

GENTA INC DE/  
Form 10-Q  
November 07, 2007

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**(Mark One)**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d)**

**OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 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

**GENTA INCORPORATED**

**(Exact name of Registrant as specified in its charter)**

Delaware

33-0326866

**(State or other jurisdiction of**

**(I.R.S. Employer**

**incorporation or organization)**

**Identification Number)**

200 Connell Drive

Berkeley Heights, NJ

07922

**(Address of principal executive offices)**

**(Zip Code)**

(908) 286-9800

**(Registrant's telephone number, including area code)**

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

Yes  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

Yes  No

As of October 31, 2007, the registrant had 30,620,558 shares of common stock outstanding.

**Genta Incorporated**

**INDEX TO FORM 10-Q**

Page

**PART I.**

**FINANCIAL INFORMATION**

Item 1.

Consolidated Financial Statements (unaudited):

Consolidated Balance Sheets at September 30, 2007 and December 31, 2006

3

Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2007 and 2006

4

Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2007 and 2006

5

Notes to Consolidated Financial Statements

6

Item 2.

Management's Discussion and Analysis of Financial Condition and Results of Operations

18

Item 3.

Quantitative and Qualitative Disclosures about Market Risk

26

Item 4.

Controls and Procedures

27

**PART II.**

**OTHER INFORMATION**

Item 1.

Legal Proceedings

28

Item 1A.

Risk Factors

29

Item 2.

Unregistered Sales of Equity Securities and Use of Proceeds

42

Item 3.

Defaults Upon Senior Securities

42

Item 4.

Submission of Matters to a Vote of Security Holders

42

Item 5.

Other Information

42

Item 6.

Exhibits

43

**SIGNATURES**

44

**CERTIFICATIONS**

46

2

---

**GENTA INCORPORATED**

**CONSOLIDATED BALANCE SHEETS**

**(Unaudited)**

(In thousands, except par value data)

**September 30, 2007**

**December 31, 2006**

**ASSETS**

Current assets:



Cash and cash equivalents

\$

4,571

\$

9,554

Marketable securities (Note 4)

10,972

19,942

Accounts receivable - net of allowances of \$40 at September 30, 2007 and \$42 at December 31, 2006, respectively

23

17

Inventory (Note 6)

239

308

Prepaid expenses and other current assets (Note 7)

18,561

19,997

Total current assets

34,366

49,818

Property and equipment, net (Note 8)

164

271

Other assets

1,720

1,689

Total assets

\$

36,250

\$

51,778

LIABILITIES AND STOCKHOLDERS EQUITY

Current liabilities:

Accounts payable and accrued expenses (Note 7)

\$

31,728

\$

36,494

Notes payable (Note 9)

139

642

Total current liabilities

31,867

37,136

Commitments and contingencies (Note 7 and Note 14)

Stockholders' equity (Note 10):

Preferred stock, 5,000 shares authorized:

Series A convertible preferred stock, \$.001 par value; 8 shares issued and outstanding, liquidation value of \$385 at September 30, 2007 and December 31, 2006, respectively

Series G participating cumulative preferred stock, \$.001 par value; 0 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively

Common stock, \$.001 par value; 250,000 shares authorized, 30,621 and 25,621 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively

31

26

Additional paid-in capital

440,671

429,425

Accumulated deficit

(436,386

)

(414,840

)

Accumulated other comprehensive income

67

31

Total stockholders' equity

4,383

14,642

Total liabilities and stockholders' equity

\$

36,250

\$

51,778



See accompanying notes to consolidated financial statements.

3

---



**GENTA INCORPORATED**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**(Unaudited)**

**Three Months Ended September 30,**

**Nine Months Ended September 30,**

(In thousands, except per share data)

**2007**

**2006**

**2007**

**2006**

Product sales - net

\$

115

\$

145

\$

314

\$

591

Cost of goods sold

20

41

68

79

Gross margin

95

104

246

512

Operating expenses:

Research and development

4,763

8,514

12,244

21,900

Selling, general and administrative

4,083

6,939

12,870

19,112

Reduction in liability for settlement of litigation, net (Note 7)

(800

)

(2,600

)

Total operating expenses

8,046

15,453

22,514

41,012

Other income/(expense):

Gain on maturity of marketable securities

49

124



93

245

Interest income and other income, net

195

303

738

829

Interest expense

(25

)

(18

)

(134

)

(51

)

Total other income/(expense), net

219

409

697

1,023

Net loss

\$

(7,732

)

\$

(14,940

)

\$

(21,571

)

\$

(39,477

)

Net loss per basic and diluted share

\$

(0.25

)

\$

(0.66

)

\$

(0.74

)

\$

(1.83

)

Shares used in computing net loss per basic and diluted share

30,621

22,598

29,284

21,519

See accompanying notes to consolidated financial statements.

4

---



**GENTA INCORPORATED**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(Unaudited)**

**Nine Months Ended September 30,**

(In thousands)

**2007**

**2006**

**Operating activities:**

Net loss

\$

(21,571

)

\$

(39,477

)

Adjustments to reconcile net loss to net cash used in operating activities:

Depreciation and amortization

117

843

Share-based compensation (Note 11)

1,187

2,298

Provision for sales returns

(300

)

Gain on maturity of marketable securities

(94

)

(245

)

Reduction in liability for settlement of litigation, net (Note 7)

(2,600

)



Changes in operating assets and liabilities:

Accounts receivable

(6  
)

22

Inventory

69

79

Prepaid expenses and other current assets

1,235

820

Accounts payable and accrued expenses

(1,966

)

2,433

Other assets

(31

)

(21

)

Net cash used in operating activities

(23,660

)

(33,548

)

**Investing activities:**

Purchases of marketable securities

(13,900

)

(34,880

)

Maturities of marketable securities

23,000

35,716

Purchases of property and equipment

(10

)

(83

)

Net cash provided by investing activities

9,090

753

**Financing activities:**

Repayments of note payable

(739

)

(886

)

Issuance of note payable

236

275

Issuance of common stock, net (Note 10)

10,090

52,691

Issuance of common stock upon exercise of options

155

Net cash provided by financing activities

9,587

52,235

Decrease in cash and cash equivalents

(4,983

)

19,440

Cash and cash equivalents at beginning of period

9,554

9,314

Cash and cash equivalents at end of period

\$

4,571

\$

28,754

See accompanying notes to consolidated financial statements.

