

GENTA INC DE/  
Form 10-Q  
May 08, 2007

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**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, 2007

**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



As of April 30, 2007, the registrant had 183,724,815 shares of common stock outstanding.

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**Genta Incorporated**

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**CONSOLIDATED BALANCE SHEETS****(Unaudited)**

(In thousands, except par value data)

ASSETS	March 31, 2007	December 31, 2006
Current assets:		
Cash and cash equivalents	\$ 5,539	\$ 9,554
Marketable securities (Note 3)	23,876	19,942
Accounts receivable - net of allowances of \$26 at March 31, 2007 and \$42 at December 31, 2006, respectively		17
Inventory (Note 5)	286	308
Prepaid expenses and other current assets (Note 12)	19,555	19,997
Total current assets	49,256	49,818
Property and equipment, net (Note 6)	215	271
Other assets	1,700	1,689
Total assets	\$ 51,171	\$ 51,778

**LIABILITIES AND STOCKHOLDERS' EQUITY**

Current liabilities:		
Accounts payable and accrued expenses (Note 12)	\$ 31,191	\$ 36,494
Notes payable (Note 7)	257	642
Total current liabilities	31,448	37,136

Commitments and contingencies (Note 12)

Stockholders' equity (Note 8):

Preferred stock, 5,000 shares authorized:

Series A convertible preferred stock, \$.001 par value; 8 shares issued and outstanding, liquidation value of \$385 at March 31, 2007 and December 31, 2006, respectively

Series G participating cumulative preferred stock, \$.001 par value; 0 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively

Common stock, \$.001 par value; 250,000 shares authorized, 183,725 and 153,725 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively

Additional paid-in capital

Accumulated deficit

Accumulated other comprehensive income

Total stockholders' equity

Total liabilities and stockholders' equity	\$	51,171	\$	51,778
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See accompanying notes to consolidated financial statements.

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**GENTA INCORPORATED**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**

(In thousands, except per share data)	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2007</b>	<b>2006</b>
Product sales net	\$ 94	\$ 67
Cost of goods sold	22	16
Gross margin	72	51
Operating expenses:		
Research and development	3,383	4,750
Selling, general and administrative	4,052	5,456
Provision for settlement of litigation, net (Note 12)	(1,560)	
Total operating expenses	5,875	10,206
Other income/(expense):		
Gain on maturity of marketable securities	8	92
Interest income and other income, net	274	184
Interest expense	(84)	(16)
Total other income, net	198	260
Net loss	\$ (5,605)	\$ (9,895)
Net loss per basic and diluted share	\$ (0.04)	\$ (0.08)

Shares used in computing net loss per basic and diluted share	159,391	118,186
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See accompanying notes to consolidated financial statements.

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**GENTA INCORPORATED**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**

(In thousands)	<b>Three Months Ended March</b>	
	<b>2007</b>	<b>31, 2006</b>
<b>Operating activities:</b>		
Net loss	\$ (5,605)	\$ (9,895)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	56	334
Share-based compensation (Note 9)	570	597
Gain on maturity of marketable securities	(8)	(92)
Provision for settlement of litigation, net (Note 12)	(1,560)	
Changes in operating assets and liabilities:		
Accounts receivable	17	41
Inventory (Note 5)	22	16
Prepaid expenses and other current assets	442	404
Accounts payable and accrued expenses	(3,743)	(2,926)

Other assets	(11)	(7)
Net cash used in operating activities	(9,820)	(11,528)
<b>Investing activities:</b>		
Purchase of marketable securities (Note 3)	(13,900)	(25,931)
Maturities of marketable securities (Note 3)	10,000	12,000
Purchase of property and equipment		(9)
Net cash used in investing activities	(3,900)	(13,940)
<b>Financing activities:</b>		
Repayments of note payable	(385)	(451)
Issuance of common stock, net (Note 8)	10,090	37,736
Issuance of common stock upon exercise of warrants and options	-	98
Net cash provided by financing activities	9,705	37,383
Increase/(decrease) in cash and cash equivalents	(4,015)	11,915
Cash and cash equivalents at beginning of period	9,554	9,314
Cash and cash equivalents at end of period	\$ 5,539	\$ 21,229

See accompanying notes to consolidated financial statements.

**GENTA INCORPORATED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2007**

**(Unaudited)**



1.

**Organization and Business**

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

The Company has had recurring annual operating losses since its inception. Management expects that such losses will continue at least until its lead product, Genasense® (oblimersen sodium) Injection, receives approval for commercial sale in one or more indications. Achievement of profitability for the Company is currently dependent on the timing of Genasense® regulatory approval. 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 the Company's ability to obtain additional funding or identify potential partners.

The Company had \$29.4 million of cash, cash equivalents and marketable securities on hand at March 31, 2007. On March 14, 2007, the Company sold 30.0 million shares of its common stock at a price of \$0.36 per share, raising net proceeds of \$10.1 million. Net cash used in operating activities during the three months ended March 31, 2007 was \$9.8 million.

On December 15, 2006, the Company received a non-approvable notice from the FDA for its New Drug Application ( NDA ) for the use of Genasense® plus chemotherapy in patients with chronic lymphocytic leukemia ( CLL ). The Company believes that its application met the regulatory requirements for approval and on April 4, 2007, announced that it had filed a formal appeal of this non-approvable notice. The appeal was filed pursuant to the FDA's Formal Dispute Resolution process that exists within FDA's Center for Drug Evaluation and Research ( CDER ). Responses for CDER appeals are typically made within 30 to 60 days.

The Company also has a pending Marketing Authorization Application ( MAA ) before the European Medicines Agency ( EMEA ) for the use of Genasense® plus chemotherapy for treatment of patients with advanced melanoma. On April 27, 2007, the Company announced that it had been informed that the Committee for Medicinal Products for Human Use ( CHMP ) of the EMEA had issued a negative opinion on the MAA. The EMEA has a formal process whereby the sponsor of a MAA may request re-examination of the initial CHMP opinion, including a review by a specialist Oncology Scientific Advisory Group ( SAG ). The Company announced on April 27, 2007 that it would seek re-examination of the MAA.

