

GENTA INC DE/  
Form 10-Q  
August 14, 2009

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2009

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 0-19635

GENTA INCORPORATED  
(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

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

07922  
(Zip Code)

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

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

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer (Do not check if a smaller reporting company)  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes  No

As of August 7, 2009, the registrant had 133,745,061 shares of common stock outstanding.

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Genta Incorporated  
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GENTA INCORPORATED  
CONSOLIDATED BALANCE SHEETS

(In thousands, except par value data)

	June 30, 2009 (unaudited)	December 31, 2008
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 696	\$ 4,908
Accounts receivable - net of allowances of \$5 at June 30, 2009 and \$12 at December 31, 2008, respectively	34	2
Inventory (Note 4)	119	121
Prepaid expenses and other current assets	584	973
<b>Total current assets</b>	<b>1,433</b>	<b>6,004</b>
Property and equipment, net	271	300
Deferred financing costs and debt discount (Note 6)	8,546	6,389
<b>Total assets</b>	<b>\$ 10,250</b>	<b>\$ 12,693</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 11,259	\$ 11,224
Convertible notes due June 9, 2010, \$2,829 outstanding, net of debt discount of (\$1,969) (Note 6)	860	-
<b>Total current liabilities</b>	<b>12,119</b>	<b>11,224</b>
Long-term liabilities		
Office lease settlement obligation (Note 5)	1,979	1,979
Convertible notes due June 9, 2010, \$15,540 outstanding, net of debt discount of (\$11,186) (Note 6)	-	4,354
Convertible notes due April 2, 2012, \$5,950 outstanding, net of debt discount of (\$5,466) (Note 6)	484	-
<b>Total long-term liabilities</b>	<b>2,463</b>	<b>6,333</b>
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Preferred stock, 5,000 shares authorized:		
Series A convertible preferred stock, \$.001 par value; 8 shares issued and outstanding, liquidation value of \$385 at June 30, 2009 and December 31, 2008, respectively	-	-
Series G participating cumulative preferred stock, \$.001 par value; 0 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	-	-
Common stock, \$.001 par value; 6,000,000 and 6,000,000 shares authorized, 99,771 and 9,734 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	100	10
<b>Additional paid-in capital</b>	<b>993,843</b>	<b>939,252</b>

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Accumulated deficit	(998,275)	(944,126)
Total stockholders' deficit	(4,332)	(4,864)
Total liabilities and stockholders' deficit	\$ 10,250	\$ 12,693

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED  
CONSOLIDATED STATEMENTS OF OPERATIONS  
(Unaudited)

(In thousands, except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Product sales - net	\$ 69	\$ 131	\$ 131	\$ 248
Cost of goods sold	1	29	1	54
Gross margin	68	102	130	194
<b>Operating expenses:</b>				
Research and development	3,674	4,454	5,972	10,891
Selling, general and administrative	1,968	2,587	4,140	6,225
Settlement of office lease obligation (Note 5)	-	3,307	-	3,307
Reduction in liability for settlement of litigation, net	-	(80)	-	(340)
Total operating expenses	5,642	10,268	10,112	20,083
<b>Other income/(expense):</b>				
Gain on maturity of marketable securities	-	-	-	31
Interest income and other income, net	1	40	16	100
Interest expense	(189)	(198)	(576)	(223)
Amortization of deferred financing costs and debt discount (Note 7)	(10,625)	(840)	(16,912)	(840)
Fair value - conversion feature liability (Note 6)	(19,040)	(720,000)	(19,040)	(720,000)
Fair value - warrant liability (Note 6)	(7,655)	(7,200)	(7,655)	(7,200)
Total other income/(expense)	(37,508)	(728,198)	(44,167)	(728,132)
Net loss	\$ (43,082)	\$ (738,364)	\$ (54,149)	\$ (748,021)
Net loss per basic and diluted share	\$ (0.63)	\$ (1,004.84)	\$ (1.24)	\$ (1,060.69)
Shares used in computing net loss per basic and diluted share	68,870	735	43,575	705

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)

(In thousands)	Six Months Ended June 30,	
	2009	2008
<b>Operating activities:</b>		
Net loss	\$ (54,149)	\$ (748,021)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	80	83
Amortization of deferred financing costs and debt discount (Note 6)	16,912	840
Share-based compensation (Note 8)	107	305
Gain on maturity of marketable securities	-	(31)
Reduction in liability for settlement of litigation, net (Note 5)	-	(340)
Change in fair value - conversion feature liability (Note 6)	19,040	720,000
Change in fair value - warrant liability (Note 6)	7,655	7,200
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(32)	(24)
Inventory	2	54
Prepaid expenses and other current assets	389	444
Accounts payable and accrued expenses	545	5,094
<b>Net cash used in operating activities</b>	<b>(9,451)</b>	<b>(14,396)</b>
<b>Investing activities:</b>		
Maturities of marketable securities	-	2,000
Elimination of restricted cash deposits	-	1,731
Purchase of property and equipment	(51)	(11)
<b>Net cash provided by (used in) investing activities</b>	<b>(51)</b>	<b>3,720</b>
<b>Financing activities:</b>		
Repayments of note payable	-	(512)
Issuance of convertible notes net of financing cost of \$660 (Note 6)	5,290	18,795
Issuance of common stock, net	-	2,857
<b>Net cash provided by financing activities</b>	<b>5,290</b>	<b>21,140</b>
<b>Increase/(decrease) in cash and cash equivalents</b>	<b>(4,212)</b>	<b>10,464</b>
Cash and cash equivalents at beginning of period	4,908	5,814
<b>Cash and cash equivalents at end of period</b>	<b>\$ 696</b>	<b>\$ 16,278</b>

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
June 30, 2009  
(Unaudited)

1. Reverse Stock Split

At a Special Meeting of Stockholders of Genta Incorporated (“Genta” or the “Company”) held on June 26, 2009, the Company’s stockholders 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 on June 26, 2009 at a ratio of one for fifty shares. 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 prior to June 26, 2009.

2. Organization, Business and Liquidity

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 outcomes with respect to approval by the U.S. Food and Drug Administration (“FDA”) and/or European Medicines Agency (“EMA”) could negatively impact the Company’s ability to obtain additional funding or identify potential partners.

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

On June 9, 2008, the Company placed \$20 million of senior secured convertible notes, or the 2008 Notes, with certain institutional and accredited investors. The notes bear interest at an annual rate of 15% payable at quarterly intervals in other senior secured convertible promissory notes to the holder, and originally were convertible into shares of Genta common stock at a conversion rate of 2,000 shares of common stock for every \$1,000.00 of principal, (adjusted for the reverse stock split). As a result of issuing convertible notes on April 2, 2009, (see below), these notes are presently convertible into shares of Genta common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal. The 2008 Notes are secured by a first lien on all assets of Genta.

On April 2, 2009, the Company entered into a securities purchase agreement with certain accredited institutional investors to place up to \$12 million of senior secured convertible notes, or the April 2009 Notes, and corresponding warrants to purchase common stock. The Company closed on approximately \$6 million of such notes and warrants on April 2, 2009. The April 2009 Notes bear interest at an annual rate of 8% payable semi-annually in other senior secured convertible promissory notes to the holder, and are convertible into shares of the Company’s common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal amount outstanding. The April 2009 Notes are also secured by a first lien on all assets of Genta, which security interest is pari passu with the security interest held by the holders of the 2008 Notes.