5

---

## **GENTA INCORPORATED**

### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2007**

**(Unaudited)**

**1.**

#### **Reverse Stock Split**

At the Annual Meeting of Genta Incorporated ( Genta or the Company ) on July 11, 2007, the Company s shareholders authorized its Board of Directors to effect a reverse stock split of all outstanding shares of common stock, and the Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of one for six shares, which became effective on July 13, 2007. All share and per share data in these consolidated financial statements and related notes hereto have been retroactively adjusted to account for the effect of the reverse stock split for all periods presented.

**2.**

#### **Organization and Business**

Genta Incorporated 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 \$15.5 million of cash, cash equivalents and marketable securities on hand at September 30, 2007. On March 14, 2007, the Company sold 5.0 million shares of its common stock at a price of \$2.16 per share, raising net proceeds of \$10.1 million. Net cash used in operating activities during the nine months ended September 30, 2007 was \$23.7 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 ). On June 18, 2007, the Company announced that the initial appeal was denied and that it would further appeal the decision to the next level within CDER. On October 25, 2007, the Company announced that it had completed the filing of the Company s formal appeal to CDER. Responses to CDER appeals are typically made within 30 to 60 days.



The Company submitted a Marketing Authorization Application ( MAA ) to 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 and the Company indicated that it would seek re-examination of the MAA. On July 19, 2007, the Company announced that it had received notice from the EMEA that the requested re-examination reaffirmed the negative opinion for approval of the Company s MAA for Genasense®. No further action on this MAA is contemplated by the Company.



On April 27, 2007, the Company announced that it would file a formal complaint and request for correction of information with the FDA under the Federal Data Quality Act. As submitted, the complaint challenges as erroneous a key statistical analysis of the Company's data on Genasense® 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® 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 seeks 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. The Company was advised in October 2007 that FDA has elected to extend its review period on this matter for an additional 60 days.

Irrespective of whether the pending NDA for Genasense® is approved, the Company will require additional cash in order to maximize this commercial opportunity and to continue its clinical development opportunities. The Company has undertaken discussions with other companies regarding partnerships for the further development and global commercialization of Genasense®. 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, asset 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. The Company will need substantial additional funds before it can expect to realize significant product revenue.

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. Earlier in the year, Management projected that a smaller workforce and concentrated effort on the development of Genasense® would result in the Company having sufficient funds to maintain its operations into the second quarter of 2008. Presently, without taking into account any further financings, Management projects that the Company should have sufficient cash funds to maintain its present operations into the first quarter of 2008. The current projection is primarily based on additional months of actual expenditures and no reduction to its workforce.

In March 2007, the Company announced that it had entered into a Supply and Distribution Agreement (the 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 first sale under this program occurred during the three-month period ended September 30, 2007.



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 will pay IDIS a termination fee in the event it terminates either or both products within the first three years of the Agreement.

3.

### **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 September 30, 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 ( SEC ). 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. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the condensed consolidated balance sheet as of September 30, 2007 and the results of operations and cash flows for the periods ended September 30, 2007 and 2006 have been made. 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.

#### *Revenue Recognition*

The Company 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, the Company will supply Ganite® and Genasense® to IDIS on a consignment basis. The Company recognizes 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. The first sale under this program of \$23 thousand occurred during the three-month period ended September 30, 2007.

#### *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 nine months ended September 30, 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. 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 returns have 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 Assessment (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 September 30, 2007, the Company had accrued a tax liability of \$533 thousand, penalties of \$27 thousand and interest of \$196 thousand related to this assessment. The Company is in the process of appealing this assessment.

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 was 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 Company's Consolidated Statements of Operations. The Company recorded \$118 thousand and \$49 thousand in interest expense related to the State of New Jersey assessment during the nine months ended September 30, 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 did not restate results for prior periods. Under SFAS 123R, 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 11 and Note 12 to the Consolidated Financial Statements for a further discussion on share-based compensation.

### *Net Loss Per Common Share*

Net loss per common share for the three and nine months ended September 30, 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 2.2 million shares on September 30, 2007 and 2006, respectively, reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants.

### **Recent Accounting Pronouncements**

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, which is effective for calendar year companies on January 1, 2008. The Task Force concluded that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. The Company is currently assessing the potential impacts of implementing this standard.

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 does not expect that adoption of this standard will have a material impact on its 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. The Company is required to adopt SFAS No. 157 beginning January 1, 2008. The Company does not expect that adoption of this standard will have a material impact on its financial statements.





4.

**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):

**September 30,  
2007**

**December 31,  
2006**

Cost

\$

10,905

\$

19,911

Gross unrealized gains

67

31

Gross unrealized losses

Fair value

\$

10,972

\$

19,942



The fair value of each marketable security has been compared to its cost and therefore, an unrealized gain of \$67 thousand and \$31 thousand has been recognized in accumulated other comprehensive income in the Company's Consolidated Balance Sheets at September 30, 2007 and December 31, 2006, respectively.

**5.**

**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. At that time, 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 for the year ended 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 and was completed by June 30, 2007.

**6.**

**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):

**September 30,  
2007**

**December 31,  
2006**

Raw materials

\$

24

\$

24

Work in process

93

94

Finished goods

122

190

\$

239

\$

308

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



7.

**Reduction in Liability for Legal Settlement**

The Company reached an agreement to settle a class action litigation in consideration for issuance of 2.0 million shares of common stock of the Company (adjusted for any subsequent event that results in a change in the number of shares outstanding as of January 31, 2007) and \$18.0 million in cash for the benefit of plaintiffs and the shareholder class, (see Note 14 to the Consolidated Financial Statements). The cash portion of the proposed settlement will be covered by the Company's insurance carriers. Effective June 25, 2007, the Company and plaintiffs executed a written Stipulation and Agreement of Settlement, which was filed with the United States District Court for the District of New Jersey, or the Court, on August 13, 2007, seeking preliminary approval. The Company has also entered into release and settlement agreements with its insurance carriers, pursuant to which insurance will cover the settlement fee and various costs incurred in connection with the action. 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, comprised of 2.0 million shares of the Company's common stock valued at a market price of \$2.64 on December 31, 2006. At September 30, 2007, the revised estimated value of the common shares portion of the litigation settlement is \$2.7 million, based on a closing price of Genta's common stock of \$1.34 per share as of September 30, 2007, resulting in a reduction in the provision of \$2.6 million recognized in the nine months ended September 30, 2007. The amount of the liability will continue to be adjusted based on the market price of the Company's stock until final approval of the settlement by the Court, at which time the value of the shares to be issued will be fixed. The liability for the settlement of litigation, originally recorded at \$23.2 million at December 31, 2006, is measured at \$20.7 million at September 30, 2007 and is included in accounts payable and accrued expenses in the Company's Consolidated Balance Sheets. An insurance receivable of \$18.0 million is included in prepaid expenses and other current assets in the Company's Consolidated Balance Sheets.