Also, on April 27, 2007, the Company announced that it will file a formal complaint and request for correction of information with the FDA under the Federal Data Quality Act. The complaint will challenge as erroneous a key

statistical analysis of the Company's data on Genasense<sup>®</sup> for melanoma used by FDA at the Oncology Drug Advisory Committee ( ODAC ) meeting on May 3, 2004. That analysis sought to discredit the finding that Genasense<sup>®</sup> yielded a statistically significant increase in progression-free survival ( PFS ). At that meeting, ODAC voted unanimously that PFS was an endpoint that would support full approval in the absence of a survival improvement in patients with advanced melanoma. The Company will seek a formal public acknowledgement of the error, removal of the analysis from the FDA website (with a note that the previous analysis was in error), and revision of the transcript.

Irrespective of whether the co-pending NDA and MAA for Genasense<sup>®</sup> are approved, the Company will require additional cash in order to maximize this commercial opportunity and to continue its clinical development opportunities. The Company has had discussions with other companies regarding partnerships for the further development and global commercialization of Genasense<sup>®</sup>. 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, profits from named-patient sales, and other potential sources of financing. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available to us on favorable terms, if at all.

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

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

The Company will maintain an appropriate level of spending over the upcoming fiscal year, given the uncertainties inherent in its business and its current liquidity position. Management believes that at the current rate of spending, the Company should have sufficient cash funds to maintain its present operations into the second quarter of 2008.

On March 7, 2007, the Company announced that it had entered into a Supply and Distribution Agreement with IDIS Limited (a privately owned company based in the United Kingdom) whereby IDIS will distribute Ganite® and Genasense® on a named patient basis. The global agreement covers territories outside the United States. Named patient distribution refers to the distribution or sale of a product to a specific healthcare professional for the treatment of an individual patient. IDIS will manage the named patient programs for the Company.

The Agreement provides that the Company will supply the two products to IDIS on a consignment basis. The Company will be paid after sales are made by IDIS, which payment shall be based off of a monthly sales report received from IDIS. The Company will invoice IDIS based upon this monthly report, which invoice shall be calculated based upon a price minus a fee credited to IDIS. The agreement also provides for distribution by IDIS of a limited amount of drug product free of charge to indigent patients. The Company intends that a percentage of proceeds from the named patient program will be used to support the compassionate use program. The Company has agreed to pay a nominal one time start-up fee for this program to IDIS and the Company will pay IDIS a termination fee in the event it terminates either or both products within the first three years.

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, 2007 have been considered in preparing the consolidated financial statements. Such financial statements include the accounts of the Company and all majority-owned subsidiaries. The accompanying consolidated financial statements included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements have been condensed or omitted from this report, as is permitted by such rules and regulations; however, the Company believes that the disclosures are adequate to make the information presented not misleading. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make certain estimates and assumptions that affect reported earnings, financial position and various disclosures. Actual results could differ from those estimates. Certain reclassifications were made to prior-year amounts to conform to the current-year presentation that were not considered material. The Consolidated Statements of Operations for the quarter ended March 31, 2006 include a reclassification of \$92 thousand for Gain on maturity of marketable securities and \$16 thousand for Interest expense from Other Income in order to report such amounts separately. 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, 2006. 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.

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### *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.

Under the Company's Supply and Distribution agreement with IDIS Limited, the Company will supply Ganit® and Genasense® to IDIS on a consignment basis. The Company will recognize revenue when IDIS reports that it has delivered product to customers, which is the point in time that title to the product and risk of loss has passed.

### *Research and Development*

Research and development costs are expensed as incurred, including raw material costs required to manufacture products for clinical trials.

On March 23, 2006, the Company entered into an exclusive, worldwide licensing agreement with Emisphere Technologies, Inc., ( "Emisphere" ), to develop an oral formulation of a gallium-containing compound. Under the terms of the agreement, Genta will pay Emisphere a monthly fee for continuing research, and potentially up to \$24.0 million, but only upon the achievement of certain milestones during the course of product development plus royalties based upon sales. To date, no milestone or royalty payments have been made.

### *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. 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 corporate offices are being amortized over the shorter of the remaining life of the leases or the life of the assets. 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. The Company generated additional net operating losses during the three months ended March 31, 2007 and continues to maintain a full valuation allowance against its net deferred tax assets.

In July 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109 ( FIN 48 ), which clarifies the accounting and disclosure for uncertainty in tax positions, as defined. FIN 48 seeks to reduce the diversity in practice associated

with certain aspects of the recognition and measurement related to accounting for income taxes. The Company is subject to the provisions of FIN 48 as of January 1, 2007 and has analyzed filing positions in all of the federal and state jurisdictions where it is required to file income tax returns, as well as all open tax years in these jurisdictions. The Company's federal tax return has never been audited. In January 2006, the State of New Jersey concluded its fieldwork with respect to a tax audit for the years 2000 through 2004. The State of New Jersey took the position that amounts reimbursed to Genta by Aventis Pharmaceutical Inc. for co-development expenditures during the audit period were subject to Alternative Minimum Tax (AMA), resulting in a liability at that time of approximately \$533 thousand. Although the Company and its outside tax advisors believe the State of New Jersey's position on the AMA liability is unjustified, there is little, if any, case law on the matter and it is probable that the Company will be required to pay the liability. In March 2007, the Company received a formal assessment from the State of New Jersey for \$712 thousand. As of March 31, 2007, the Company had accrued a tax liability of \$533 thousand, penalties of \$27 thousand and interest of \$152 thousand related to this assessment. The Company will appeal this assessment during 2007.

The Company believes that its other income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to FIN 48. In addition, the Company did not record a cumulative effect adjustment related to the adoption of FIN 48. If such adjustment were recorded, it would have been fully offset by a change in a valuation allowance.

The Company's policy for recording interest and penalties associated with audits is that penalties and interest expense are recorded in Interest expense in the Consolidated statements of operations. The Company recorded \$78 thousand and \$16 thousand in interest expense related to the State of New Jersey assessment during the three months ended March 31, 2007 and 2006, respectively.

### *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 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 9 and Note 10 to our Consolidated Financial Statements for a further discussion on share-based compensation.

