered to be sufficient demonstration of clinical benefit.

Ultimately, our efforts may not prove to be as effective as those of our competitors. In the United States and elsewhere, our products will face significant competition. The principal conditions on which our product development efforts are focused and some of the other disorders for which we are conducting additional studies, are currently treated with several drugs, many of which have been available for a number of years or are available in inexpensive generic forms. Thus, even if we obtain regulatory approvals, we will need to demonstrate to physicians, patients and third-party payors that the cost of our products is reasonable and appropriate in light of their safety and efficacy, the price of competing products and the relative health care benefits to the patient. If we are unable to demonstrate that the costs of our products are reasonable and appropriate in light of these factors, we will likely be unsuccessful in commercializing our products.

Recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern.

Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements for the year ended December 31, 2005 with respect to this uncertainty. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of the common shares of our stock and we may have a more difficult time obtaining financing.

We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

Our business will suffer if we fail to obtain timely funding. We may be unable to raise additional capital when needed and may not continue as a going concern.

Our operations to date have required significant cash expenditures. As a result of Aventis' termination of the Collaborative Agreement, after May 8, 2005, we became solely responsible for all Genasense® related costs. Our future capital requirements will depend on the results of our research and development activities, preclinical studies and clinical trials, competitive and technological advances, and regulatory activities of the FDA and other regulatory authorities. In order to commercialize our products, we will need to raise additional funds. On March 13, 2006, we sold 19.0 million shares of our common stock at a price of \$2.15 per share raising approximately \$37.7 million, net of estimated fees and expenses. During the first three months of 2006, cash used in operating activities was \$11.5 million.

Management plans to increase its spending from April through September to an average rate of approximately \$5 million per month. We anticipate that we will have sufficient cash funds to maintain our present operations into the first quarter of 2007.

We will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing. We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. Future collaborations or similar arrangements may require us to license valuable intellectual property to, or to share substantial economic benefits with, our collaborators. If we raise additional capital by issuing additional equity or securities convertible into equity, our stockholders may experience dilution and our share price may decline. Any debt financing may result in restrictions on our spending.

If we are unable to raise additional funds, we will need to do one or more of the following:

- o delay, scale back or eliminate some or all of our research and product development programs and sales and marketing activity;
- o license third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;
- o attempt to sell our company;
- o cease operations; or
- o declare bankruptcy.

We intend to be a direct marketer of some products in the United States. This effort will consume large amounts of our resources and management time and we may not be successful in our efforts.

Currently we do not have a sales force. Our sales force was eliminated in 2004 following our decision to withdraw the NDA for Genasense® for the treatment of advanced melanoma. We intend to begin the recruitment of a sales force in the second half of 2006. In January 2006, we announced that we had appointed W. Lloyd Sanders as Vice-President of Sales and Marketing. Most recently, Mr. Sanders was Vice President, Oncology Sales, at sanofi-aventis Group. If we are unable to recruit a sales force capable of marketing our products, our sales will be adversely affected, and the commercial success of our products will be limited.

On May 10, 2005, we announced that we and Aventis Pharmaceuticals Inc., part of sanofi-aventis Group, or Aventis, had signed an agreement to terminate their development and commercialization collaboration for Genasense®. We lost a significant source of funding for Genasense® as a result of this termination.

In April 2002, we entered into a series of agreements relating to the development and commercialization of Genasense®, to which we refer collectively as the Collaborative Agreement, with Aventis and its affiliates. On November 8, 2004, we received from Aventis a notice of termination of the Collaborative Agreement. On May 10, 2005, we announced that we had signed an agreement with Aventis to terminate our development and commercialization collaboration for Genasense®. The termination agreement provided for no future financial obligations by either party. Aventis also returned its then current inventory of Genasense® drug supply to us. In addition, we assumed responsibility for the randomized clinical trial of Genasense® in combination with docetaxel (Taxotere®; sanofi-aventis) in patients with hormone-refractory prostate cancer, which recently completed accrual. Among other provisions, the Standstill and Voting Agreement and Registration Rights Agreement that were established pursuant to the Aventis investment in our common stock in 2002 did not terminate at this time.