8.

**Property and Equipment, Net**

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

**Estimated  
Useful Lives**

**September 30,  
2007**

**December 31,  
2006**

Computer equipment

3

\$

2,763

\$

2,950

Software

3

3,090

3,406

Furniture and fixtures

5

936

936

Leasehold improvements

3-7

420

410

Equipment

5

182

182

7,391

7,884

Less accumulated depreciation and amortization



(7,227

)

(7,613

)

Property and equipment, net

\$

164

\$

271

**9.**

**Notes Payable**

The Company issued notes payable to finance premiums for its corporate insurance policies during the nine months ended September 30, 2007 of \$0.2 million at an interest rate of 5.9%, during 2006 of \$1.2 million at interest rates running from 5.4% to 5.6% and during 2005 of \$1.3 million at interest rates running from 4.6% to 5.7%. Payments were scheduled over ten monthly installments for the notes initiated in fiscal 2007, seven equal monthly installments for the notes initiated in fiscal 2006 and for seven or eight equal monthly installments for the notes initiated in 2005.

**10.**

**Stockholders Equity**

*Common Stock*

In March 2007, the Company sold 5.0 million shares of the Company's common stock at a price of \$2.16 per share, raising \$10.1 million, net of fees and expenses.

12

---



*Series A Preferred Stock*

Each share of Series A Preferred Stock is immediately convertible into shares of the Company's common stock, at a rate determined by dividing the aggregate liquidation preference of the Series A Preferred Stock by the conversion price. The conversion price is subject to adjustment for antidilution. As of September 30, 2007 and December 31, 2006, each share of Series A Preferred Stock was convertible into 2.3469 and 1.9969 shares of common stock, respectively. At September 30, 2007 and December 31, 2006, the Company had 7,700 shares of Series A Convertible Preferred Stock issued and outstanding.

*Common Stock Reserved*

At September 30, 2007, the Company had 30.6 million shares of common stock outstanding, 2.2 million additional shares reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants and 0.8 million additional shares of common stock authorized for issuance and remaining to be granted under the Company's Non-Employee Directors' 1998 Stock Option Plan, as amended and restated and 1998 Stock Incentive Plan, as amended and restated. In addition, the Company has reserved 8.5 million shares and granted 5.4 million options under the 2007 Stock Option Plan, subject to shareholder approval, (see Note 12 to the Consolidated Financial Statements).

**11.**

**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 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 nine months ended September 30, 2007 and 2006, respectively:

**Nine Months Ended  
September 30,**

**2007**

**2006**

Expected volatility

102

%

97

%

Expected dividends

Expected term (in years)

6.25

6.25

Risk-free rate

4.6

%

4.6

%

13

---



The share-based compensation expense recognized for the three and nine months ended September 30, 2007 and 2006, respectively, was comprised as follows:

**Three months ended  
September 30**

**Nine months ended  
September 30**

**(\$ thousands, except per share data)**

**2007**

**2006**

**2007**

**2006**

Research and development expenses

\$

95



\$

342

\$

446

\$

740

Selling, general and administrative

163

513

740

1,558

Total share-based compensation expense

\$

258

\$

855

\$

1,186

\$

2,298

Share-based compensation expense, per basic and diluted common share

\$

0.01

\$

0.04

\$

0.04

\$

0.11

12.

### **Stock Option Plans**

As of September 30, 2007, the Company has three share-based compensation plans, which are described below:

#### *2007 Stock Incentive Plan*

On September 17, 2007, the Company's Board of Directors approved the Company's 2007 Stock Incentive Plan pursuant to which 8.5 million shares of the Company's common stock will be authorized for issuance, subject to approval of the Company's shareholders. Awards may be made under the plan to officers, employees, directors and consultants in the form of incentive stock options, non-qualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards. Awards granted under the plan prior to shareholder approval of the plan are subject to and conditioned upon receipt of such approval on or before September 17, 2008. Should such shareholder approval not be obtained on or before such date, the plan will terminate and any awards granted pursuant to the plan will terminate and cease to be outstanding.

On September 17, 2007 and September 20, 2007, the Board of Directors approved the issuance of a combined total of 5.4 million options under the 2007 Stock Option Plan. The Company has not recognized compensation expense for these grants, because a grant date as defined in SFAS 123R has not occurred. This is because the grant of these options is contingent upon shareholder approval, which cannot be assured.

#### *Acquisition Bonus Program*

On September 17, 2007, the Board of Directors approved an Acquisition Bonus Program. Under the program, participants are eligible to share in a portion of the proceeds realized from a change in control of the Company that occurs prior to the earlier of (i) December 31, 2008 or (ii) the approval by the Company's shareholders of the 2007 Stock Incentive Plan.

Pursuant to the program, participants selected by the Board of Directors will be awarded a number of units with a designated base value. The amount of a participant's bonus award will be determined by multiplying (i) the difference between the unit value and the base value by (ii) the number of units awarded to such participant. The unit value for each unit will be determined by dividing the change in control proceeds (as defined in the award agreement) by the total number of shares of the Company's common stock outstanding at the time of the change in control. The units will be subject to a vesting schedule, if any, determined by the Board of Directors at the time the unit award is made. Bonus awards will generally be paid in cash within 30 days after the later of (i) the effective date of the change in control or (ii) the date the change in control proceeds are paid to the Company's shareholders. The maximum number of units that may be awarded under the Acquisition Bonus Program is 8.5 million units, which equals the number of shares of the Company's common stock that are authorized for issuance under the Company's 2007 Stock Incentive Plan. On September 27, 2007, 5.4 million acquisition bonus units were granted under the Acquisition Bonus Program.

Any stock options granted to a participant under the 2007 Stock Incentive Plan will terminate and cease to be outstanding in the event the participant becomes entitled to receive a payment under the Acquisition Bonus Program.





*1998 Stock Incentive Plan*

Pursuant to the Company's 1998 Stock Incentive Plan, as amended and restated (the "1998 Plan"), 3.4 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 stock option activity under the 1998 Plan as of September 30, 2007 and changes during the nine months 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

1,936

\$26.22

Granted

121

2.45

Exercised

Forfeited or expired

90

16.01

Outstanding at September 30, 2007

1,967



\$25.59

4.9

\$13

Vested and expected to vest at September 30, 2007

1,180

\$25.59

4.9

\$13

Exercisable at September 30, 2007

1,298

\$24.36

3.5

\$13

The intrinsic value to all outstanding stock options is \$13 thousand as the exercise prices of virtually all outstanding options are above the market price of the Company's stock at September 30, 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 nine months ended September 30, 2007 was \$2.05.