### *Net Loss Per Common Share*

Net loss per common share for the three months ended March 31, 2007 and 2006, respectively, are based on the weighted average number of shares of common stock outstanding during the periods. Basic and diluted loss per share

are identical for all periods presented as potentially dilutive securities have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would be antidilutive. The potentially dilutive securities include 12.8 million and 12.7 million shares on March 31, 2007 and 2006, respectively, reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants.

### **Recent Accounting Pronouncements**

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No. 159 permits all entities to choose to elect, at specified election dates, to measure eligible financial instruments at fair value. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date and recognize upfront costs and fees related to those items in earnings as incurred and not deferred. SFAS No. 159 applies to fiscal years beginning after November 15, 2007, with early adoption permitted for an entity that has also elected to apply the provisions of SFAS No. 157, *Fair Value Measurements*. The Company is currently evaluating the impact, if any, the adoption of SFAS No. 159 may have on its financial statements.

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In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States of America and expands disclosures about fair value measurements. SFAS No. 157 applies under other accounting pronouncements that require or permit fair value measurements. Accordingly, this pronouncement does not require any new fair value measurements. The Company is required to adopt SFAS No. 157 beginning January 1, 2008. The Company is currently evaluating the impact, if any, the adoption of SFAS No. 157 may have on its financial statements.

3.

### **Marketable Securities**

The carrying amounts of the Company's marketable securities, which are primarily securities of government-backed agencies, approximate fair value due to the short-term nature of these instruments. The fair value of available-for-sale marketable securities is as follows (\$ thousands):

	March 31, 2007	December 31, 2006
Cost	\$23,819	\$19,911
Gross unrealized gains	57	31
Gross unrealized losses	—	—
Fair value	\$23,876	\$19,942

The fair value of each marketable security has been compared to its cost and therefore, an unrealized gain of \$57 thousand and \$31 thousand has been recognized in Accumulated other comprehensive income at March 31, 2007 and December 31, 2006, respectively.

#### 4.

##### Workforce reduction

In December 2006, due to the FDA's non-approval of the Company's NDA for CLL, the Company initiated a series of steps that were designed to conserve cash. The Company reduced its workforce by 34 positions, or approximately 35%, including the elimination of 18 positions classified as research and development, 9 in sales and marketing and 7 in administration. Severance costs of \$0.7 million were recognized in operating expenses as of December 31, 2006, including \$0.3 million in research and development expenses and \$0.4 million in selling, general and administrative expenses in the Company's Consolidated Statements of Operations. Payment of the severance began in January 2007.

The activity in the Employee termination cost liability for the period ended March 31, 2007 is presented in the table below (\$ thousands):

	Employee termination costs
Accrued as of January 1, 2007	\$ 747
Paid through March 31, 2007	668
Accrued as of March 31, 2007 (1)	\$ 79

(1)

Included in Accounts payable and accrued expenses.



## 5.

**Inventory**

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

	March 31, 2007	December 31, 2006
Raw materials	\$ 24	\$ 24
Work in process	94	94
Finished goods	168	190
	\$ 286	\$ 308

The Company has substantial quantities of Genasense<sup>®</sup> drug supply which are recorded at zero cost. Such inventory would be available for the commercial launch of this product, should Genasense<sup>®</sup> be approved.

## 6.

**Property and Equipment, Net**

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

	Estimated Useful Lives	March 31, 2007	December 31, 2006
Computer equipment	3	\$ 2,763	\$ 2,950
Software	3	3,090	3,406
Furniture and fixtures	5	936	936
	3 -		
Leasehold improvements	7	410	410

Equipment	5	182	182
		7,381	7,884
Less accumulated depreciation and amortization		(7,166)	(7,613)
		\$ 215	\$ 271

7.

**Notes Payable**

During 2006, the Company issued notes payable to finance premiums for its corporate insurance policies of \$1.2 million at interest rates running from 5.4% to 5.6% and during 2005, \$1.3 million at 4.6% to 5.7%. Payments were scheduled over seven equal monthly installments for the notes initiated in 2006 and for seven or eight equal monthly installments for the notes initiated in 2005.

8.

**Stockholders Equity***Common Stock*

In March 2007, the Company sold 30.0 million shares of the Company's common stock at a price of \$0.36 per share, raising \$10.1 million, net of fees and expenses.

*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, 2007 and December 31, 2006,

each share of Series A Preferred Stock was convertible into 14.0813 and 11.9813 shares of common stock, respectively. At March 31, 2007 and December 31, 2006, the Company had 7,700 shares of Series A Convertible Preferred Stock issued and outstanding.

*Common Stock Reserved*

At March 31, 2007, the Company had 183.7 million shares of common stock outstanding, 12.8 million additional shares reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants and 5.1 million additional shares of common stock authorized for issuance and remaining to be granted under the Company's stock option plans.

**9.**

**Share-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. The Company adopted SFAS 123R using the modified prospective transition method, which required 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 standard also requires the Company to estimate forfeiture rates for all unvested awards, which it does 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 three months ended March 31, 2007 and 2006, respectively:

	Three Months Ended March 31,	
	2007	2006
Expected volatility	102%	98%
Expected dividends	—	—

Expected term (in years)	6.25	6.25
Risk-free rate	4.6%	4.6%

The share-based compensation expense recognized for the three months ended March 31, 2007 and 2006, respectively, was comprised as follows:

(\$ thousands, except per share data)	Three Months Ended	
	March 31,	
	2007	2006
Research and development expenses	\$ 207	\$ 207
Selling, general and administrative	363	390
Total share-based compensation expense	\$ 570	\$ 597
Share-based compensation expense, per basic and diluted common share	\$ 0.00	\$ 0.01

**10.****Stock Option Plans**

As of March 31, 2007, 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"), 20.5 million shares have been provided for the grant of stock options to employees, directors, consultants and advisors of the Company. 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, 2007 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, 2007	11,616	\$ 4.37		
Granted	583	0.46		
Exercised	—	—		
Forfeited or expired	319	1.68		
Outstanding at March 31, 2007	11,880	\$ 4.25	5.4	\$ —
Vested and expected to vest at March 31, 2007	7,128	\$ 4.25	5.4	\$ —
Exercisable at March 31, 2007	7,893	\$ 4.09	4.1	\$ —

There is no intrinsic value to outstanding stock options as the exercise prices of all outstanding options are above the market price of the Company's stock at March 31, 2007. The amount of aggregate intrinsic value will change based on the market value of the Company's stock. The weighted-average grant-date fair value of options granted during the three months ended March 31, 2007 was \$0.38.