We are seeking a new partner for the development and commercialization of Genasense®, and if we are unable to do so, we may not have sufficient resources to fully develop and commercialize Genasense®.

If we are unable to identify a partner, we will be solely responsible for the development and commercialization of Genasense®, including the costs associated therewith. We may not have sufficient resources to do so. Even if we are able to identify a partner, we may not be able to enter into an agreement on acceptable terms or at all.

We have relied on and continue to rely on our contractual collaborative arrangements with research institutions and corporate partners for development and commercialization of our products. Our business could suffer if we are not able to enter into suitable arrangements, maintain existing relationships, or if our collaborative arrangements are not successful in developing and commercializing products.

We have entered into collaborative relationships relating to the conduct of clinical research and other research activities in order to augment our internal research capabilities and to obtain access to specialized knowledge and expertise. Our business strategy depends in part on our continued ability to develop and maintain relationships with leading academic and research institutions and with independent researchers. The competition for these relationships is intense, and we can give no assurances that we will be able to develop and maintain these relationships on acceptable terms.

We also seek strategic alliances with corporate partners, primarily pharmaceutical and biotechnology companies, to help us develop and commercialize drugs. Various problems can arise in strategic alliances. A partner responsible for conducting clinical trials and obtaining regulatory approval may fail to develop a marketable drug. A partner may decide to pursue an alternative strategy or focus its efforts on alliances or other arrangements with third parties. A partner that has been granted marketing rights for a certain drug within a geographic area may fail to market the drug successfully. Consequently, strategic alliances that we may enter into may not be scientifically or commercially successful. In this regard, in April 2002, we entered into a series of agreements relating to the development and commercialization of Genasense® with Aventis and its affiliates. On November 8, 2004, we received from Aventis a notice of termination of the Collaborative Agreement. On May 10, 2005, we announced that we and Aventis had signed an agreement to terminate our development and commercialization collaboration for Genasense® as described above.

We cannot control the resources that any collaborator may devote to our products. Any of our present or future collaborators may not perform their obligations as expected. These collaborators may breach or terminate their agreements with us, for instance upon changes in control or management of the collaborator, or they may otherwise fail to conduct their collaborative activities successfully and in a timely manner.

In addition, our collaborators may elect not to develop products arising out of our collaborative arrangements or to devote sufficient resources to the development, regulatory approval, manufacture, marketing or sale of these products. If any of these events occur, we may not be able to develop our products or commercialize our products.

An important part of our strategy involves conducting multiple product development programs. We may pursue opportunities in fields that conflict with those of our collaborators. In addition, disagreements with our collaborators could develop over rights to our intellectual property. The resolution of such conflicts and disagreements may require us to relinquish rights to our intellectual property that we believe we are entitled to. In addition, any disagreement or conflict with our collaborators could reduce our ability to obtain future collaboration agreements and negatively impact our relationship with existing collaborators. Such a conflict or disagreement could also lead to delays in collaborative research, development, regulatory approval or commercialization of various products or could require or result in litigation or arbitration, which would be time consuming and expensive, divert the attention of our management and could have a significant negative impact on our business, financial condition and results of operations.

We anticipate that we will incur additional losses and we may never be profitable.

We have never been profitable. We have incurred substantial annual operating losses associated with ongoing research and development activities, preclinical testing, clinical trials, regulatory submissions and manufacturing activities. From the period since our inception to March 31, 2006, we have incurred a cumulative net loss of \$368.1 million. We may never achieve revenue sufficient for us to attain profitability. Achieving profitability is unlikely unless Genasense® receives approval from the FDA for commercial sale in one or more indications.

Our business depends heavily on a small number of products.

We currently market and sell one product, Ganite® and the principal patent covering its use for the approved indication expired in April 2005. We do not expect to expand our marketed product portfolio significantly in the short term unless Genasense® receives marketing approval. If Genasense® is not approved, if approval is significantly delayed, or if in the event of approval, the product is commercially unsuccessful, we do not expect significant sales of other products to offset this loss of potential revenue.