On July 7, 2009, the Company entered into a securities purchase agreement with certain accredited institutional investors to place up to \$10 million in aggregate principal amount of units consisting of (i) 70% unsecured subordinated convertible notes, or the July 2009 Notes, and (ii) 30% common stock. In connection with the sale of the units, the Company also issued to the investors two-year warrants to purchase common stock in an amount equal to 25% of the number of shares of common stock issuable upon conversion of the July 2009 Notes purchased by each investor. The Company closed on \$3 million of such July 2009 Notes, common stock and warrants on July 7, 2009.

On August 6, 2009, the Company entered into an amendment whereby, among other things, the certain accredited institutional investors who were parties to the July 2009 securities purchase agreement agreed to purchase \$10 million of additional notes and warrants having the same terms of the July 2009 Notes as well as shares of common stock, increasing their aggregate investment to \$13 million.

Net cash used in operating activities during the six months ended June 30, 2009 was \$9.5 million. Presently, with no further financing, management projects that the Company will run out of funds in September 2009. The terms of the July 2009 financing, as amended, commit those investors to purchase \$10.0 million of additional notes and warrants having the same terms of the July 2009 Notes as well as shares of common stock. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase additional notes with similar terms. The Company does not have any additional financing in place. There can be no assurance that the Company can obtain financing, if at all, on terms acceptable to it.

The Company will require additional cash in order to maximize its commercial opportunities and continue its clinical development opportunities. The Company has had 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 development and commercialization partnerships on other products in our pipeline, financing arrangements with potential corporate partners, debt financing, asset sales, asset-based loans, royalty-based financings, equity financing and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available on favorable terms, if at all.

If the Company is unable to raise additional funds, 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 one or more of our products or technologies that the Company would otherwise seek to commercialize itself;
- attempt to sell the Company;
- cease operations; or
- declare bankruptcy.

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. The accompanying consolidated financial statements included herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements have been condensed or omitted from this report, as is permitted by such rules and regulations; however, the Company believes that the disclosures are adequate to make the information presented not misleading. The 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, 2008. 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.

Use of Estimates

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.

Cash and Cash Equivalents

Cash and cash equivalents consist of highly liquid instruments with maturities of three months or less from the date acquired and are stated at cost that approximates their fair market value. At June 30, 2009, the amounts on deposit that exceeded the \$250,000 federally insured limit was \$0.2 million.

Revenue Recognition

Genta recognizes revenue from product sales when title to product and associated risk of loss has passed to the customer and the Company is reasonably assured of collecting payment for the sale. All revenue from product sales are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances. The Company allows return of its product for up to twelve months after product expiration.

Research and Development

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

## 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 six months ended June 30, 2009 and continues to maintain a full valuation allowance against its net deferred tax assets. Utilization of the Company's net operating loss (NOL) and research and development (R&D) credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the Code), as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups.

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's position on the AMA liability is unjustified, there is little case law on the matter and it is probable that the Company will be required to ultimately pay the liability. As of June 30, 2009, the Company had accrued a tax liability of \$533 thousand, penalties of \$27 thousand and interest of \$308 thousand related to this assessment. The Company appealed this decision to the State and on February 13, 2008, the State notified the Company that its appeal had not been granted. On April 25, 2008, the Company filed a complaint with the Tax Court of the State of New Jersey to appeal the assessment. A hearing has been scheduled in September 2009.

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 \$27 thousand and \$34 thousand in interest expense related to the State of New Jersey assessment during the six months ended June 30, 2009 and 2008, respectively.

## Stock Options

Stock Options are accounted for using 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. Under the standard, all share-based payments, including grants of employee stock options, are recognized in the Consolidated Statement of Operations based on their fair values. The amount of compensation cost is measured based on the grant-date fair value of the equity instrument issued. The Company utilizes a Black-Scholes option-pricing model to measure the fair value of stock options granted to employees. See Note 8 and Note 9 to the Consolidated Financial Statements for a further discussion on share-based compensation.

### Deferred Financing Costs

Deferred financing costs are amortized over the term of its associated debt instrument. The Company evaluates the terms of debt instruments to determine if any embedded derivatives or beneficial conversion features exist. The Company allocates the aggregate proceeds of debt instruments between warrants and notes based on their relative fair values in accordance with Accounting Principle Board No. 14 (APB 14), "Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants." The fair value of the warrants issued as a result of the issuance of the 2008 notes and the warrants issued as a result of the issuance of the April 2009 notes are calculated utilizing the Black-Scholes option-pricing model. The Company is amortizing the resultant discount or other features over the term of the notes through its earliest maturity date using the effective interest method. Under this method, interest expense recognized each period will increase significantly as the instrument approaches its maturity date. If the maturity of the debt is accelerated because of conversions or defaults, then the amortization is accelerated.

### Net Loss Per Common Share

Net loss per common share for the three and six months ended June 30, 2009 and 2008, respectively, are based on the weighted average number of shares of common stock outstanding during the periods. Basic and diluted net 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, as the inclusion of such securities would be antidilutive. At June 30, 2009 and 2008, respectively, the potentially dilutive securities include approximately 107.2 million shares and approximately 0.8 million shares, respectively, reserved for the conversion of convertible notes, convertible preferred stock and the exercise of outstanding options and warrants.

### Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting. SFAS 168 represents the last numbered standard to be issued by FASB under the old (pre-Codification) numbering system, and amends the GAAP hierarchy. On July 1, 2009, FASB will launch new FASB's Codification (full name: the FASB Accounting Standards Codification TM.) The Codification will supersede existing GAAP for nongovernmental entities; governmental entities will continue to follow standards issued by FASB's sister organization, the Governmental Accounting Standards Board (GASB). This pronouncement has no effect on Company's financial statements.

In May 2009, the FASB issued SFAS 165, Subsequent Events. SFAS 165 incorporates into authoritative accounting literature certain guidance that already existed within generally accepted auditing standards, but the rules concerning recognition and disclosure of subsequent events will remain essentially unchanged. Subsequent events guidance addresses events which occur after the balance sheet date but before the issuance of financial statements. Under Statement No. 165 as under current practice, an entity must record the effects of subsequent events that provide evidence about conditions that existed at the balance sheet date and must disclose but not record the effects of subsequent events which provide evidence about conditions that did not exist at the balance sheet date. The Company adopted SFAS 165 and it did not have an impact on the Company's consolidated financial statements. There were no recognized or nonrecognized subsequent events occurring after June 30, 2009 that required accounting or disclosure in accordance with SFAS 165. Subsequent events were evaluated to August 14, 2009, the date the financial statements of the Company were issued.

In April 2009, the FASB issued FASB Staff Position SFAS 141(R)-1, Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies, to amend and clarify the initial recognition and measurement, subsequent measurement and accounting, and related disclosures arising from contingencies in a business combination under SFAS 141(R). Under the new guidance, assets acquired and liabilities assumed in a business combination that arise from contingencies should be recognized at fair value on the acquisition date if fair value can be determined during the measurement period. If fair value can not be determined, companies should typically account for the acquired contingencies using existing guidance. The implementation of this standard did not have a material effect on the Company's consolidated financial statements.