As of March 31, 2007, there was approximately \$1.6 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 1.5 years.

#### *1998 Non-Employee Directors' Plan*

Pursuant to the Company's 1998 Non-Employee Directors' 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.

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The following table summarizes the option activity under the Directors' Plan as of March 31, 2007 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, 2007	601	\$ 6.17		
Granted	—	—		
Exercised	—	—		
Forfeited or expired	—	—		
Outstanding at March 31, 2007	601	\$ 6.17	6.2	\$ —
Vested and expected to vest at March 31, 2007	361	\$ 6.17	6.2	\$ —
Exercisable at March 31, 2007	569	\$ 6.44	6.1	\$ —

There is no intrinsic value to outstanding stock options as the exercise prices of all outstanding options are above the market price of the Company's stock at March 31, 2007. The amount of aggregate intrinsic value will change based on the market value of the Company's stock.

## 11.

### Comprehensive Loss

An analysis of comprehensive loss is presented below:

(\$ in thousands)

	Three Months Ended	
	March 31,	
	2007	2006
Net loss	\$ (5,605)	\$ (9,895)
Change in market value of available-for-sale marketable securities	33	—
Less: reclassification adjustment for realized gains included in net loss	(7)	(61)
Total comprehensive loss	\$ (5,579)	\$ (9,956)

**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 the Company's 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®. In non-binding mediation, the Company has reached an agreement in principle with plaintiffs to settle the class action litigation in consideration for issuance of 12.0 million shares of common stock of the Company and \$18.0 million in cash for the benefit of plaintiffs and the shareholder class. The cash portion of the proposed settlement will be covered by the Company's insurance carriers. The Company is actively engaged in preparing the written Stipulation and Agreement of Settlement, which will be filed with the Court seeking preliminary approval. Under FASB Statement No. 5, *Accounting for Contingencies* and FASB Interpretation No. 14, *Reasonable Estimation of the Amount of a Loss, an interpretation of FASB Statement No. 5*, the Company recorded an expense of \$5.3 million, composed of the 12.0 million shares of the Company's common stock valued at a market price of \$0.44 on December 31, 2006. At March 31, 2007, the revised estimated value of the common shares portion of the litigation settlement is \$3.7 million, based on a closing price of Genta's common stock of \$0.31 per share, resulting in a reduction in the provision of \$1.6 million recognized in the first quarter of 2007. The amount of the liability will

continue to be adjusted based on the market price of the Company's stock until final Court approval of the settlement, at which time, the value of the shares to be issued will be fixed. The Company also originally recorded a liability for the settlement of litigation of \$23.2 million, which at March 31, 2007, was reduced to \$21.7 million. The liability for the settlement of litigation is included in Accounts payable and accrued expenses and an insurance receivable of \$18.0 million is included in Prepaid expenses and other current assets.

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.

Genta has reached a final agreement with the Federal shareholder derivative plaintiffs to settle the Federal shareholder derivative action. On October 10, 2006, the United States District Court for the District of New Jersey gave preliminary approval to the parties' settlement agreement. On May 7, 2007, the proposed settlement received final approval from the Court. On October 31, 2006, Genta and the defendants entered into a Release and Settlement Agreement with the Company's insurance carrier, pursuant to which the Company's insurance will cover the settlement fee, the costs of notice to shareholders required by the court's preliminary approval order and defense costs incurred in connection with the action. The amount of the proposed settlement is \$200 thousand, which will be covered by the Company's insurance carriers. The Company recorded a liability for the settlement of litigation of \$200 thousand, which is included in Accounts payable and accrued expenses and an insurance receivable of \$200 thousand, which is included in Prepaid expenses and other current assets.

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' motion for reconsideration was denied and they filed a notice of appeal. On December 11, 2006, plaintiffs filed their appellate brief and on January 18, 2007, the Company filed its response. The matter is pending before the appellate court. The Company has continued to deny all of the allegations in all of these proceedings, and their potential settlements do not constitute an admission of guilt or liability.



No interest or income taxes were paid for the three months ended March 31, 2007, and 2006, respectively.

14.

**Subsequent Event**

On May 2, 2007, the Company announced that it had received a notice of delisting from the NASDAQ Global Market because the closing bid price of the Company's common stock is not in compliance with the \$1.00 minimum closing bid price requirement, as set forth in Marketplace Rule 4450(a)(5). Subsequently, the Board of Directors unanimously approved a proposal that authorized the Board to effect a reverse stock split of all outstanding shares of the Company's Common Stock, at a ratio of either 1-for-2, 1-for-3, 1-for-4, 1-for-5 or 1-for-6. This proposal will be submitted to shareholders for their approval at the Company's annual meeting of shareholders on July 11, 2007.

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**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. We intend 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 our 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:

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the Company's financial projections;

- the Company's projected cash flow requirements and estimated timing of sufficient cash flow;
- the Company's current and future license agreements, collaboration agreements, and other strategic alliances;
- 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 (EMA);
- the safety and efficacy of the Company's products;
- the commencement and completion of clinical trials;
- the Company's ability to develop, manufacture and sell its products;
- the adequacy of the Company's capital resources and the Company's ability to obtain sufficient financing to maintain the Company's planned operations;
- the adequacy of the Company's patents and proprietary rights;
- the impact of litigation that has been brought against the Company and its officers and directors and any proposed settlement of such litigation;
- the Company's ability to regain compliance with NASDAQ's listing qualifications; and
- the other risks described under Risk Factors in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and in this Form 10-Q.

We do 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. We are dedicated to the identification, development and commercialization of novel drugs for the treatment of cancer and related diseases. We have had recurring annual operating losses since 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 the eventual establishment of a sales and marketing organization. From our inception to March 31, 2007, we have incurred a cumulative net loss of \$420.6 million. We expect that such losses will continue at least until our lead product, Genasense<sup>®</sup>, receives approval from the FDA or EMEA for commercial sale in one or more indications. Achievement of profitability is currently dependent on the timing of Genasense<sup>®</sup> regulatory approvals. We have experienced significant quarterly fluctuations in operating results and we expect that these fluctuations in revenues, expenses and losses will continue.