To diversify our product line in the long term, it will be important for us to identify suitable technologies and products for acquisition or licensing and development. If we are unable to identify suitable technologies and products, or if we are unable to acquire or license products we identify, we may be unable to diversify our product line and to generate long-term growth.

We may be unable to obtain or enforce patents, other proprietary rights and licenses to protect our business; we could become involved in litigation relating to our patents or licenses that could cause us to incur additional costs and delay or prevent our introduction of new drugs to market.

Our success will depend to a large extent on our ability to:

- obtain U.S. and foreign patent or other proprietary protection for our technologies, products and processes;
- preserve trade secrets; and
- operate without infringing the patent and other proprietary rights of third parties.

Legal standards relating to the validity of patents covering pharmaceutical and biotechnological inventions and the scope of claims made under these types of patents are still developing, and they involve complex legal and factual questions. As a result, our ability to obtain and enforce patents that protect our drugs is highly uncertain. If we are unable to obtain and enforce patents and licenses to protect our drugs, our business, results of operations and financial condition could be adversely affected.

We hold numerous U.S., foreign and international patents covering various aspects of our technology, which include novel compositions of matter, methods of large-scale synthesis and methods of controlling gene expression and methods of treating disease. In the future, however, we may not be successful in obtaining additional patents despite pending or future applications. Moreover, our current and future patents may not be sufficient to protect us against competitors who use similar technology. Additionally, our patents, the patents of our business partners and the patents for which we have obtained licensing rights may be challenged, narrowed, invalidated or circumvented. Furthermore, rights granted under our patents may not be broad enough to cover commercially valuable drugs or processes and therefore may not provide us with sufficient competitive advantage with respect thereto.

The pharmaceutical and biotechnology industries have been greatly affected by time-consuming and expensive litigation regarding patents and other intellectual property rights. We may be required to commence, or may be made a party to, litigation relating to the scope and validity of our intellectual property rights or the intellectual property rights of others. Such litigation could result in adverse decisions regarding the patentability of our inventions and products, the enforceability, validity or scope of protection offered by our patents or our infringement of patents held by others. Such decisions could make us liable for substantial money damages, or could bar us from the manufacture, sale or use of certain products. Moreover, an adverse decision may also compel us to seek a license from a third party. The costs of any license may be prohibitive and we may not be able to enter into any required licensing arrangement on terms acceptable to us.

The cost to us of any litigation or proceeding relating to patent or license rights, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of complex patent or licensing litigation more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of any patent or related litigation could have a material adverse effect on our ability to compete in the marketplace.

We also may be required to participate in interference proceedings declared by the U.S. Patent and Trademark Office in opposition or similar proceedings before foreign patent offices and in International Trade Commission proceedings aimed at preventing the importation of drugs that would compete unfairly with our drugs. These types of proceedings could cause us to incur considerable costs.

The principal patent covering the use of Ganite® for its approved indication expired, including Hatch-Waxman extensions, in April 2005.

We have licensed a portfolio of U.S. patents and applications from the University of Pennsylvania and the NIH relating to Genasense® and its backbone chemistry that expire between 2008 and 2015. Corresponding patent applications have been filed in Canada, Europe and Japan. The claims of these patents cover our proprietary antisense oligonucleotide molecules which target the Bcl-2 mRNA and methods employing them. We also hold several U.S. patent applications relating to methods of using Genasense® that expire in 2020, with approximately 45 corresponding foreign patent applications.

Most of our products are in an early stage of development, and we may never receive regulatory approval for these products.

Most of our resources have been dedicated to the research and development of potential antisense pharmaceutical products such as Genasense®, based upon oligonucleotide technology. While we have demonstrated the activity of antisense oligonucleotide technology in model systems in vitro and in animals, Genasense® is our only antisense product to have been tested in humans. Several of our other technologies that serve as a possible basis for pharmaceutical products are only in preclinical testing. Results obtained in preclinical studies or early clinical investigations are not necessarily indicative of results that will be obtained in extended human clinical trials. Our products may prove to have undesirable and unintended side effects or other characteristics that may prevent our obtaining FDA or foreign regulatory approval for any indication. In addition, it is possible that research and discoveries by others will render our oligonucleotide technology obsolete or noncompetitive.