#### 4. 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):

	June 30, 2009	December 31, 2008
Raw materials	\$ 24	\$ 24
Finished goods	95	97
	\$ 119	\$ 121

During the three and six months ended June 30, 2009, sales of Ganite® were mostly from product that had been previously accounted for as excess inventory.

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.

#### 5. Office Lease Settlement Obligation

In January 2009, the Company entered into an amendment of its lease agreement with The Connell Company, whereby the Company's future payment of \$2.0 million, related to an earlier amendment of its lease for office space, is payable on January 1, 2011. The Company will pay 6.0% interest in arrears to Connell from July 1, 2009 through the new payment date.

#### 6. Convertible Notes and Warrants

On June 9, 2008, the Company placed \$20 million of senior secured convertible notes, or the 2008 Notes, with certain institutional and accredited investors. The notes bear interest at an annual rate of 15% payable at quarterly intervals in other senior secured convertible promissory notes to the holder, and originally were convertible into shares of Genta common stock at a conversion rate of 2,000 shares of common stock for every \$1,000.00 of principal, (adjusted for the reverse stock split). As a result of issuing convertible notes on April 2, 2009, (see below), these notes are presently convertible into shares of Genta common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal. The 2008 Notes are secured by a first lien on all assets of Genta, which security interest is pari passu with the security interest held by the holders of the April 2009 Notes.

At the time the 2008 Notes were issued, the Company recorded a debt discount (beneficial conversion) relating to the conversion feature in the amount of \$20.0 million. The aggregate intrinsic value of the difference between the market price of the Company's share of stock on June 9, 2008 and the conversion price of the notes was in excess of the face value of the \$20.0 million notes, and thus, a full debt discount was recorded in an amount equal to the face value of the debt. The Company is amortizing the resultant debt discount over the term of the notes through their maturity date.



From January 1, 2009 through June 30, 2009, holders of the 2008 Notes voluntarily converted approximately \$13.2 million, resulting in an issuance of 90.0 million shares of common stock. At June 30, 2009, approximately \$2.8 million of the 2008 Notes were outstanding.

Upon the occurrence of an event of default, holders of the 2008 notes have the right to require the Company to prepay all or a portion of their 2008 notes as calculated as the greater of (a) 150% of the aggregate principal amount of the note plus accrued interest or (b) the aggregate principal amount of the note plus accrued interest divided by the conversion price; multiplied by a weighted average price of the Company's common stock. Pursuant to a general security agreement, entered into concurrently with the notes (the "Security Agreement"), the notes are secured by a first lien on all assets of the Company, subject to certain exceptions set forth in the Security Agreement, which security interest is *pari passu* with the security interest held by the holders of the April 2009 Notes.

In addition, in connection with the placement of the 2008 Notes, the Company issued a warrant to its private placement agent to purchase 800,000 shares of common stock at an exercise price of \$1.00 per share and incurred a financing fee of \$1.2 million. The financing fees are being amortized over the life of the convertible notes and the initial value of the warrant is being amortized over the two-year term of the convertible notes. At June 30, 2009 and December 31, 2008, the unamortized balances of the financing fee were \$0.6 million and \$0.9 million and the warrant were \$3.6 million and \$5.4 million, respectively.

On April 2, 2009, the Company entered into a securities purchase agreement with certain accredited institutional investors to place up to \$12 million of senior secured convertible notes, or the April 2009 Notes, and corresponding warrants to purchase common stock. The Company closed on approximately \$6 million of such notes and warrants on April 2, 2009. The April 2009 Notes bear interest at an annual rate of 8% payable semi-annually in other senior secured convertible promissory notes to the holder, and are convertible into shares of the Company's common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal amount outstanding. In addition, the April 2009 Notes included certain events of default, including a requirement that the Company effect a reverse stock split of its Common Stock within 105 days of April 2, 2009. At June 30, 2009, \$6.0 million of the April 2009 Notes were outstanding.

The Company concluded that it should initially account for conversion options embedded in the 2008 Notes and April 2009 Notes in accordance with SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133") and EITF 00-19 "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" ("EITF 00-19"). SFAS 133 generally requires companies to bifurcate conversion options embedded in convertible notes from their host instruments and to account for them as free standing derivative financial instruments in accordance with EITF 00-19. EITF 00-19 states that if the conversion option requires net cash settlement in the event of circumstances that are not solely within the Company's control, that the notes should be classified as a liability measured at fair value on the balance sheet. In this case, if the Company was not successful in obtaining approval of its stockholders to increase the number of authorized shares to accommodate the potential number of shares that the notes convert into, the Company would have been required to cash settle the conversion option.

At the time the April 2009 Notes were issued, the Company recorded a debt discount (beneficial conversion) relating to the conversion feature in the amount of \$6.0 million. The aggregate intrinsic value of the difference between the market price of the Company's share of stock on April 2, 2009 and the conversion price of the notes was in excess of the face value of the \$6.0 million notes, and thus, a full debt discount was recorded in an amount equal to the face value of the debt. The Company is amortizing the resultant debt discount over the three-year term of the notes through their maturity date. At April 2, 2009, there were an insufficient number of authorized shares of common stock in order to permit exercise of all of the issued convertible notes. In accordance with EITF 00-19, when there are insufficient authorized shares, the conversion obligation for the notes should be classified as a liability measured at



fair value on the balance sheet. At April 2, 2009, in connection with the \$6.0 million closing, the fair value of the conversion feature, \$67.8 million, exceeded the proceeds of \$6.0 million. The difference of \$61.8 million was charged to expense as the change in the fair market value of conversion liability.

On June 26, 2009, at a Special Meeting of Stockholders, the Company's stockholders authorized its Board of Directors to effect a reverse stock split in any ratio up to 1-for-100, while not reducing the number of authorized shares and not changing the par value of the common stock. The Board of Directors implemented a reverse stock split in a ratio of 1-for-50 and in so doing, the Company had enough shares to accommodate the potential number of shares that the April 2009 Notes convert into. The fair value of the conversion feature was re-measured at June 26, 2009 at \$25.0 million and credited to permanent equity, resulting in total expense for the three months ended June 30, 2009 of \$19.0 million. The conversion option was valued at April 2, 2009 and June 26, 2009 using the Black-Scholes valuation model using the following assumptions:

	June 26, 2009	April 2, 2009
Price of share of Genta common stock	\$ 0.425	\$ 1.15
Volatility	258%	240%
Risk-free interest rate	1.50%	1.25%
Remaining contractual lives	2.8	3.0

As a result of issuing the April 2009 Notes, the conversion rate for the 2008 Notes was adjusted to be the same conversion rate as the April 2009 Notes. Accordingly, the 2008 Notes that originally were convertible into shares of Genta common stock at a conversion rate of 2,000 shares of common stock for every \$1,000.00 of principal were adjusted to be convertible into shares of Genta common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal. In accordance with EITF 00-27, the Company valued this change in the conversion rate on April 2, 2009; the aggregate intrinsic value of the difference in conversion rates was in excess of the \$10.7 million face value of the 2008 Notes. Thus, a full debt discount was recorded in an amount equal to the face value of the 2008 Notes, and the Company is amortizing the resultant debt discount over the remaining term of the 2008 Notes.