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We had \$29.4 million of cash, cash equivalents and marketable securities on hand at March 31, 2007. In March 2007, we sold 30.0 million shares of our common stock at a price of \$0.36 per share, raising net proceeds of \$10.1 million. Cash used in operating activities during the first three months of 2007, was \$9.8 million.

Irrespective of whether a New Drug Application (NDA) or Marketing Authorization Application (MAA) for Genasense<sup>®</sup> are approved, we anticipate that we will require additional cash in order to maximize the commercial opportunity and continue its clinical development opportunities. Alternatives available to us to sustain our operations include collaborative agreements, equity financing and other financing arrangements with potential corporate partners and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available on favorable terms, if at all. We will need substantial additional funds before we can expect to realize significant product revenue.

We will maintain an appropriate level of spending over the upcoming fiscal year, given the uncertainties inherent in our business and our current liquidity position. We believe that at the current rate of spending, we should have sufficient cash funds to maintain our present operations into the second quarter of 2008.

On March 7, 2007, we announced that we had entered into a Supply and Distribution Agreement with IDIS Limited (a privately owned company based in the United Kingdom) whereby IDIS will distribute Ganite<sup>®</sup> and Genasense<sup>®</sup> on a named patient basis. The global agreement covers territories outside the United States. Named patient distribution refers to the distribution or sale of a product to a specific healthcare professional for the treatment of an individual patient. IDIS will manage the named patient programs for us.

The agreement provides that we will supply the two products to IDIS on a consignment basis. We will be paid after sales are made by IDIS, which payment shall be based off of a monthly sales report received from IDIS. We will invoice IDIS based upon this monthly report, which invoice shall be calculated based upon a price minus a fee credited to IDIS. The agreement also provides for distribution by IDIS of a limited amount of drug product free of charge to indigent patients. We intend that a percentage of proceeds from the named patient program will be used to support the compassionate use program. We have agreed to pay a nominal one-time start-up fee for this program to IDIS and to pay IDIS a termination fee in the event it terminates either or both products within the first three years.

Our financial results in 2007 have been and will continue to be significantly affected by FDA and EMEA actions with respect to Genasense<sup>®</sup>.

In melanoma, we submitted a NDA to the FDA in 2003 for the use of Genasense<sup>®</sup> plus chemotherapy in patients with advanced melanoma. In May 2004, a majority of the Oncologic Drugs Advisory Committee (ODAC) failed to recommend approval of our NDA. As a consequence, we withdrew the NDA, which allows us to potentially resubmit the application. In 2005, we presented updated data from this trial, which show statistically significant increases in overall response, complete response, durable response and progression-free survival. An independent review of the X-rays confirmed the previously reported major responses with high concordance. An increase in overall survival by intent-to-treat analysis, which was the study's primary endpoint, approached but did not reach statistical significance (P=0.077). Our analysis identified a statistically significant treatment interaction for blood levels of an enzyme known as LDH, which was a prospectively specified component of stratification. When this effect was analyzed by treatment arm, survival was shown to be significantly superior for patients with a non-elevated LDH who received Genasense<sup>®</sup> (P=0.018; n=508). Safety and efficacy data from this trial were published in a scientific journal in October 2006.

On April 27, 2007, we announced that we will file a formal complaint and request for correction of information with the FDA under the Federal Data Quality Act. The complaint will challenge as erroneous a key statistical analysis of our data on Genasense<sup>®</sup> for melanoma used by FDA at the ODAC meeting on May 3, 2004. That analysis sought to discredit the finding that Genasense<sup>®</sup> yielded a statistically significant increase in progression-free survival ( PFS ). At that meeting, ODAC voted unanimously that PFS was an endpoint that would support full approval in the absence of a survival improvement in patients with advanced melanoma. We will seek a formal public acknowledgement of the error, removal of the analysis from the FDA website (with a note that the previous analysis was in error), and revision of the transcript.

On January 3, 2006, we announced that we had completed a 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 April 27, 2007, we announced that we had been informed that the Committee for Medicinal Products for Human Use ( CHMP ) of the EMEA had issued a negative opinion on the MAA. The EMEA has a formal process whereby the sponsor of a MAA may request re-examination of the initial CHMP opinion, including a review by a specialist Oncology Scientific Advisory Group ( SAG ). We announced on April 27, 2007 that we would seek re-examination of the MAA.

On April 18, 2007, we announced that we will conduct a new randomized controlled Phase 3 trial of Genasense® in patients with advanced melanoma. We have sought scientific advice on final aspects of the trial design from regulatory authorities in Europe and the United States. We are actively recruiting experienced investigative sites in Europe, Australia, and North and South America, and expect to initiate patient enrollment during the summer of 2007.

The trial is designed to expand evidence for the safety and efficacy of Genasense® combined with dacarbazine for patients who have not previously been treated with chemotherapy. The study will prospectively target patients using a biomarker that identified patients who derived maximal benefit in a preceding trial of Genasense®, including significant increases in overall and progression-free survival. We expect to enroll approximately 300 subjects in this trial. Genasense® in melanoma has been designated an Orphan Drug in Australia and the United States, and the drug has Fast Track designation in the United States.

In chronic lymphocytic leukemia (CLL), we conducted a Phase 3 trial in 241 patients with relapsed or refractory disease who were treated with fludarabine and cyclophosphamide (Flu/Cy) with or without Genasense®. The trial achieved its primary endpoint: a statistically significant increase in the proportion of patients who achieved a complete or nodular partial response (CR/nPR), (17% vs. 7%; P=0.025). Patients who achieved this level of response experienced disappearance of predefined disease symptoms, including fever, night sweats, fatigue, abdominal discomfort due to an enlarged spleen and impaired mobility due to swollen lymph nodes. A key secondary endpoint, duration of CR/nPR, was also significantly longer for patients treated with Genasense®, (median not reached but exceeding 36+ months in the Genasense® group, versus 22 months in the chemotherapy-only group).