As of September 30, 2007, there was approximately \$1.1 million of total unrecognized compensation cost related to non-vested share-based compensation granted under the 1998 Plan, which is expected to be recognized over a weighted-average period of 1.4 years.

In September 2007, the Company granted 60,000 Restricted Stock Units (RSUs), which contain performance vesting criteria, to a member of senior management. RSUs entitle the holder to receive at the end of a vesting term, a specified number of shares of Genta common stock and are accounted for at fair value at the date of the grant. The fair value of the grant, \$85 thousand, based on a grant date fair value per share of \$1.42, is amortized evenly over the vesting period. This particular grant of 60,000 RSUs vests in two equal tranches of 20,000 shares each upon the completion of one or more financial transactions including, but not limited to, partnerships, asset sales or other transactions that raise working capital for the Company and one tranche of 20,000 shares that vests on July 1, 2008 upon satisfactory provision of certain other financial and accounting services.

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

Pursuant to the Company's 1998 Non-Employee Directors' Plan, as amended and restated (the *Directors' Plan*), 0.6 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.

15





The following table summarizes the stock option activity under the Directors' Plan as of September 30, 2007 and changes during the nine months 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

100

\$37.02

Granted

20

1.80

Exercised

Forfeited or expired

7

40.08

Outstanding at September 30, 2007

113

\$30.61

6.6

\$

Vested and expected to vest at September 30, 2007

68

\$30.61

6.6

\$

Exercisable at September 30, 2007

111

\$31.18

6.6

\$



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 September 30, 2007. The amount of aggregate intrinsic value will change based on the market value of the Company's stock.

**13.**

**Comprehensive Loss**

An analysis of comprehensive loss is presented below:

**Three months ended  
September 30,**

**Nine months ended  
September 30,**

**(\$ in thousands)**

**2007**

**2006**

**2007**

**2006**

Net loss

\$

(7,732

)

\$

(14,940

)

\$

(21,571

)

\$

(39,477

)

Change in market value of available-for-sale marketable securities

47

(42

)

122

(15

)

Total comprehensive loss

\$  
 (7,685  
 )  
 \$  
 (14,982  
 )  
 \$  
 (21,449  
 )  
 \$  
 (39,492  
 )

**14.**

**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, or the Court, 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 were consolidated into a single action and alleged 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 sought monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. The Company reached an agreement with plaintiffs to settle the class action litigation in consideration for the issuance of 2.0 million shares of common stock of the Company (adjusted for any subsequent event that results in a change in the number of shares outstanding as of January 31, 2007) 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. Effective June 25, 2007, the Company and plaintiffs executed a written Stipulation and Agreement of Settlement which was filed with the Court on August 13, 2007, seeking preliminary approval. The unopposed Motion for Preliminary Approval of Settlement was granted on October 30, 2007, and the Settlement Fairness Hearing is scheduled for March 3, 2008.

In addition, two separate shareholder derivative actions were 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 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 covered the \$200 thousand payment for plaintiffs' attorney fees, the costs of notice to shareholders required by the court's preliminary approval order and defense costs incurred in connection with the action and this amount was paid by the Company's insurance carrier during the three months ended June 30, 2007.

The Company has continued to deny all of the allegations in all of these proceedings, and settlement and potential settlement do not constitute an admission of guilt or liability.

Based on facts substantially similar to those asserted in the shareholder class actions, the State derivative plaintiffs claimed that defendants had 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. In view of the settlement of the Federal derivative action, on June 4, 2007, the Company filed a motion to dismiss plaintiffs' appeal. That motion was granted on June 25, 2007.

In February 2007, a complaint against the Company was filed in the Superior Court of New Jersey by Howard H. Fingert, M.D., a former employee of the Company. The complaint alleges, among other things, breach of contract as to the Company's stock option plan and as to a consulting agreement allegedly entered into by the Company and Dr. Fingert subsequent to termination of Dr. Fingert's employment with the Company, breach of implied covenant of good faith and fair dealing with respect to the Company's stock option plan and the alleged consulting agreement, promissory estoppel with respect to the exercise of stock options and provision of consulting services after termination of employment, and fraud and negligent misrepresentation with respect to exercise of stock options and provision of consulting services after termination of employment. The complaint seeks monetary damages, including punitive and consequential damages. The Company filed an answer to the complaint on May 29, 2007, and on August 8, 2007, filed a request for production of documents. The Court has required two hours of mandatory mediation to attempt voluntary resolution of the case and has appointed a mediator. The parties and the mediator are working to set a mutually acceptable mediation date. The Company denies the allegations in the complaint and intends to vigorously defend this lawsuit.

15.

#### **Supplemental Disclosure of Cash Flows Information and Non-cash Investing and Financing Activities**

No interest expense or income taxes were paid for the nine months ended September 30, 2007 and 2006, respectively.



**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:

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 meet the conditions for continued listing on the NASDAQ Global Market; 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.

#### **Reverse Stock Split**

At our Annual Meeting of Stockholders held on July 11, 2007, shareholders authorized our Board of Directors to effect a reverse stock split of all outstanding shares of common stock, and our Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of one for six shares, which became effective on July 13, 2007. All share and per share data in this Form 10-Q have been retroactively adjusted to account for the effect of the reverse stock split for all periods presented.



## 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 September 30, 2007, we have incurred a cumulative net deficit of \$436.4 million. We expect that such losses will continue at least until our lead product, Genasense®, 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® regulatory approvals. We have experienced significant quarterly fluctuations in operating results and we expect that these fluctuations in revenues, expenses and losses will continue.

We had \$15.5 million of cash, cash equivalents and marketable securities on hand at September 30, 2007. In March 2007, we sold 5.0 million shares of our common stock at a price of \$2.16 per share, raising net proceeds of \$10.1 million. Net cash used in operating activities during the first nine months of 2007 was \$23.7 million.

Irrespective of whether a New Drug Application (NDA) or Marketing Authorization Application (MAA) for Genasense® 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. Earlier in the year, we projected that a smaller workforce and concentrated effort on the development of Genasense® would result in the Company having sufficient funds to maintain its operations into the second quarter of 2008. Presently, without taking into account any further financings, we project that we should have sufficient cash funds to maintain our present operations into the first quarter of 2008. The current projection is primarily based on additional months of actual expenditures and no reduction to our workforce.

In March 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® 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 us.

The IDIS 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 IDIS a termination fee in the event we terminate either or both products within the first three years of the agreement. The first sale under this program occurred during the three-month period ended September 30, 2007.