As there were an insufficient number of authorized shares of common stock in order to fulfill all existing obligations, as required by EITF 00-19, the Company classified the warrant obligations as liabilities to be measured at fair value on the balance sheet. Accordingly, at April 2, 2009, the Company recorded the warrant liabilities at a fair value of \$1.125 per warrant, or \$20.8 million, based upon the Black-Scholes valuation model. The warrant liability was re-measured at June 26, 2009 at a fair value of \$0.415 per warrant, or \$7.7 million, and credited to permanent equity, resulting in an expense of \$7.7 million for the three months ended June 30, 2009. The warrant liability was valued at April 2, 2009 and June 26, 2009 using the Black-Scholes valuation model using the following assumptions:

	June 26, 2009	April 2, 2009
Price of share of Genta common stock	\$ 0.425	\$ 1.15
Volatility	244%	224%
Risk-free interest rate	1.75%	1.89%
Remaining contractual lives	3.3	3.5

The Company is in compliance with all debt-related covenants at June 30, 2009.

7.

#### Share-Based Compensation

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") and Staff Accounting Bulletin 110 ("SAB 110"), using a "simplified" method. The Company will continue to use the simplified method as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate an expected term. The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of the Company's stock options. There were no grants of stock options during the six months ended June 30, 2009 and 2008, respectively.



Share-based compensation expense recognized for the three and six months ended June 30, 2009 and 2008, respectively, was comprised as follows:

(\$ thousands, except per share data)	Three months ended June 30		Six months ended June 30	
	2009	2008	2009	2008
Research and development expenses	\$ 11	\$ 52	\$ 32	\$ 96
Selling, general and administrative	23	108	75	209
<b>Total share-based compensation expense</b>	<b>\$ 34</b>	<b>\$ 160</b>	<b>\$ 107</b>	<b>\$ 305</b>
Share-based compensation expense, per basic and diluted common share	\$ 0.00	\$ 0.22	\$ 0.00	\$ 0.43

#### 8. Stock Option Plans

As of June 30, 2009, the Company has two outstanding share-based compensation plans, which are described below:

##### 1998 Stock Incentive Plan

Pursuant to the Company's 1998 Stock Incentive Plan, as amended (the "1998 Plan"), 68 thousand shares had been provided for the grant of stock options to employees, directors, consultants and advisors of the Company. Option awards were 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 vested over a four-year period in equal increments of 25%, beginning on the first anniversary of the date of the grant. All options granted had contractual terms of ten years from the date of the grant. As of May 27, 2008, the authorization to provide grants under the 1998 Plan expired.

The following table summarizes the option activity under the 1998 Plan as of June 30, 2009 and changes during the six months then ended:

	Number of Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Stock Options				
Outstanding at December 31, 2008	37	\$ 1,191.50		
Granted	-	-		
Exercised	-	-		
Forfeited or expired	(3)	134.16		
Outstanding at June 30, 2009	34	\$ 1,293.00	2.8	\$ -
Vested and exercisable at June 30, 2009	26	\$ 1,725.00	2.0	\$ -

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 June 30, 2009. The amount of aggregate intrinsic value may change based on the market value of the Company's stock.

As of June 30, 2009, there was approximately \$68 thousand of total unrecognized compensation cost related to non-vested share-based compensation resulting from stock options granted under the 1998 Plan, which is expected to be recognized over a weighted-average period of 0.8 years.



The following table summarizes the restricted stock unit (RSU) activity under the 1998 Plan as of June 30, 2009 and changes during the six months then ended:

Restricted Stock Units	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value per Share
Outstanding nonvested RSUs at January 1, 2009	5	\$ 20.50
Granted	-	-
Vested	(3)	\$ 20.50
Forfeited or expired	-	-
Outstanding nonvested RSUs at June 30, 2009	2	\$ 20.50

As of June 30, 2009, there was no unrecognized compensation cost related to non-vested share-based compensation resulting from RSUs granted under the 1998 Plan.

#### 1998 Non-Employee Directors' Plan

Pursuant to the Company's 1998 Non-Employee Directors' Plan as amended (the "Directors' Plan"), 12 thousand shares have been provided for the grant of non-qualified stock options to the Company's non-employee members of the Board of Directors. Option awards must be granted with an exercise price at not less than the fair market price of the Company's common stock on the date of the grant. Initial option grants vest over a three-year period in equal increments, beginning on the first anniversary of the date of the grant. Subsequent grants generally vest on the date of the grant. All options granted have contractual terms of ten years from the date of the grant.

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

The following table summarizes the option activity under the Directors' Plan as of June 30, 2009 and changes during the six 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, 2009	2	\$ 1,130.47		
Granted	-	-		
Exercised	-	-		
Forfeited or expired	-	-		
Outstanding at June 30, 2009	2	\$ 1,130.47	6.0	\$ -
Vested and exercisable at June 30, 2009	2	\$ 1,130.47	6.0	\$ -

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 June 30, 2009. The amount of aggregate intrinsic value may change based on the market value of the Company's stock.

9. Commitments and Contingencies

Litigation and Potential Claims

In September 2008, several shareholders of the Company, on behalf of themselves and all others similarly situated, filed a class action complaint against the Company, the Board of Directors, and certain of its executive officers in Superior Court of New Jersey, captioned Collins v. Warrell, Docket No. L-3046-08. The complaint alleged that in issuing convertible notes, the Board of Directors, and certain officers breached their fiduciary duties, and the Company aided and abetted the breach of fiduciary duty. On March 20, 2009, the Superior Court of New Jersey granted the motion of the Company to dismiss the class action complaint and dismissed the complaint with prejudice. On April 30, 2009, the plaintiffs filed a notice of appeal with the Appellate Division. On May 13, 2009, the plaintiffs filed a motion for relief from judgment based on a claim of new evidence, which was denied on June 12, 2009. The plaintiffs also asked the Appellate Division for a temporary remand to permit the Superior Court judge to resolve the issues of the new evidence plaintiffs sought to raise. By order dated June 25, 2009, and filed on July 6, 2009, the Appellate Division granted the motion for temporary remand, and directed the issues on remand to be resolved in 30 days. A hearing on the plaintiffs' motion was held on July 31, 2009, at which time the Court permitted letter briefing on the issues raised during that hearing. The plaintiffs submitted a letter brief on August 3, 2009, and the Company submitted a letter brief on August 5, 2009. No ruling has yet issued. The Company strongly denies the allegations of this complaint and intends to vigorously defend this lawsuit.

In November 2008, a complaint against the Company and its transfer agent, BNY Mellon Shareholder Services, was filed in the Supreme Court of the State of New York by an individual stockholder. The complaint alleges that the Company and its transfer agent caused or contributed to losses suffered by the stockholder. The Company denies the allegations of this complaint and intends to vigorously defend this lawsuit.