Several secondary endpoints were not improved by the addition of Genasense® including overall response rate (i.e., the percentage of patients who achieved CR/nPR plus partial response), time-to-disease progression or overall survival. 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, 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 had previously received fludarabine. Genasense® had previously received Fast Track designation in CLL, meaning that the indication represented an unmet medical need, as well as designation as an Orphan Drug, by the FDA.

On September 6, 2006, the ODAC voted seven to three not to recommend approval of Genasense® and on December 15, 2006, we received a non-approvable notice from the FDA. The Company believes that its application met the regulatory requirements for approval and on April 4, 2007, announced that it had filed a formal appeal of this non-approvable notice. The appeal was filed pursuant to the FDA's Formal Dispute Resolution process that exists within FDA's Center for Drug Evaluation and Research (CDER). Responses for CDER appeals are typically made within 30 to 60 days. In seeking reconsideration, the appeal reflects several views:

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Complete response confers clinical benefit in CLL. By definition, a complete response requires elimination of all evident disease, normalization of blood counts, and resolution of specific disease-related symptoms.

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Complete responses - the primary endpoint of the Genasense® trial - were more than doubled if the chemotherapy regimen included Genasense® compared to chemotherapy used alone - an increase that was statistically significant.

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The median duration of complete response exceeded 3 years, at least 50% longer, if the chemotherapy regimen included Genasense® - a clinically meaningful and statistically significant increase in a prospectively specified secondary endpoint.

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The Genasense® study is the only randomized controlled trial ever conducted in this population.

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The number, type, and severity of adverse reactions encountered with Genasense® were comparable to other leukemia drugs, and these reactions are managed by specialists.

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. On December 8, 2006, we announced that we had been notified that preliminary results from a randomized Phase 3 trial of chemotherapy with or without Genasense® in patients with acute myeloid leukemia, (AML), suggested the study was unlikely to meet its primary endpoint. On February 23, 2007, we announced that preliminary results from a randomized Phase 2 study of Genasense® plus chemotherapy in patients with advanced prostate cancer showed no between-group difference in prostate-specific antigen. While follow-up and analyses of the AML and prostate trials are continuing, we do not believe any of these trials will

support regulatory approval of Genasense® in these indications.

We have completed accrual into a randomized Phase 2 trial of chemotherapy with or without Genasense® in previously treated patients with non-small cell lung cancer. We expect that the data from this trial will be available in 2007. 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.

On October 13, 2006, we announced the initiation of a Phase 1 clinical trial using a new anticancer drug derived from our DNA/RNA Medicines program. The new compound (G4460) uses antisense technology to target a proto-oncogene known as *c-myb* that regulates key functions in cancer cells. Using an accelerated dosing schedule, this study will evaluate dosing regimens, safety, biologic activity, and down-regulation of *c-myb* in patients with advanced hematologic cancers. The clinical trial is being conducted at the University of Pennsylvania. G4460 has been granted Orphan Drug Designation by the FDA for treatment of patients with chronic myelocytic leukemia (CML).

## Results of Operations

(\$ thousands)	Summary Operating Results For the three months ended March 31,			
	2007	2006	Increase (Decrease)	
			\$	%
Product sales net	\$ 94	\$ 67	\$ 27	41%
Cost of goods sold	22	16	6	38%
Gross margin	72	51	21	42%
Operating expenses:				
Research and development	3,383	4,750	(1,367)	(29%)
Selling, general and administrative	4,052	5,456	(1,404)	(26%)
Provision for settlement of litigation, net	(1,560)	—	(1,560)	(100%)
Total operating expenses	5,875	10,206	(4,331)	(43%)
Other income, net	198	260	(62)	(24%)
Net loss	\$ (5,605)	\$ (9,895)	4,290	44%

### Total revenues

Product sales-net of Ganite® increased to \$94 thousand for the three months ended March 31, 2007 compared with \$67 thousand for the three months ended March 31, 2006, partly due to a price increase initiated in November 2006.

### Cost of goods sold

There was a higher cost of goods sold in the three months ended March 31, 2007 than in the three months ended March 31, 2006 as a result of higher product sales.

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#### Research and development expenses

Research and development expenses were \$3.4 million for the three months ended March 31, 2007 compared to \$4.8 million for the three months ended March 31, 2006. The first quarter of 2006 included higher manufacturing and other expenses incurred in preparation for the possible commercial launch of Genasense® and expenses related to regulatory review. The decline in expenses in 2007 reflects the comparison to this higher level of expenses in 2006 as well as the impact of a staff reduction in December 2006, which was implemented after the FDA's non-approval of our NDA for Genasense® in CLL.

Research and development expenses incurred on the Genasense® project during the three months ended March 31, 2007 were approximately \$2.7 million, representing 84% of research and development expenses (before share-based compensation expense, see Note 9 to our Consolidated Financial Statements).

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are 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 \$4.1 million for the three months ended March 31, 2007 compared to \$5.5 million for the three months ended March 31, 2006. The first quarter of 2006 included a buildup of sales and marketing expenses incurred in preparation for a possible commercial launch of Genasense®. The decline in expenses in 2007 reflects the comparison to this higher level of expenses in 2006 as well as the impact of the December 2006 staff reduction.

#### Provision for settlement of litigation, net

In the fourth quarter of 2006, we recorded an expense of \$5.3 million that provides for the issuance of 12.0 million shares of Genta common stock, for a settlement in principle of class action litigation. The expense is net of insurance



recovery of \$18.0 million. At March 31, 2007, the revised estimated value of the common shares portion of the litigation settlement is \$3.7 million, based on a closing price of Genta's common stock of \$0.31 per share, resulting in a reduction in the provision of \$1.6 million, recognized in the first quarter of 2007.

Other income, net

Other income, net of \$0.2 million for the three months ended March 2007 declined from \$0.3 million for the prior-year period, primarily due to interest expense resulting from a State of New Jersey income tax audit.