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



We submitted a NDA to the FDA in 2003 for the use of Genasense® 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® ( $P=0.018$ ;  $n=508$ ). Safety and efficacy data from this trial were published in a scientific journal in October 2006.

On April 27, 2007, we announced that we would file a formal complaint and request for correction of information with the FDA under the Federal Data Quality Act. As submitted, the complaint challenges as erroneous a key statistical analysis of our data on Genasense® for melanoma used by FDA at the ODAC meeting on May 3, 2004. That analysis sought to discredit the finding that Genasense® 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 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 and we indicated that we would seek re-examination of the MAA. On July 19, 2007 we announced that we had received notice from the EMEA that the requested re-examination reaffirmed the negative opinion for approval of our MAA for Genasense®. No further action on the MAA is contemplated by us. We have announced that we plan to conduct at least one additional clinical trial with Genasense® in melanoma, and if positive, we intend to submit a new MAA in this indication.

On August 21, 2007, we announced that the first patients had been enrolled in our confirmatory Phase 3 trial of Genasense® in advanced melanoma. The trial, known as AGENDA, is a randomized, double-blind, placebo-controlled study in which patients are randomly assigned to receive Genasense® plus dacarbazine (DTIC) or DTIC alone. The study will prospectively target patients using LDH as a biomarker that identified patients who derived maximal benefit in the preceding melanoma trial of Genasense®, including significant increases in overall and progression-free survival. AGENDA will accrue approximately 300 patients and will be conducted at approximately 100 sites worldwide, including North America, Europe and Australia. Accrual is expected to take approximately 18 months, with initial data expected shortly thereafter. On October 17, 2007 we announced that the French Health Products Safety Agency ( AFSSAPS ) granted authorization to open the Company's Phase 3 trial of Genasense® in patients with advanced melanoma.

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).

20

---





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). On June 18, 2007, we announced that the initial appeal was denied and that we would further appeal the decision to the next level within CDER. On October 25, 2007, we announced that we had completed the filing of our formal appeal to CDER. Responses to CDER appeals are typically made within 30 to 60 days.

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 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 serum levels of 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. Results of this trial that were presented in the third quarter of 2007 do not indicate that this trial will support registration in this indication. 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).

On August 1, 2007, we announced that, together with Emisphere Technologies, Inc. we submitted an IND to the Endocrinologic and Metabolic Drugs Division of the FDA for a new drug known as G4544. Developed out of a joint

collaboration announced last year, G4544 is a new tablet formulation that enables oral absorption of the active ingredient contained in Ganite®. The IND was allowed by FDA in September 2007 and initial dosing of normal volunteers with G4544 began in the third quarter of 2007.



**Results of Operations for the Three Months Ended September 30, 2007 and September 30, 2006**

**Summary Operating Results**

**(\$ thousands)**

**Increase (Decrease)**

**2007**

**2006**

\$

%

Product sales net

\$

115

\$

145

\$

(30

)

(21

%)

Cost of goods sold

20

41

(21

)

(51

%)

Gross margin

95

104

(9

)

(9

%)

Operating expenses:

Research and development

4,763

8,514

(3,751

)

(44

%)

Selling, general and administrative



4,083

6,939

(2,856

)

(41

%)

Reduction in liability for settlement of litigation, net

(800

)

(800

)

(100

%)

Total operating expenses

8,046

15,453

(7,407

)

(48

%)

Other income, net

219

409

(190

)

(46

%)

Net loss

\$

(7,732

)

\$

(14,940

)

\$

7,208

48

%

Product sales net

Net sales of Ganite® declined to \$92 thousand for the three months ended September 30, 2007, from \$145 thousand for the prior-year period. Product sales-net for the three months ended September 30, 2007 include a sale in the amount of \$23 thousand of Genasense® through the named-patient program managed for us by IDIS.

Cost of goods sold

Cost of goods sold for the three months ended September 30, 2007 declined from the three months ended September 30, 2006 due to lower sales of Ganite® and sales of Genasense® that are recorded at zero cost.

Research and development expenses

Research and development expenses were \$4.8 million for the three months ended September 30, 2007, compared to \$8.5 million for the three months ended September 30, 2006. The prior-year period 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. In addition, share-based compensation declined by \$0.2 million, (see Note 11 to our Consolidated Financial Statements).

Research and development expenses incurred on the Genasense® project during the three months ended September 30, 2007 were approximately \$3.6 million, representing 76 percent of research and development expenses.

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 September 30, 2007, compared to \$6.9 million for the three months ended September 30, 2006. The prior-year period included a buildup of sales and marketing expenses incurred in preparation for a possible commercial launch of Genasense®. The decline in expenses in 2007 primarily reflects the comparison to this higher level of expenses in 2006, as well as the impact of our December 2006 staff reduction. In addition, share-based compensation declined by \$0.4 million, (see Note 11 to our Consolidated Financial Statements).

Reduction in liability 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 2.0 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 June 30, 2007, the revised estimated value of the common shares portion of the litigation settlement was \$3.5 million. At September 30, 2007, the revised estimated value of the common shares portion of the litigation settlement was \$2.7 million based on a closing price of Genta's common stock of \$1.34 per share, resulting in a reduction in the provision of \$0.8 million during the three months ended September 30, 2007.

Other income, net

Other income, net of \$0.2 million for the three months ended September 30, 2007 declined from \$0.4 million for the prior-year period, primarily due to lower interest income, resulting from lower investment balances during the period.

Net loss

We incurred a net loss of \$7.7 million, or \$0.25 per share for the three months ended September 30, 2007 and \$14.9 million, or \$0.66 per share, for the three months ended September 30, 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, the lower loss in 2007 reflects our staff reduction in December 2006, lower share-based compensation expense and includes a benefit of \$0.8 million due to a reduction in the provision for settlement of litigation.

**Results of Operations for the Nine Months Ended September 30, 2007 and September 30, 2006**

**Summary Operating Results**

(\$ thousands)

**Increase (Decrease)**

**2007**

**2006**

**\$**

**%**

Product sales net

**\$**

314

\$

591

\$

(277

)

(47

%)

Cost of goods sold

68

79

(11

)

(14

%)

Gross margin



246

512

(266

)

(52

%)

Operating expenses:

Research and development

12,244

21,900

(9,656

)

(44

%)

Selling, general and administrative

12,870

19,112

(6,242

)

(33

%)

Reduction in liability for settlement of litigation, net

(2,600

)

(2,600

)

(100

%)

Total operating expenses

22,514

41,012

(18,498

)

(45

%)

Other income, net

697

1,023

(326

)

(32

%)

Net loss

\$

(21,571

)

\$

(39,477

)

\$

17,906

45

%

23

---



Product sales - net

Product sales-net of Ganite® were \$0.3 million for the nine months ended September 30, 2007, compared to \$0.6 million for the nine months ended September 30, 2006. The prior-year nine-month period included a \$0.3 million favorable adjustment to the provision for returns of Ganite®. In the second quarter of 2006, we revised our forecast of expected Ganite® returns based on actual experience to date, product expiration dates and data obtained from wholesalers.