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

No interest or income taxes were paid with cash during the six months ended June 30, 2009 and 2008, respectively. On March 9, 2009, the Company issued approximately \$386 thousand of convertible notes in lieu of interest due on its 2008 Notes. On June 9, 2009, the Company issued approximately \$125 thousand of convertible notes in lieu of interest due on its 2008 Notes.

From January 1, 2009 through June 30, 2009, holders of the Company's convertible notes voluntarily converted approximately \$13.2 million, resulting in an issuance of 90.0 million shares of common stock.

11. Subsequent Events

From July 1, 2009 through July 31, 2009, holders of 2008 Notes have voluntarily converted approximately \$0.7 million of their notes, resulting in an issuance of approximately 7.0 million shares of common stock. At July 31, 2009, approximately \$2.2 million of the 2008 notes were outstanding.

From July 1, 2009 through July 31, 2009 holders of April 2009 Notes have voluntarily converted approximately \$0.7 million of their notes resulting in an issuance of approximately 7.0 million shares of common stock. At July 31, 2009, approximately \$5.3 million of the April 2009 Notes were outstanding.

On July 7, 2009, the Company entered into a securities purchase agreement with certain accredited institutional investors to place up to \$10 million in aggregate principal amount of units consisting of (i) 70% unsecured subordinated convertible notes, or the July 2009 Notes, and (ii) 30% common stock. The notes bear interest at an annual rate of 8% payable at quarterly intervals in other convertible notes to the holder, and are convertible into shares of Genta common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal. In connection with the sale of the units, the Company also issued to the investors two-year warrants to purchase common stock in an amount equal to 25% of the number of shares of common stock issuable upon conversion of the July 2009 Notes purchased by each investor. The Company closed on \$3.0 million of such July 2009 Notes, common stock and warrants on July 7, 2009. In accordance with EITF 00-27, the Company will measure the fair value of the July 2009 Notes and the warrants. As the fair value of the beneficial conversion feature of the July 2009 Notes exceeds the face value of the \$2.1 million, the Company will record a full debt discount in an amount equal to the face value of the debt and amortize this discount over the life of the July 2009 Notes.

On August 6, 2009, the Company entered into an amendment whereby, among other things, the certain accredited institutional investors who were parties to the July 2009 securities purchase agreement agreed to purchase \$10 million of additional notes and warrants having the same terms of the July 2009 Notes as well as shares of common stock, increasing their aggregate investment to \$13 million.

From July 7, 2009 through July 31, 2009, holders of July 2009 Notes have voluntarily converted approximately \$1.4 million of their notes, resulting in an issuance of approximately 13.5 million shares of common stock. At July 31, 2009, approximately \$0.8 million of the July 2009 Notes were outstanding.



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. Such forward-looking statements include those which express plan, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. The words “potentially”, “anticipate”, “expect”, “could”, “calls for” and similar expressions also identify forward-looking statements. 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. Factors that could affect actual results include risks associated with:

- 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, license and sell its products or product candidates;
- the Company's ability to enter into and successfully execute license and collaborative agreements, if any;
- the adequacy of the Company's capital resources and cash flow projections, 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; 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, 2008 and in this Form 10-Q.

We do not undertake to update any forward-looking statements.

We make available free of charge on our Internet website (<http://www.genta.com>) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. The content on the Company's website is available for informational purposes only. It should not be relied upon for investment purposes, nor is it incorporated by reference into this Form 10-Q.

## Overview

Genta Incorporated is a biopharmaceutical company engaged in pharmaceutical research and development. We are dedicated to the identification, development and commercialization of novel drugs for the treatment of cancer and related diseases. Our research portfolio consists of two major programs: DNA/RNA Medicines (which includes our lead oncology drug, Genasense®); and Small Molecules (which includes our marketed product, Ganite®, and the investigational compounds tesetaxel and G4544). 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 June 30, 2009, we have incurred a cumulative net deficit of \$998.3 million. Our recurring losses from operations and our negative cash flow from operations raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. We expect that such losses will continue at least until our lead product, Genasense®, is approved by one or more regulatory authorities 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.

Irrespective of whether regulatory applications, such as 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, debt 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 funds 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 had \$0.7 million of cash and cash equivalents on hand at June 30, 2009. Cash used in operating activities during the first six months of 2009 was \$9.5 million.

On June 9, 2008, we placed \$20 million of senior secured convertible notes with certain institutional and accredited investors. On April 2, 2009, we entered into a securities purchase agreement with certain accredited institutional investors to place up to \$12 million of senior secured convertible notes, or the April 2009 Notes, and corresponding warrants to purchase common stock. We closed on approximately \$6 million of such notes and warrants on April 2, 2009. On July 7, 2009, we entered into a securities purchase agreement with certain accredited institutional investors to place up to \$10 million in aggregate principal amount of units consisting of (i) 70% unsecured subordinated convertible notes, or the July 2009 Notes, and (ii) 30% common stock. The notes bear interest at an annual rate of 8% payable at quarterly intervals in other convertible notes to the holder, and are convertible into shares of our common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal. In connection with the sale of the units, we also issued to the investors two-year warrants to purchase common stock in an amount equal to 25% of the number of shares of common stock issuable upon conversion of the July 2009 Notes purchased by each investor. We closed on \$3.0 million of such July 2009 Notes, common stock and warrants on July 7, 2009.

On August 6, 2009, we entered into an amendment whereby, among other things, the certain accredited institutional investors who were parties to the July 2009 securities purchase agreement agreed to purchase \$10 million of additional notes and warrants having the same terms of the July 2009 Notes as well as shares of common stock, increasing their aggregate investment to \$13 million.



Presently, with no further financing, we project that we will run out of funds in September, 2009. The terms of the July 2009 financing, as amended, commit those investors to purchase \$10 million of additional notes and warrants having the same terms of the July 2009 Notes, as well as shares of common stock. If that additional financing is consummated, we project that we will run out of funds in January 2010. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase additional notes with similar terms. We currently do not have any additional financing in place. If we are unable to raise additional funds, we could be required to reduce our spending plans, reduce our workforce, license one or more of our products or technologies that we would otherwise seek to commercialize ourselves, or sell certain assets. There can be no assurance that we can obtain financing, if at all, on terms acceptable to us.

Our principal goal has been to secure regulatory approval for the marketing of Genasense®. Genasense® has been studied in combination with a wide variety of anticancer drugs in a number of different cancer indications. We have reported results from randomized trials of Genasense® in a number of diseases. Under our own sponsorship or in collaboration with others, we are currently conducting additional clinical trials. We are especially interested in the development, regulatory approval, and commercialization of Genasense® in at least three diseases: melanoma; chronic lymphocytic leukemia, referred to herein as CLL; and non-Hodgkin's lymphoma, referred to herein as NHL.

Genasense® has been submitted for regulatory approval in the U.S. on two occasions and to the European Union (EU) once. These applications proposed the use of Genasense® plus chemotherapy for patients with advanced melanoma (U.S. and EU) and relapsed or refractory chronic lymphocytic leukemia (CLL) (U.S.-only). None of these applications resulted in regulatory approval for marketing. Nonetheless, we believe that Genasense® can ultimately be approved and commercialized and we have undertaken a number of initiatives in this regard that are described below.