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results or if our clinical trials do not demonstrate safety and efficacy in humans.

Our success will depend on the success of our currently ongoing clinical trials and subsequent clinical trials that have not yet begun. It may take several years to complete the clinical trials of a product, and a failure of one or more of our clinical trials can occur at any stage of testing. We believe that the development of each of our product candidates involves significant risks at each stage of testing. If clinical trial difficulties and failures arise, our product candidates may never be approved for sale or become commercially viable. We do not believe that any of our product candidates have alternative uses if our current development activities are unsuccessful.

There are a number of difficulties and risks associated with clinical trials. These difficulties and risks may result in the failure to receive regulatory approval to sell our product candidates or the inability to commercialize any of our product candidates. The possibility exists that:

- we may discover that a product candidate does not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude regulatory approval or limit commercial use if approved;
- the results from early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;
- institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;
- subjects may drop out of our clinical trials;
- our preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials; and
- the cost of our clinical trials may be greater than we currently anticipate.

For example, in November 2004, we reported that our 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 previously had received extensive therapy. Based on the results of the Phase 3 trial, we have no plans to submit an NDA in this indication to the FDA at the current time. We have not yet determined what additional clinical trials, if any, may be undertaken in patients with multiple myeloma.

We cannot assure you that our ongoing preclinical studies and clinical trials will produce successful results in order to support regulatory approval of Genasense® in any territory or for any indication. Failure to obtain approval, or a substantial delay in approval of Genasense® for these or any other indications would have a material adverse effect on our results of operations and financial condition.

Clinical trials are costly and time consuming and are subject to delays; our business would suffer if the development process relating to our products were subject to meaningful delays.

Clinical trials are very costly and time-consuming. The length of time required to complete a clinical study depends upon many factors, including but not limited to the size of the patient population, the ability of patients to get to the site of the clinical study, the criteria for determining which patients are eligible to join the study and other issues. Delays in patient enrollment and other unforeseen developments could delay completion of a clinical study and increase its costs, which could also delay any eventual commercial sale of the drug that is the subject of the clinical trial.

Our commencement and rate of completion of clinical trials also may be delayed by many other factors, including the following:

- inability to obtain sufficient quantities of materials for use in clinical trials;
- inability to adequately monitor patient progress after treatment;
- unforeseen safety issues;
- the failure of the products to perform well during clinical trials and
- government or regulatory delays.

If we fail to obtain the necessary regulatory approvals, we cannot market and sell our products in the United States or in other countries.

The FDA and comparable regulatory agencies in foreign countries (such as the EMEA) impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve lengthy and detailed preclinical and clinical testing and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more depending upon the type, complexity and novelty of the product. We cannot apply for FDA approval to market any of our products under development until preclinical and clinical trials on the product are successfully completed. Several factors could prevent successful completion or cause significant delays of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that the product is safe and effective for use in humans. If safety concerns develop, the FDA could stop our trials before completion. We may not market or sell any product for which we have not obtained regulatory approval. In May 2004, the application failed to gain a majority vote for marketing approval from ODAC. As a consequence, we withdrew the NDA, which allows us to potentially resubmit the application.

We cannot assure you that the FDA, the EMEA or other regulatory agencies will ever approve the use of our products that are under development. If the patient populations for which our products are approved are not sufficiently broad, or if approval is accompanied by unanticipated labeling restrictions, the commercial success of our products could be limited and our business, results of operations and financial condition could consequently be materially adversely affected.

If the third party manufacturers upon which we rely fail to produce our products in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of, or be unable to meet demand for, our products and may lose potential revenues.

We do not manufacture any of our products or product candidates and we do not plan to develop any capacity to do so. We have contracted with third-party manufacturers to manufacture Ganite® and Genasense®. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Our third-party manufacturers may not perform as agreed or may terminate their agreements with us.

In addition to product approval, any facility in which Genasense® is manufactured or tested for its ability to meet required specifications must be approved by the FDA and/or the EMEA before it can manufacture Genasense®. Failure of the facility to be approved could delay the approval of Genasense®.