Cost of goods sold

Cost of goods sold for the nine months ended September 30, 2007 declined from the nine months ended September 30, 2006 primarily due to lower sales of Ganite®.

Research and development expenses

Research and development expenses were \$12.2 million for the nine months ended September 30, 2007, compared to \$21.9 million for the nine months ended September 30, 2006. The prior-year period 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 our staff reduction in December 2006. In addition, share-based compensation declined by \$0.3 million, (see Note 11 to our Consolidated Financial Statements).

Research and development expenses incurred on the Genasense® project during the nine months ended September 30, 2007 were approximately \$10.1 million, representing 83 percent of research and development expenses.

Selling, general and administrative expenses

Selling, general and administrative expenses were \$12.9 million for the nine months ended September 30, 2007, compared to \$19.1 million for the nine months ended September 30, 2006. The prior-year period 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 our December 2006 staff reduction. In addition, depreciation expense declined by \$0.7 million and share-based compensation declined by \$0.8 million, (see Note 11 to our Consolidated Financial Statements).

Reduction in liability for settlement of litigation, net

At September 30, 2007, the revised estimated value of the common shares portion of the litigation settlement was \$2.7 million based on a closing price of Genta's common stock of \$1.34 per share, resulting in a reduction in the provision of \$2.6 million for the nine months ended September 30, 2007.

Other income, net

Other income, net of \$0.7 million for the nine months ended September 30, 2007 declined from \$1.0 million for the prior-year period, primarily due to lower interest income, resulting from lower investment balances, along with higher interest expense.

Net loss

Genta incurred a net loss of \$21.6 million, or \$0.74 per share for the nine months ended September 30, 2007 and \$39.5 million, or \$1.83 per share, for the nine months ended September 30, 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, the lower loss in 2007 reflects our staff reduction in December 2006, lower share-based compensation expense, lower depreciation expense and includes a benefit of \$2.6 million due to a reduction in the provision for settlement of litigation.





## Liquidity and Capital Resources

At September 30, 2007, we had cash, cash equivalents and marketable securities totaling \$15.5 million compared with \$29.5 million at December 31, 2006. During the first nine months of 2007, cash used in operating activities was \$23.7 million compared with \$33.5 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 5.0 million shares of our common stock at a price of \$2.16 per share, raising net proceeds of \$10.1 million.

We issued notes payable to finance premiums for our corporate insurance policies during the nine months ended September 30, 2007 of \$0.2 million at an interest rate of 5.9%, during fiscal 2006 of \$1.2 million at interest rates running from 5.4% to 5.6% and during fiscal 2005 of \$1.3 million at interest rates running from 4.6% to 5.7%. Payments were scheduled over ten monthly installments for the notes initiated in 2007, seven equal monthly installments for the notes initiated in 2006 and for seven or eight equal monthly installments for the notes initiated in 2005. We will attempt to finance our remaining insurance premiums in fiscal 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, asset 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. Earlier in the year, we projected that a smaller workforce and concentrated effort on the development of Genasense® would result in the Company having sufficient funds to maintain its operations into the second quarter of 2008. Presently, without taking into account any further financings, we project that we should have sufficient cash funds to maintain our present operations into the first quarter of 2008. The current projection is primarily based on additional months of actual expenditures and no reduction to our workforce.

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 June 2007, the Financial Accounting Standards Board (FASB) issued EITF Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities, which is effective for calendar year companies on January 1, 2008. The Task Force concluded that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the

related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. We are currently assessing the potential impacts of implementing this standard.



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*. We do not expect that adoption of this standard will have a material impact 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 do not expect that adoption of this standard will have a material impact on our financial statements.

### **Critical Accounting Policies**

Our significant accounting policies are more fully described in Note 3 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:

*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 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. The first sale under this program occurred during the three-month period ended September 30, 2007.

*Research and development costs.* All 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, cash equivalents, marketable securities, accounts payable, accrued expenses and notes payable 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 3 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 September 30, 2007. Therefore, there will be no ongoing exposure to a potential material adverse effect on our business, financial condition or results of operation 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 were consolidated into a single action and alleged 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 seeks monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. The Company has reached an agreement in principle with plaintiffs to settle the class action litigation in consideration for the issuance of 2.0 million shares of common stock of the Company, (adjusted for any subsequent event that results in a change in the number of shares outstanding as of January 31, 2007) 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. Effective June 25, 2007, the Company and plaintiffs executed a written Stipulation and Agreement of Settlement which was filed with the Court on August 13, 2007, seeking preliminary approval. The unopposed Motion for Preliminary Approval of Settlement was granted on October 30, 2007, and the Settlement Fairness Hearing is scheduled for March 3, 2008.

In addition, two separate shareholder derivative actions were 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 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 covered the \$200 thousand payment for plaintiffs' attorney fees, the costs of notice to shareholders required by the court's preliminary approval order and defense costs incurred in connection with the action and this amount was paid by the Company's insurance carrier during the three months ended June 30, 2007.

The Company has continued to deny all of the allegations in all of these proceedings, and settlement and potential settlement do not constitute an admission of guilt or liability.

Based on facts substantially similar to those asserted in the shareholder class actions, the State derivative plaintiffs claimed that defendants had 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. In view of the settlement of the Federal derivative action, on June 4, 2007, the Company filed a motion to dismiss plaintiffs' appeal. That motion was granted on June 25, 2007.

In February 2007, a complaint against the Company was filed in the Superior Court of New Jersey by Howard H. Fingert, M.D., a former employee of the Company. The complaint alleges, among other things, breach of contract as to the Company's stock option plan and as to a consulting agreement allegedly entered into by the Company and Dr. Fingert subsequent to termination of Dr. Fingert's employment with the Company, breach of implied covenant of

good faith and fair dealing with respect to the Company's stock option plan and the alleged consulting agreement, promissory estoppel with respect to the exercise of stock options and provision of consulting services after termination of employment, and fraud and negligent misrepresentation with respect to exercise of stock options and provision of consulting services after termination of employment. The complaint seeks monetary damages, including punitive and consequential damages. The Company filed an answer to the complaint on May 29, 2007, and on August 8, 2007, filed a request for production of documents. The Court has required two hours of mandatory mediation to attempt voluntary resolution of the case, and has appointed a mediator. The parties and the mediator are working to set a mutually acceptable mediation date. The Company denies the allegations in the complaint and intends to vigorously defend this lawsuit.