In January 2006 the State of New Jersey concluded its fieldwork with respect to a tax audit for the years 2000 through 2004. The State of New Jersey took the position that amounts reimbursed to us by Aventis Pharmaceutical Inc. for co-development expenditures during the audit period were subject to Alternative Minimum Tax (AMA), resulting in a liability at that time of approximately \$533 thousand. Although we and our outside tax advisors believe the State of New Jersey's position on the AMA liability is unjustified, there is little, if any, case law on the matter and it is probable that we will be required to pay the liability. In March 2007, we received a formal assessment from the State of New Jersey for \$712 thousand. We will appeal this assessment during 2007.

Net loss

Genta incurred a net loss of \$5.6 million, or \$0.04 per share for the three months ended March 31, 2007 and \$9.9 million, or \$0.08 per share, for the three months ended March 31, 2006.

The lower net loss in 2007 is primarily due to a comparison with a prior-year period that reflected a buildup of sales, marketing and manufacturing expenses incurred in anticipation of a possible commercial launch of Genasense®. In addition, results in 2007 reflect the staff reduction in December 2006 and include a benefit of \$1.6 million due to a reduction in the provision for settlement of litigation.

**Liquidity and Capital Resources**

At March 31, 2007, we had cash, cash equivalents and marketable securities totaling \$29.4 million compared with \$29.5 million at December 31, 2006. During the first three months of 2007, cash used in operating activities was \$9.8 million compared with \$11.5 million for the same period in 2006. The prior period reflects higher spending in

anticipation of a potential commercial launch of Genasense®.

In March 2007, we sold 30.0 million shares of our common stock at a price of \$0.36 per share, raising net proceeds of \$10.1 million.

On May 2, 2007, we announced that we had received a notice of delisting from the NASDAQ Global Market because the closing bid price of our common stock is not in compliance with the \$1.00 minimum closing bid price requirement, as set forth in NASDAQ Marketplace Rule 4450(a)(5). Subsequently, our Board of Directors unanimously approved a proposal that authorized our Board to effect a reverse stock split of all outstanding shares of our common stock, at a ratio of either 1-for-2, 1-for-3, 1-for-4, 1-for-5 or 1-for-6. This proposal will be submitted to shareholders for their approval at our annual meeting of shareholders on July 11, 2007.

During 2006, we issued notes payable to finance premiums for our corporate insurance policies of \$1.2 million at interest rates running from 5.4% to 5.6%. Payments were scheduled over seven equal monthly installments for the notes initiated in 2006. The remaining balance on the notes payable was \$0.3 million at March 31, 2007. We will attempt to finance our insurance premiums in 2007.

Irrespective of whether an NDA or MAA for Genasense® are approved, we will require additional cash in order to maximize this commercial opportunity and to continue its clinical development opportunities. We have had discussions with other companies regarding partnerships for the further development and global commercialization of Genasense®. Additional alternatives available to us to sustain our operations include financing arrangements with potential corporate partners, debt financing, asset-based loans, royalty-based financing, equity financing, profits from named-patient sales, and other potential sources of financing. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available to us on favorable terms, if at all.

We will maintain an appropriate level of spending over the upcoming fiscal year, given the uncertainties inherent in our business and our current liquidity position. Management believes that at the current rate of spending, we should have sufficient cash funds to maintain our present operation into the second quarter of 2008.

We anticipate seeking additional product development opportunities through potential acquisitions or investments. Such acquisitions or investments may consume cash reserves or require additional cash or equity. Our working capital and additional funding requirements will depend upon numerous factors, including: (i) the progress of our research and development programs; (ii) the timing and results of pre-clinical testing and clinical trials; (iii) the level of resources that we devote to sales and marketing capabilities; (iv) technological advances; (v) the activities of competitors; (vi) our ability to establish and maintain collaborative arrangements with others to fund certain research and development efforts, to conduct clinical trials, to obtain regulatory approvals and, if such approvals are obtained, to manufacture and market products and (vii) legal costs and the outcome of outstanding legal proceedings.

## Recent Accounting Pronouncements

In February 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No. 159 permits all entities to choose to elect, at specified election dates, to measure eligible financial instruments at fair value. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date and recognize upfront costs and fees related to those items in earnings as incurred and not deferred. SFAS No. 159 applies to fiscal years beginning after November 15, 2007, with early adoption permitted for an entity that has also elected to apply the provisions of SFAS No. 157, *Fair Value Measurements*. We are currently evaluating the impact, if any, the adoption of SFAS No. 159 may have on our financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States of America and expands disclosures about fair value measurements. SFAS No. 157 applies under other accounting pronouncements that require or permit fair value measurements. Accordingly, this pronouncement does not require any new fair value measurements. We are required to adopt SFAS No. 157 beginning January 1, 2008. We are currently evaluating the impact, if any, the adoption of SFAS No. 157 may have on our financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes*. FIN 48 prescribes detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. Tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon the adoption of FIN 48 and in subsequent periods. FIN 48 is effective for fiscal years beginning after December 15, 2006 and the provisions of FIN 48 are applied to all tax positions upon initial adoption of the Interpretation. The cumulative effect of applying the provisions of this Interpretation will be reported as an adjustment to the opening balance of retained earnings for that fiscal year. As we have provided a full valuation allowance to reserve for our net deferred tax assets at December 31, 2006, the adoption of this standard did not have a material impact on our results of operations, financial condition, or cash flows.

## Critical Accounting Policies

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements. In preparing our financial statements in accordance with accounting principles generally accepted in the United States of America, management is required to make estimates and assumptions that, among other things, affect the reported amounts of assets and liabilities and reported amounts of revenues and expenses. These estimates are most significant

in connection with our critical accounting policies, namely those of our accounting policies that are most important to the portrayal of our financial condition and results and require management's most difficult, subjective or complex judgments. These judgments often result from the need to make estimates about the effects of matters that are inherently uncertain. Actual results may differ from those estimates under different assumptions or conditions. We believe that the following represents our critical accounting policies:

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*Revenue recognition.* We recognize revenue from product sales when title to product and associated risk of loss has passed to the customer and we are reasonably assured of collecting payment for the sale. All revenue from product sales are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances. We allow return of our product for up to twelve months after product expiration.

Under our Supply and Distribution agreement with IDIS Limited, we will supply Ganite® and Genasense® to IDIS on a consignment basis. We will recognize revenue when IDIS reports that it has delivered product to customers, which is the point in time that title to the product and risk of loss has passed.