We do not currently have alternate manufacturing plans in place. The number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture bulk drug substance on a commercial scale is limited, and it would take a significant amount of time to arrange for alternative manufacturers. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must approve these manufacturers facilities and processes prior to our use, which would require new testing and compliance inspections, and the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our products.

Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of our products or product candidates, entail higher costs and result in our being unable to effectively commercialize our products. Furthermore, if our third-party manufacturers fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenues.

Even if we obtain regulatory approval, we will be subject to ongoing regulation, and any failure by us or our manufacturers to comply with such regulation could suspend or eliminate our ability to sell our products.

Ganite®, Genasense®, if it obtains regulatory approval, and any other product we may develop will be subject to ongoing regulatory oversight, primarily by the FDA. Failure to comply with post-marketing requirements, such as maintenance by us or by the manufacturers of our products of current Good Manufacturing Practices as required by the FDA, or safety surveillance of such products or lack of compliance with other regulations could result in suspension or limitation of approvals or other enforcement actions. Current Good Manufacturing Practices are FDA regulations that define the minimum standards that must be met by companies that manufacture pharmaceuticals and apply to all drugs for human use including those to be used in clinical trials as well as those produced for general sale after approval of an application by the FDA. These regulations define requirements for personnel, buildings and facilities, equipment, control of raw materials and packaging components, production and process controls, packaging and label controls, handling and distribution, laboratory controls and recordkeeping. Furthermore, the terms of any product candidate approval, including the labeling content and advertising restrictions, may be so restrictive that they could adversely affect the marketability of our product candidates. Any such failure to comply or the application of such restrictions could limit our ability to market our product candidates and may have a material adverse effect on our business, results of operations and financial condition. Such failures or restrictions may also prompt regulatory recalls of one or more of our products, which could have material and adverse effects on our business.

The raw materials for our products are produced by a limited number of suppliers, and our business could suffer if we cannot obtain needed quantities at acceptable prices and qualities.

The raw materials that we require to manufacture our drugs, particularly oligonucleotides, are available from only a few suppliers. If these suppliers cease to provide us with the necessary raw materials or fail to provide us with an adequate supply of materials at an acceptable price and quality, we could be materially adversely affected.

If third-party payors do not provide coverage and reimbursement for use of our products, we may not be able to successfully commercialize our products.

Our ability to commercialize drugs successfully will depend in part on the extent to which various third-party payors are willing to reimburse patients for the costs of our drugs and related treatments. These third-party payors include government authorities, private health insurers and other organizations, such as health maintenance organizations. Third-party payors often challenge the prices charged for medical products and services. Accordingly, if less costly drugs are available, third-party payors may not authorize or may limit reimbursement for our drugs, even if they are safer or more effective than the alternatives. In addition, the federal government and private insurers have changed and continue to consider ways to change the manner in which health care products and services are provided and paid for in the United States. In particular, these third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products. In the future, it is possible that the government may institute price controls and further limits on Medicare and Medicaid spending. These controls and limits could affect the payments we collect from sales of our products. Internationally, medical reimbursement systems vary significantly, with some countries requiring application for, and approval of, government or third-party reimbursement. In addition, some medical centers in foreign countries have fixed budgets, regardless of levels of patient care. Even if we succeed in bringing therapeutic products to market, uncertainties regarding future health care policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in quantities, or at prices, that will enable us to achieve profitability.

Our business exposes us to potential product liability that may have a negative effect on our financial performance and our business generally.

The administration of drugs to humans, whether in clinical trials or commercially, exposes us to potential product and professional liability risks, which are inherent in the testing, production, marketing and sale of human therapeutic products. Product liability claims can be expensive to defend and may result in large judgments or settlements against us, which could have a negative effect on our financial performance and materially and adversely affect our business. We maintain product liability insurance (subject to various deductibles), but our insurance coverage may not be sufficient to cover claims. Furthermore, we cannot be certain that we will always be able to maintain or increase our insurance coverage at an affordable price. Even if a product liability claim is not successful, the adverse publicity and time and expense of defending such a claim may interfere with or adversely affect our business and financial performance.