**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 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). On June 18, 2007, we announced that the initial appeal was denied and that we would further appeal the decision to the next level within CDER. On October 25, 2007, we announced that we had completed the filing of our formal appeal to CDER. Responses to 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® 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 and we indicated that we would seek re-examination of the MAA. On July 19, 2007, we announced that we had received notice from the EMEA that the requested re-examination reaffirmed the negative opinion for approval of our MAA for Genasense®. No further action on the MAA is contemplated by us. We have announced that we plan to conduct at least one additional clinical trial with Genasense® in melanoma, and if positive, we intend to submit a new MAA in this indication.



On August 21, 2007, we announced that the first patients had been enrolled in our confirmatory Phase 3 trial of Genasense® in advanced melanoma. The trial, known as AGENDA, is a randomized, double-blind, placebo-controlled study in which patients are randomly assigned to receive Genasense® plus dacarbazine (DTIC) or DTIC alone. The study will prospectively target patients using LDH, a biomarker that identified patients who derived maximal benefit in a preceding trial of Genasense®, including significant increases in overall and progression-free survival. AGENDA will accrue approximately 300 patients and will be conducted at approximately 100 sites worldwide, including North America, Europe and Australia. Accrual is expected to take approximately 18 months, with initial data expected shortly thereafter. On October 17, 2007 we announced that the French Health Products Safety Agency ( AFSSAPS ) granted authorization to open the Company's Phase 3 trial of Genasense® in patients with advanced melanoma.

On April 27, 2007, we announced that we would file a formal complaint and request for correction of information with the FDA under the Federal Data Quality Act. As submitted, the complaint challenges as erroneous a key statistical analysis of our data on Genasense® for melanoma used by FDA at the ODAC meeting on May 3, 2004. That analysis sought to discredit the finding that Genasense® 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 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. The Company was advised in October 2007 that FDA has elected to extend its review period on this matter for an additional 60 days.

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 5.0 million shares of the Company's common stock at a price of \$2.16 per share, raising \$10.1 million, net of fees and expenses. Cash used in operating activities during the nine months ended September 30, 2007 was \$23.7 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. Earlier in the year, we projected that a smaller workforce and concentrated effort on the development of Genasense® would result in the Company having sufficient funds to maintain its operations into the second quarter of 2008. Presently, without taking into account any further financings, we project that we should have sufficient cash funds to maintain our present operations into the first quarter of 2008. The current projection is primarily based on additional months of actual expenditures and no reduction to our workforce.

***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 September 30, 2007, we have incurred a cumulative net deficit of \$436.4 million. We may never achieve revenue sufficient for us to attain profitability. Achieving profitability is unlikely unless Genasense® 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® and the principal patent covering its use for the approved indication expired in April 2005. Genasense® has not yet been approved, and if approved continues to be significantly delayed, or if in the event of approval the product is commercially unsuccessful, we do not expect significant sales of other products to offset this loss of potential revenue.

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

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

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

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

preserve trade secrets; and

operate without infringing the patent and other proprietary rights of third parties.

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

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

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



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

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

The principal patent covering the use of Ganite® for its approved indication, 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:



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

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

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

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

inability to obtain sufficient quantities of materials for use in clinical trials;

inability to adequately monitor patient progress after treatment;

unforeseen safety issues;

the failure of the products to perform well during clinical trials and

government or regulatory delays.



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

The FDA imposes substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve lengthy and detailed preclinical and clinical testing and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more depending upon the type, complexity and novelty of the product. We cannot apply for FDA approval to market any of our products under development until preclinical and clinical trials on the product are successfully completed. Several factors could prevent successful completion or cause significant delays of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that the product is safe and effective for use in humans. If safety concerns develop, the FDA could stop our trials before completion. We may not market or sell any product for which we have not obtained regulatory approval. For example, on December 15, 2006, we received a non-approvable notice from the FDA of an NDA 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.

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

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

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

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

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

Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of our products or product candidates, entail higher costs and result in our being unable to effectively commercialize our products. Furthermore, if our third-party manufacturers fail to deliver the required

commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenues.





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

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

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

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

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

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





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

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

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

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

difficulties in assimilating the operations and personnel of acquired companies;

diversion of our management's attention from ongoing business concerns;

our potential inability to maximize our financial and strategic position through the successful incorporation of acquired technology and rights into our products and services;

additional expense associated with amortization of acquired assets;

maintenance of uniform standards, controls, procedures and policies; and

impairment of existing relationships with employees, suppliers and customers as a result of the integration of new management personnel.

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

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

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



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

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

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

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

#### **Risks Related to Outstanding Litigation**

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

In 2004, numerous complaints were filed in the United States District Court for the District of New Jersey, or the Court, against us and certain of our principal officers on behalf of purported classes of the Company's shareholders who purchased its securities during several class periods. The complaints were consolidated into a single action and alleged 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 sought monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. We reached an agreement with plaintiffs to settle the class action litigation in consideration for the issuance of 2.0 million shares of common stock of the Company (adjusted for any subsequent event that results in a change in the number of shares outstanding as of January 31, 2007) 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. Effective June 25, 2007, we and the plaintiffs executed a written Stipulation and Agreement of Settlement which was filed with the Court on August 31, 2007, seeking preliminary approval. The unopposed Motion for Preliminary Approval of Settlement was granted on October 30, 2007, and the Settlement Fairness Hearing is scheduled for March 3, 2008.

In addition, two separate shareholder derivative actions were 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.

We 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 covered the \$200 thousand payment for plaintiffs' attorney fees, the costs of notice to shareholders required by the court's preliminary approval order and defense costs incurred in connection with the action and this amount was paid by our insurance carrier during the three months ended June 30, 2007.





We have continued to deny all of the allegations in all of these proceedings, and settlement and potential settlement do not constitute an admission of guilt or liability.

Based on facts substantially similar to those asserted in the shareholder class actions, the State derivative plaintiffs claimed that defendants had 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. In view of the settlement of the Federal derivative action, on June 4, 2007, we filed a motion to dismiss plaintiffs' appeal. That motion was granted on June 25, 2007.