Our major current initiative is a randomized controlled trial that tests whether the addition of Genasense® to standard chemotherapy can improve outcomes for patients with advanced melanoma. In 2004, we withdrew our New Drug Application (NDA) for Genasense® in melanoma after an advisory committee to the Food and Drug Administration (FDA) failed to recommend approval. A negative decision was also received for a similar application in melanoma from the European Medicines Agency (EMA) in 2007. Data from the Phase 3 trial that comprised the basis for these applications were published in 2006. These results showed that treatment with Genasense® plus dacarbazine compared with dacarbazine alone in patients with advanced melanoma was associated with a statistically significant increase in overall response, complete response, durable response, and progression-free survival (PFS). However, the primary endpoint of overall survival approached but did not quite reach statistical significance ( $P=0.077$ ). Subsequently, our analysis of this trial showed that there was a significant treatment interaction effect related to levels of a blood enzyme known as LDH. 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® ( $P=0.018$ ;  $n=508$ ). Moreover, this benefit was particularly noteworthy for patients whose baseline LDH did not exceed 80% of the upper limit of normal for this lab value. LDH had also been previously described by others as the single most important prognostic factor in advanced melanoma.

Based on these data, in August 2007 we initiated a new Phase 3 trial of Genasense® plus chemotherapy in advanced melanoma. This trial, known as AGENDA, is a randomized, double-blind, placebo-controlled study in which patients are randomly assigned to receive Genasense® plus dacarbazine or dacarbazine alone. The study uses LDH as a biomarker to identify patients who are most likely to respond to Genasense®, based on data obtained from our preceding trial in melanoma. The co-primary endpoints of AGENDA are progression-free survival (PFS) and overall survival.

AGENDA is designed to expand evidence for the safety and efficacy of Genasense® when combined with dacarbazine for patients who have not previously been treated with chemotherapy. The study prospectively targets patients who have low-normal levels of LDH. In March 2009, we completed accrual of 315 patients into AGENDA. In May 2009, an analysis by an independent Data Monitoring Committee for both safety and futility indicated that the study passed an evaluation for futility and safety. Accordingly, the Committee recommended that the study should continue to completion. We expect results on the primary assessment of PFS in the fourth quarter of 2009. If those data are positive, we currently expect to submit regulatory applications based upon confirmation that the addition of Genasense® to chemotherapy results in a statistically significant improvement in PFS. Approval by FDA and EMEA will allow Genasense® to be commercialized by us, alone or with a partner, in the U.S. and EU. Genasense® in melanoma has been designated an Orphan Drug in Australia and the U.S., and the drug has received Fast Track designation in the U.S.

We are conducting other trials of Genasense® in melanoma, including a Phase 2 trial of Genasense® plus chemotherapy consisting of Abraxane® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus temozolomide (Temodar®). We also expect to examine different dosing regimens that will improve the dosing convenience and commercial acceptance of Genasense®, including its administration by brief (1-2 hour) IV infusions.

Our NDA for the use of Genasense® plus chemotherapy in patients with relapsed or refractory CLL was not approved. We conducted a randomized Phase 3 trial in 241 patients with relapsed or refractory CLL who were treated with fludarabine and cyclophosphamide (Flu/Cy) with or without Genasense®. The trial achieved its primary endpoint: a statistically significant increase (17% vs. 7%;  $P=0.025$ ) in the proportion of patients who achieved a complete response (CR), defined as a complete or nodular partial response. Patients who achieved this level of response also experienced disappearance of predefined disease symptoms. A key secondary endpoint, duration of CR, was also significantly longer for patients treated with Genasense® (median exceeding 36+ months in the Genasense® group, versus 22 months in the chemotherapy-only group).

Several secondary endpoints were not improved by the addition of Genasense®. 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®.

We submitted our NDA to the FDA in December 2005 in which we sought accelerated approval for the use of Genasense® in combination with Flu/Cy for the treatment of patients with relapsed or refractory CLL who had previously received fludarabine. In December 2006, we received a “non-approvable” notice for that application from FDA. In April 2007, we filed an appeal of the non-approvable notice using FDA’s Formal Dispute Resolution process. In March 2008, we received a formal notice from FDA that indicated additional confirmatory evidence would be required to support approval of Genasense® in CLL, either from a new clinical trial or from collection of additional information regarding the progression of disease in patients from the completed trial.

In June 2008, we announced results from 5 years of follow-up on patients who had been accrued to our completed Phase 3 trial. These data showed that patients treated with Genasense® plus chemotherapy who achieved either a complete response (CR) or a partial response (PR) also achieved a statistically significant increase in survival compared with patients treated with chemotherapy alone (median = 56 months vs. 38 months, respectively). After 5 years of follow-up, 22 of 49 (45%) responders in the Genasense® group were alive compared with 13 of 54 (24%) responders in the chemotherapy-only group (hazard ratio = 0.6;  $P = 0.038$ ). Moreover, with 5 years of follow-up, 12 of 20 patients (60%) in the Genasense® group who achieved CR were alive, 5 of these patients remained in continuous CR without relapse, and 2 additional patients had relapsed but had not required additional therapy. By contrast, only 3 of 8 CR patients in the chemotherapy-only group were alive, all 3 had relapsed, and all 3 had required additional

anti-leukemic treatment.

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These data were again submitted to FDA in the second quarter of 2008, and the application was again denied in December 2008. Genta re-appealed the denial, and in March 2009, CDER decided that available data were still insufficient to support approval of Genasense® in CLL, and the Agency recommended conducting another clinical trial. We have made no decision whether to conduct this study.

As with melanoma, we believe the clinical activity in CLL should be explored with additional clinical research. We plan to explore combinations of Genasense® with other drugs that are used for the treatment of CLL, and to examine more convenient dosing regimens.

Several trials have shown definite evidence of clinical activity for Genasense® in patients with NHL. We would like to conduct additional clinical studies in patients with NHL to test whether Genasense® can be approved in this indication. Previously, we reported that randomized trials of Genasense® in patients with myeloma, AML, hormone-refractory prostate cancer, small cell lung cancer and non small cell lung cancer were not sufficiently positive to warrant further investigation on the dose-schedules that were examined or with the chemotherapy that was employed in these trials. Data from these trials have been presented at various scientific meetings. However, we believe that alternate dosing schedules, in particular the use of brief high-dose IV infusions, provide an opportunity to re-examine the drug's activity in some of these indications.

In March 2008, we obtained an exclusive worldwide license for tesetaxel from Daiichi Sankyo Company Ltd. Tesetaxel is a novel taxane compound that is taken by mouth. Tesetaxel has completed Phase 2 trials in a number of cancer types, and the drug has shown definite evidence of antitumor activity in gastric cancer and breast cancer. Tesetaxel also appears to be associated with a lower incidence of peripheral nerve damage, a common side effect of taxanes that limits the maximum amount of these drugs that can be given to patients. At the time we obtained the license, tesetaxel was on "clinical hold" by FDA due to the occurrence of several fatalities in the setting of severe neutropenia. In the second quarter of 2008, we filed a response to the FDA requesting a lift of the clinical hold, which was granted in June 2008. In January 2009, we announced initiation of a new clinical trial with tesetaxel to examine the clinical pharmacology of the drug over a narrow dosing range around the established Phase 2 dose.