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*Research and development costs.* All such costs are expensed as incurred, including raw material costs required to manufacture drugs for clinical trials.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Our carrying values of cash, marketable securities, accounts payable, accrued expenses and debt are a reasonable approximation of their fair value. The estimated fair values of financial instruments have been determined by us using available market information and appropriate valuation methodologies (see Note 2 to our 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.

Our 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, 2007. Therefore, there will be no ongoing exposure to a potential material adverse effect on our business, financial condition or results of operation for sensitivity to changes in interest rates or to changes in currency exchange rates.

**Item 4. Controls and Procedures**

***Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures***

As required by Rule 13a-15(b), Genta'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 effective 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**

**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 Genta and certain of our principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of malignant melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action complaint in the various actions seeks monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. On September 30, 2005, the court granted in part and denied in part our motion to dismiss the plaintiffs' complaint. The court dismissed plaintiffs' claim that the defendants engaged in a scheme or artifice to defraud plaintiffs, but allowed

plaintiffs' claims to proceed with respect to their allegations that defendants issued false and misleading public statements about Genasense®. In non-binding mediation, we have reached an agreement in principle with plaintiffs to settle the class action litigation in consideration for issuance of 12.0 million shares of our common stock and \$18.0 million in cash for the benefit of plaintiffs and the shareholder class. The cash portion of the proposed settlement will be covered by our insurance carriers. We are actively engaged in preparing the written Stipulation and Agreement of Settlement, which will be filed with the Court seeking preliminary approval.

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.

Genta has reached a final agreement with the Federal shareholder derivative plaintiffs to settle the Federal shareholder derivative action. On October 10, 2006, the United States District Court for the District of New Jersey gave preliminary approval to the parties' settlement agreement. On May 7, 2007, the proposed settlement received final approval from the Court. On October 31, 2006, we and the defendants entered into a Release and Settlement Agreement with our insurance carrier, pursuant to which our insurance will cover the settlement fee, the costs of notice to shareholders required by the court's preliminary approval order and defense costs incurred in connection with the action. The amount of the proposed settlement is \$200 thousand, which will be covered by our insurance carriers.

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' motion for reconsideration was denied and they filed a notice of appeal. On December 11, 2006, plaintiffs filed their appellate brief and on January 18, 2007, we filed our response. The matter is pending before the appellate court. We have continued to deny all of the allegations in all of these proceedings, and their potential settlements do not constitute an admission of guilt or liability.

#### **Item 1A. Risk Factors**

*You should carefully consider the following risks and all of the other information set forth in this Form 10-Q and the Form 10-K for the year ended December 31, 2006 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.*

***Risks 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 September 6, 2006, ODAC voted seven to three not to recommend approval of Genasense® for the treatment of patients with relapsed or refractory CLL and on December 15, 2006, we received a non-approvable notice

from the FDA. The Company believes that its application met the regulatory requirements for approval and on April 4, 2007, announced that it had filed a formal appeal for this non-approvable notice. The appeal was filed pursuant to the FDA's Formal Dispute Resolution process that exists within FDA's Center for Drug Evaluation and Research (CDER). Responses for CDER appeals are typically made within 30 to 60 days.

On January 3, 2006, we announced that we had completed a MAA to the EMEA that seeks approval for use of Genasense<sup>®</sup> plus dacarbazine for the treatment of patients with advanced melanoma who have not previously received chemotherapy. 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 were appointed as rapporteur and co-rapporteur countries, respectively. On April 27, 2007, we announced that we had been informed that the Committee for Medicinal Products for Human Use (CHMP) of the EMEA had issued a negative opinion on the MAA. The EMEA has a formal process whereby the sponsor of a MAA may request re-examination of the initial CHMP opinion, including a review by a specialist Oncology Scientific Advisory Group. We announced on April 27, 2007 that we would seek re-examination of the MAA.

On April 27, 2007, we announced that we will file a formal complaint and request for correction of information with the FDA under the Federal Data Quality Act. The complaint will challenge as erroneous a key statistical analysis of our data on Genasense<sup>®</sup> for melanoma used by FDA at the ODAC meeting on May 3, 2004. That analysis sought to discredit the finding that Genasense<sup>®</sup> yielded a statistically significant increase in progression-free survival (PFS). At that meeting, ODAC voted unanimously that PFS was an endpoint that would support full approval in the absence of a survival improvement in patients with advanced melanoma. We will seek a formal public acknowledgement of the error, removal of the analysis from the FDA website (with a note that the previous analysis was in error), and revision of the transcript.

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.

***Our business will suffer if we fail to obtain timely funding.***

Our operations to date have required significant cash expenditures. 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, seek new product candidates and continue our research and development programs, we will need to raise additional funds. In March 2007, we sold 30.0 million shares of the Company's common stock at a price of \$0.36 per share, raising \$10.1 million, net of fees and expenses. Cash used in operating activities during the quarter ended March 31, 2007 was \$9.8 million.

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:

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

We will maintain an appropriate level of spending over the upcoming fiscal year, given the uncertainties inherent in our business and our current liquidity position. We believe that at the current rate of spending, we should have sufficient cash funds to maintain our present operations into the second quarter of 2008.

***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.

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, 2007, we have incurred a cumulative net loss of \$420.6 million. We may never achieve revenue sufficient for us to attain profitability. Achieving profitability is unlikely unless Genasense<sup>®</sup> receives approval from the FDA or EMEA 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<sup>®</sup> and the principal patent covering its use for the approved indication expired in April 2005. If Genasense<sup>®</sup> 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.

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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:

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obtain U.S. and foreign patent or other proprietary protection for our technologies, products and processes;

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preserve trade secrets; and

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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<sup>®</sup> for its approved indication, including Hatch-Waxman extensions, expired 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:

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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. On December 8, 2006, we announced that we had been notified that preliminary results from a randomized Phase 3 trial of chemotherapy with or without Genasense® in patients with AML suggested the study was unlikely to meet its primary endpoint. On February 23, 2007, we announced that preliminary results from a randomized Phase 2 study of Genasense® plus chemotherapy in patients with advanced prostate cancer showed no between-group difference in prostate-specific antigen. While follow-up