In February 2007, a complaint against the Company was filed in the Superior Court of New Jersey by Howard H. Fingert, M.D., a former employee of the Company. The complaint alleges, among other things, breach of contract as to the Company's stock option plan and as to a consulting agreement allegedly entered into by the Company and Dr. Fingert subsequent to termination of Dr. Fingert's employment with the Company, breach of implied covenant of good faith and fair dealing with respect to the Company's stock option plan and the alleged consulting agreement, promissory estoppel with respect to the exercise of stock options and provision of consulting services after termination of employment, and fraud and negligent misrepresentation with respect to exercise of stock options and provision of consulting services after termination of employment. The complaint seeks monetary damages, including punitive and consequential damages. We filed an answer to the complaint on May 29, 2007, and on August 8, 2007, filed a request for production of documents. The court has required two hours of mandatory mediation to attempt voluntary resolution of the case, and has appointed a mediator. The parties and the mediator are working to set a mutually acceptable mediation date. We deny the allegations in the complaint and intends to vigorously defend this lawsuit.

### **Risks Related to Our Common Stock**

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

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

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

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

takeover and prevent our stockholders from receiving a premium for their shares.

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

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



***Our stock price is volatile.***

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

the results of preclinical studies and clinical trials by us or our competitors;

announcements of technological innovations or new therapeutic products by us or our competitors;

government regulation;

developments in patent or other proprietary rights by us or our respective competitors, including litigation;

fluctuations in our operating results; and

market conditions for biopharmaceutical stocks in general.

At September 30, 2007 we had 30.6 million shares of common stock outstanding, 2.2 million additional shares reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants and 0.8 million additional shares of common stock authorized for issuance and remaining to be granted under our stock option plans. Future sales of shares of our common stock by existing stockholders, holders of preferred stock who might convert such preferred stock into common stock and option and warrant holders who may exercise their options and warrants to purchase common stock also could adversely affect the market price of our common stock. Moreover, the perception that sales of substantial amounts of our common stock might occur could adversely affect the market price

of our common stock.

At our Annual Meeting of Shareholders held on July 11, 2007, our shareholders authorized our Board of Directors to effect a reverse stock split of all outstanding shares of common stock, and the Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of one for six shares. On July 12, 2007, we filed a Certificate of Amendment to our Restated Certificate of Incorporation, as amended, with the Delaware Secretary of State to effect the reverse stock split. As of July 12, 2007, the effective date of the reverse stock split; every six shares of old common stock were converted into one new share of common stock. Upon the open of trading on July 13, 2007, the new shares of common stock began trading on the NASDAQ Global Market on a split-adjusted basis. As a result of the 1-for-6 reverse stock split, shares of our common stock outstanding were reduced from 183.7 million shares on a pre-split basis to 30.6 million shares on a post-split basis, or 83%. The resulting decrease in the number of shares of our common stock outstanding could potentially adversely affect the liquidity of our common stock, especially in the case of larger block trades.

***Our common stock may be delisted from the NASDAQ Global Market, or NASDAQ.***

In July 2007 we underwent a reverse stock split in order to increase the price of our stock over the required threshold of \$1.00 per share. If the bid price of our common stock falls below \$1.00 for an extended period, or we are unable to continue to meet NASDAQ's listing maintenance standards for any other reason, our common stock could be delisted from NASDAQ.

On November 2, 2006, we received a notification from the NASDAQ Listing Qualifications Department providing notification that, for the last thirty consecutive business days, the bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion under NASDAQ Marketplace Rule 4450(a)(5), or the Rule. We, in accordance with NASDAQ Marketplace Rule 4450(e)(2), were provided 180 calendar days, or until May 1, 2007, to regain compliance. To regain compliance, the bid price of our common stock had to close at \$1.00 per share or more for a minimum of ten consecutive business days at any time before May 1, 2007.



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 Marketplace Rule 4450(a)(5). At our Annual Meeting held on July 11, 2007, our shareholders authorized our Board of Directors to effect a reverse stock split of all outstanding shares of Common Stock, and the Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of one for six shares. On July 12, 2007, we filed a Certificate of Amendment to our Restated Certificate of Incorporation, as amended, with the Delaware Secretary of State to effect the reverse stock split. As of July 12, 2007, the effective date of the reverse stock split; every six shares of old common stock were converted into one new share of common stock. Upon the open of trading on July 13, 2007, the new shares of common stock began trading on the NASDAQ Global Market on a split-adjusted basis. On July 30, 2007 we announced that we had been formally notified by NASDAQ that we had demonstrated compliance with all NASDAQ Marketplace Rules. As a consequence, the NASDAQ Listing Qualifications Panel determined that our common stock will continue to be listed on the NASDAQ Global Market.

We believe that the listing of our common stock on a recognized national trading market, such as NASDAQ, is an important part of our business and strategy. Such a listing helps our stockholders by providing a readily available trading market with current quotations. Without that, stockholders may have a difficult time getting a quote for the sale or purchase of our stock, the sale or purchase of our stock would likely be made more difficult and the trading volume and liquidity of our stock would likely decline. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded it by other parties. In that regard, the absence of a listing on a recognized national trading market will also affect our ability to benefit from the use of our operations and expansion plans, including for use in licensing agreements, joint ventures, the development of strategic relationships and acquisitions, which are critical to our business and strategy and none of which is currently the subject of any agreement, arrangement or understanding, with respect to any future financing or strategic relationship it may undertake. The delisting from NASDAQ would result in negative publicity and would negatively impact our ability to raise capital in the future.





**Item 2.**

*Unregistered Sales of Equity Securities and Use of Proceeds*

None.

**Item 3.**

*Defaults Upon Senior Securities*

None.

**Item 4.**

*Submission of Matters to a Vote of Security Holders*

None.

**Item 5.**

*Other Information*

None.

42

---



**Item 6. Exhibits.**

**Exhibit**

**Number**

**Description of Document**

10.1	Form of Acquisition Bonus Program Agreement (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on September 21, 2007, incorporated by reference herein)
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
31.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
32.1	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)
32.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)



**SIGNATURES**

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

Genta Incorporated

Date: November 7, 2007

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

Raymond P. Warrell, Jr., M.D.  
Chairman and Chief Executive Officer  
(principal executive officer)

Date: November 7, 2007

/s/ RICHARD J. MORAN

Richard J. Moran  
Senior Vice President, Chief Financial Officer and Corporate Secretary  
(principal financial and accounting officer)

44

---

**Exhibit Index**

**Exhibit**

**Number**

**Description of Document**

10.1	
	Form of Acquisition Bonus Program Agreement (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on September 21, 2007, incorporated by reference herein)
31.1	
	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
31.2	
	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
32.1	
	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)
32.2	
	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)