We may incur a variety of costs to engage in future acquisitions of companies, products or technologies, and the anticipated benefits of those acquisitions may never be realized.

As a part of our business strategy, we may make acquisitions of, or significant investments in, complementary companies, products or technologies, although no significant acquisition or investments are currently pending. Any future acquisitions would be accompanied by risks such as:

- difficulties in assimilating the operations and personnel of acquired companies;
- diversion of our management's attention from ongoing business concerns;
- our potential inability to maximize our financial and strategic position through the successful incorporation of acquired technology and rights into our products and services;
- additional expense associated with amortization of acquired assets;
- maintenance of uniform standards, controls, procedures and policies; and
- impairment of existing relationships with employees, suppliers and customers as a result of the integration of new management personnel.

We cannot guarantee that we will be able to successfully integrate any business, products, technologies or personnel that we might acquire in the future, and our failure to do so could harm our business.

We face substantial competition from other companies and research institutions that are developing similar products, and we may not be able to compete successfully.

In many cases, our products under development will be competing with existing therapies for market share. In addition, a number of companies are pursuing the development of antisense technology and controlled-release formulation technology and the development of pharmaceuticals utilizing such technologies. We compete with fully integrated pharmaceutical companies that have more substantial experience, financial and other resources and superior expertise in research and development, manufacturing, testing, obtaining regulatory approvals, marketing and distribution. Smaller companies may also prove to be significant competitors, particularly through their collaborative arrangements with large pharmaceutical companies or academic institutions. Furthermore, academic institutions, governmental agencies and other public and private research organizations have conducted and will continue to conduct research, seek patent protection and establish arrangements for commercializing products. Such products may compete directly with any products that may be offered by us.

Our competition will be determined in part by the potential indications for which our products are developed and ultimately approved by regulatory authorities. For certain of our potential products, an important factor in competition may be the timing of market introduction of our or our competitors' products. Accordingly, the relative speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are expected to be important competitive factors. We expect that competition among products approved for sale will be based, among other things, on product efficacy, safety, reliability, availability, price, patent position and sales, marketing and distribution capabilities. The development by others of new treatment methods could render our products under development non-competitive or obsolete.

Our competitive position also depends upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often-substantial period between technological conception and commercial sales. We cannot assure you that we will be successful in this regard.

We are dependent on our key executives and scientists, and the loss of key personnel or the failure to attract additional qualified personnel could harm our business.

Our business is highly dependent on our key executives and scientific staff. The loss of key personnel or the failure to recruit necessary additional or replacement personnel will likely impede the achievement of our development objectives. There is intense competition for qualified personnel in the pharmaceutical and biotechnology industries, and there can be no assurances that we will be able to attract and retain the qualified personnel necessary for the development of our business.

Risks Related to Outstanding Litigation

The outcome of and costs relating to pending shareholder class action and shareholder derivative actions are uncertain.

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®. As of March 2006, nonbinding mediation has not produced a settlement and the case is proceeding to 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. The Federal shareholder derivative action was consolidated with the securities action. The Federal derivative plaintiffs have not yet filed a consolidated amended complaint asserting their claims. Instead, the Federal shareholder derivative action has been stayed, pending developments in the Federal securities action.

Based on facts substantially similar to those asserted in the shareholder class actions, the State derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and committed other violations of New Jersey law. On February 9, 2006, the Superior Court of New Jersey dismissed the plaintiffs' derivative complaint in the New Jersey State case based in part on plaintiffs' failure to make a pre-suit demand on Genta's Board of Directors and in part based on plaintiffs' failure to state a cause of action. Plaintiffs served a motion for reconsideration on February 27, 2006.

We believe these litigations are without merit and will continue to vigorously defend against these suits.

Risks Related to Our Common Stock

Provisions in our restated certificate of incorporation and bylaws and Delaware law may discourage a takeover and prevent our stockholders from receiving a premium for their shares.