We have also submitted applications to FDA for designation of tesetaxel as an Orphan Drug for treatment of patients with advanced gastric cancer and for patients with advanced melanoma. Both of these designations were granted. Our initial priority for clinical testing of tesetaxel includes the evaluation of safety and efficacy in patients with advanced gastric cancer. Other disease priorities for clinical research include advanced melanoma and bladder cancer, among other disorders. Maintenance of the license from Daiichi Sankyo requires certain payments that include amortization of licensing fees and milestones. If such payments are not made, Daiichi Sankyo may elect to terminate the license; however, a portion of the licensing fees are due even in the event of termination.

Our third pipeline product is G4544, which is a novel oral formulation of a gallium-containing compound that we developed in collaboration with Emisphere Technologies, Inc. We completed a single-dose Phase 1 study of an initial formulation of this new drug known as "G4544(a)", the results of which were presented in the second quarter of 2008. We are currently contemplating a second study using a modified formulation, known as "G4544(b)", in order to test whether this formulation will prove more clinically acceptable.

If we are able to identify a clinically and commercially acceptable formulation of G4544 or another oral gallium-containing compound, we currently intend to pursue a 505(b)(2) strategy to establish bioequivalence to our marketed product, Ganite®, for its initial regulatory approval. We believe a drug of this type may also be broadly useful for treatment of other diseases associated with accelerated bone loss, such as bone metastases, Paget's disease and osteoporosis. In addition, new uses of gallium-containing compounds have been identified for treatment of certain infectious diseases. While we have no current plans to begin clinical development in the area of infectious disease, we intend to support research conducted by certain academic institutions by providing clinical supplies of our

gallium-containing drugs.

We are currently marketing Ganite® in the U.S., which is an intravenous formulation of gallium, for treatment of cancer-related hypercalcemia that is resistant to hydration. We have announced our intention to seek a buyer for Ganite®, but we have not yet found an acceptable transaction.

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## Results of Operations for the Three Months Ended June 30, 2009 and June 30, 2008

(\$ thousands)	2009	2008
Product sales – net	\$ 69	\$ 131
Cost of goods sold	1	29
Gross margin	68	102
Operating expenses:		
Research and development	3,674	4,454
Selling, general and administrative	1,968	2,587
Settlement of office lease obligation	-	3,307
Reduction in liability for settlement of litigation	-	(80)
Total operating expenses	5,642	10,268
Other (expense)/income:		
Interest income and other income, net	1	40
Interest expense	(189)	(198)
Amortization of deferred financing costs and debt discount	(10,625)	(840)
Fair value – conversion feature liability	(19,040)	(720,000)
Fair value – warrant liability	(7,655)	(7,200)
Total other income/(expense), net	(37,508)	(728,198)
Net loss	\$ (43,082)	\$ (738,364)

## Product sales-net

Product sales-net were \$69,000 for the three months ended June 30, 2009, compared with \$131,000 for the three months ended June 30, 2008. Unit sales of Ganite® declined 76% due to the continued absence of promotional support. Product sales-net include sales through the “named-patient” program managed for us by IDIS Limited (a privately owned company based in the United Kingdom), whereby IDIS distributes Ganite® and Genasense® on a “named patient” basis. “Named patient” distribution refers to the distribution or sale of a product to a specific healthcare professional for the treatment of an individual patient. Product sales-net in 2009 include named-patient program sales of \$35,000, while 2008 results include named-patient program sales of \$5,000.

## Cost of goods sold

During the three months ended June 30, 2009, virtually all sales of Ganite® were from product that had been previously accounted for as excess inventory.

## Research and development expenses

Research and development expenses were \$3.7 million for the three months ended June 30, 2009, compared with \$4.5 million for the three months ended June 30, 2008. Expenses in 2009 declined primarily due to lower expenses on the AGENDA clinical trial and lower payroll costs, resulting from lower headcount as we reduced our workforce in April 2008 and May 2008 to conserve cash.

Research and development expenses incurred on the Genasense® project during the three months ended June 30, 2009 were approximately \$3.4 million, representing 91% 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 \$2.0 million for the three months ended June 30, 2009, compared with \$2.6 million for the three months ended June 30, 2008. This decrease was primarily due to lower office rent of \$0.3 million, resulting from our termination of a lease for one floor of office space in May 2008 and lower payroll costs of \$0.2 million, resulting from the two reductions in workforce.

#### Settlement of office lease obligation

In May 2008, we entered into an amendment of our lease for office space with The Connell Company, (Connell) whereby the lease for one floor of our office space in Berkeley Heights, New Jersey was terminated. Connell received a termination payment of \$1.3 million, comprised solely of our security deposits and we agreed to pay Connell \$2.0 million upon the earlier of July 1, 2009 or our receipt of at least \$5.0 million in upfront cash from a business development deal. In January 2009, we entered into another amendment of our agreement with Connell whereby our future payment of \$2.0 million is now payable on January 1, 2011. We accrued for the \$2.0 million and it is included on our Consolidated Balance Sheets. We will pay 6.0% interest in arrears to Connell from July 1, 2009 through the new payment date. The initial interest payment of approximately \$30 thousand will be payable as of October 1, 2009.

#### Interest and other income, net

##### Interest expense

The total of interest and other income, net and interest expense resulted in expense, net of \$(0.2) million for the first three months of 2009, virtually unchanged from the prior-year period. A lower balance of our 2008 Notes, resulting in lower interest expense, was offset by interest expense on our April 2009 Notes.

#### Amortization of deferred financing costs and debt discount

On April 2, 2009, we issued approximately \$6 million of April 2009 Notes, and corresponding warrants to purchase common stock, issued our private placement agent a warrant and incurred financing fees of \$0.7 million. The deferred financing costs, including the financing fee and the issuance of the warrants, are being amortized over the three-year term of the convertible notes. On April 2, 2009, we recorded a debt discount (beneficial conversion) relating to the conversion feature in the amount of approximately \$6.0 million. We are amortizing the resultant debt discount over the term of the notes through their maturity date.

On June 9, 2008, we issued \$20 million of 2008 Notes, issued our private placement agent a warrant and incurred financing fees of \$1.2 million. The deferred financing costs, including the financing fee and the issuance of the warrant, are being amortized over the two-year term of the convertible notes. At the time the notes were issued, we recorded a debt discount (beneficial conversion) relating to the conversion feature in the amount of \$20.0 million. We are amortizing the resultant debt discount over the term of the notes through their maturity date.

As a result of issuing the April 2009 Notes, the conversion rate for the 2008 Notes was adjusted to be the same conversion rate as the April 2009 Notes. Accordingly, the 2008 Notes that originally were convertible into shares of Genta common stock at a conversion rate of 2,000 shares of common stock for every \$1,000.00 of principal were adjusted to be convertible into shares of Genta common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal. In accordance with EITF 00-27, we valued this change in the conversion rate on April 2, 2009; the aggregate intrinsic value of the difference in conversion rates was in excess of the \$10.7 million face value of the 2008 Notes. Thus, a full debt discount was recorded in an amount equal to the face value of the 2008 Notes and we are amortizing the resultant debt discount over the remaining term of the 2008 Notes.