Provisions in our restated certificate of incorporation and bylaws may discourage third parties from seeking to obtain control of us and, therefore, could prevent our stockholders from receiving a premium for their shares. Our restated certificate of incorporation gives our board of directors the power to issue shares of preferred stock without approval of the holders of common stock. Any preferred stock that is issued in the future could have voting rights, including voting rights that could be superior to that of our common stock. The affirmative vote of 66-2/3% of our voting stock is required to approve certain transactions and to take certain stockholder actions, including the amendment of certain provisions of our certificate of incorporation. Our bylaws contain provisions that regulate how stockholders may present proposals or nominate directors for election at annual meetings of stockholders.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which contains restrictions on stockholder action to acquire control of us.

On September 16, 2005, we announced that our Board of Directors approved a Stockholder Rights Plan and declared a dividend of one preferred stock purchase right (Right) for each share of our common stock held of record as of the close of business on September 27, 2005. In addition, Rights shall be issued in respect of all shares of common stock issued after such date, including the shares issued hereunder, pursuant to the Plan. The Rights contain provisions to protect stockholders in the event of an unsolicited attempt to acquire us, including an accumulation of shares in the open market, a partial or two-tier tender offer that does not treat all stockholders equally and other activities that the Board believes are not in the best interests of shareholders. The Rights may discourage a takeover and prevent our stockholders from receiving a premium for their shares.

We have not paid, and do not expect to pay in the future, cash dividends on our common stock.

We have never paid cash dividends on our common stock and do not anticipate paying any such dividends in the foreseeable future. We currently intend to retain our earnings, if any, for the development of our business.

Our stock price is volatile.

The market price of our common stock, like that of the common stock of many other biopharmaceutical companies, has been and likely will continue to be highly volatile. Factors that could have a significant impact on the future price of our common stock include but are not limited to:

- the results of preclinical studies and clinical trials by us or our competitors;
- announcements of technological innovations or new therapeutic products by us or our competitors;
- government regulation;
- developments in patent or other proprietary rights by us or our respective competitors, including litigation;
- fluctuations in our operating results; and
- market conditions for biopharmaceutical stocks in general.

At March 31, 2006, we had 133.6 million shares of common stock outstanding, 12.7 million additional shares reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants and 3.3 million additional shares of common stock authorized for issuance and remaining to be granted under our stock option plans. Future sales of shares of our common stock by existing stockholders, holders of preferred stock who might convert such preferred stock into common stock and option and warrant holders who may exercise their options and warrants to purchase common stock also could adversely affect the market price of our common stock. Moreover, the perception that sales of substantial amounts of our common stock might occur could adversely affect the market price of our common stock.

Item 2. *Unregistered Sales of Equity Securities and Use of Proceeds*

None.

Item 3. *Defaults Upon Senior Securities*

None.

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

None.

Item 5. *Other Information*

None.

Item 6. Exhibits.

(a) Exhibits

Exhibit

Number Description of Document

- 10.1 Form of Placement Agent Agreement, dated March 6, 2006 by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 7, 2006, Commission File No. 0-19635)
- 10.2 Form of Confirmation of Purchase, dated March 10, 2006 by and between the Company and certain Investors (incorporated by reference to Exhibit 10.34 to the Company's Current Report on Form 10-K for year ended December 31, 2005 filed on March 10, 2006, Commission File No. 0-19635)
- 10.3 Form of Amendment No. 1 to Placement Agent Agreement, dated as of March 10, 2006 by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.35 to the Company's Current Report on Form 10-K for year ended December 31, 2005 filed on March 10, 2006, Commission File No. 0-19635)
- 10.4 Employment Agreement, dated as of January 1, 2006, between the Company and Raymond P. Warrell, Jr., M.D.
- 10.5 Development and License Agreement, dated March 22, 2006, by and between Genta Incorporated and Emisphere Technologies, Inc*.
- 10.6 1998 Stock Incentive Plan, as amended and restated, effective April 5, 2006 (incorporated by reference to the Company's Definitive Proxy Statement on Schedule 14A filed on April 28, 2006, 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

* (Confidential treatment has been requested)

SIGNATURES

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

Date: May 9, 2006

Genta Incorporated

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

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

Date: May 9, 2006

/s/ RICHARD J. MORAN

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

Exhibit Index

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