For the three months ended June 30, 2009, the amortization of deferred financing costs and debt discount for the 2008 Notes was \$9.8 million and for the April 2009 Notes was \$0.8 million. In the prior-year quarter, the \$0.8 million amortization of deferred financing costs and debt discount resulted from the 2008 Notes.

#### Fair value – conversion feature liability

On the dates that we issued the 2008 Notes and the April 2009 Notes, there were an insufficient number of authorized shares of common stock in order to permit conversion of all of the notes. In accordance with EITF 00-19, “Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock” (EITF 00-19), when there are insufficient authorized shares to allow for settlement of convertible financial instruments, the conversion obligation for the notes should be classified as a liability and measured at fair value on the balance sheet.

On April 2, 2009, using a Black-Scholes valuation model, we calculated a fair value of the conversion feature of the April 2009 Notes of \$67.8 million and expensed \$61.8 million, the amount that exceeded the proceeds of the \$6.0 million from the closing. On June 26, 2009, our stockholders, at a Special Meeting of Stockholders, authorized our Board of Directors to effect a reverse stock split and our Board of Directors effected a 1-for-50 reverse stock split, resulting in us having enough shares of common stock in order to permit conversion of all the April 2009 Notes. We re-measured the conversion feature liability at \$25.0 million, resulting in net expense for the three months ended June 30, 2009 of \$19.0 million and credited it to permanent equity.

On June 9, 2008, based upon a Black-Scholes valuation model, we calculated a fair value of the conversion feature of the 2008 Notes of \$380.0 million and expensed \$360.0 million, the amount that exceeded the proceeds of the \$20.0 million from the closing. On June 30, 2008, we expensed an additional \$380.0 million to mark the conversion feature liability of the 2008 Note to market, resulting in a total expense in June 2008 of \$720.0 million.

#### Fair value – warrant liability

The warrants that were issued with the 2008 Notes and the April 2009 Notes were also treated as liabilities, due to the insufficient number of authorized shares of common stock at the time that they were issued.

On April 2, 2009, using a Black-Scholes valuation model, we calculated a fair value of \$1.125 per warrant for the warrants issued with the April 2009 Notes, or a total of \$20.8 million. On June 26, 2009, the date of the reverse stock split, we re-measured the warrants at a fair value per warrant of \$0.415 per warrant, or \$7.7 million, resulting in expense of \$7.7 million, and credited them to permanent equity.

The warrants issued with the 2008 Notes were initially recorded at a fair value of \$7.6 million based upon a Black-Scholes valuation model and re-measured at June 30, 2008, resulting in expense of \$7.2 million in June 2008.

#### Net loss

Genta recorded a net loss of \$43.1 million, or net loss per basic and diluted share of \$0.63, for the three months ended June 30, 2009 and incurred a net loss of \$738.4 million, or net loss per basic and diluted share of \$1,004.84, for the three months ended June 30, 2008.

The lower net loss for the three months ended June 30, 2009 was primarily due to lower expenses from marking to market the conversion feature liabilities of our notes. In addition, the results reflect our lower operational expenses, primarily attributable to reduced headcount and payroll expenses, and higher amortization of financing costs and debt discount.



## Results of Operations for the Six Months Ended June 30, 2009 and June 30, 2008

(\$ thousands)	2009	2008
Product sales – net	\$ 131	\$ 248
Cost of goods sold	1	54
Gross margin	130	194
Operating expenses:		
Research and development	5,972	10,891
Selling, general and administrative	4,140	6,225
Settlement of office lease obligation	-	3,307
Reduction in liability for settlement of litigation	-	(340)
Total operating expenses	10,112	20,083
Other (expense)/income:		
Gain on maturity of marketable securities	-	31
Interest income and other income, net	16	100
Interest expense	(576)	(223)
Amortization of deferred financing costs and debt discount	(16,912)	(840)
Fair value – conversion feature liability	(19,040)	(720,000)
Fair value – warrant liability	(7,655)	(7,200)
Total other income/(expense), net	(44,167)	(728,132)
Net loss	\$ (54,149)	\$ (748,021)

## Product sales-net

Product sales-net were \$131,000 for the six months ended June 30, 2009, compared with \$248,000 for the six months ended June 30, 2008. Unit sales of Ganite® declined 48%. Product sales-net in 2009 include named-patient program sales of \$48,000, while 2008 results include named-patient program sales of \$15,000.

## Cost of goods sold

During the six months ended June 30, 2009, virtually all sales of Ganite® were from product that had been previously accounted for as excess inventory.

## Research and development expenses

Research and development expenses were \$6.0 million for the six months ended June 30, 2009, compared with \$10.9 million for the six months ended June 30, 2008. In March 2008, we entered into a worldwide license agreement for tasetaxel. Pursuant to this agreement, we recognized \$2.5 million for license payments in March 2008. Expenses in 2009 also declined primarily due to lower payroll costs, resulting from lower headcount as we reduced our workforce in April 2008 and May 2008 to conserve cash as well as lower expenses on the AGENDA clinical trial.

Research and development expenses incurred on the Genasense® project during the six months ended June 30, 2009 were approximately \$5.4 million, representing 91% of research and development expenses.

## Selling, general and administrative expenses

Selling, general and administrative expenses were \$4.1 million for the six months ended June 30, 2009, compared with \$6.2 million for the six months ended June 30, 2008. This decrease was primarily due to lower payroll costs of \$0.9 million, resulting from the two reductions in workforce and lower office rent of \$0.8 million, resulting from our termination of a lease for one floor of office space in May 2008.



Gain on maturity of marketable securities  
Interest and other income, net  
Interest expense

The total of the above referenced accounts resulted in expense, net of \$(0.6) million for the six months ended June 30, 2009, compared with expense, net of \$(0.1) million for the prior-year period. This increase was primarily due to interest incurred on the 2008 Notes and the April 2009 Notes, as well as lower interest income, resulting from lower investment balances.

Amortization of deferred financing costs and debt discount

For the six months ended June 30, 2009, the amortization of deferred financing costs and debt discount for the 2008 Notes was \$16.1 million and for the April 2009 Notes was \$0.8 million. In the prior-year period, the \$0.8 million amortization of deferred financing costs and debt discount resulted from the 2008 Notes.

Net loss

Genta recorded a net loss of \$54.1 million, or net loss per basic and diluted share of \$1.24, for the six months ended June 30, 2009 and incurred a net loss of \$748.0 million, or net loss per basic and diluted share of \$1,060.69, for the six months ended June 30, 2008.

The lower net loss for the six months ended June 30, 2009 was primarily due to lower expenses from marking to market the conversion feature liabilities of our notes. In addition, the results reflect, our lower operational expenses, primarily attributable to last year's settlement of office lease obligation, reduced headcount and payroll expenses, and higher amortization of financing costs and debt discount.

Liquidity and Capital Resources

At June 30, 2009, we had cash and cash equivalents totaling \$0.7 million, compared with \$4.9 million at December 31, 2008, reflecting the funds used in operating our company.

On June 9, 2008, we placed \$20 million of 2008 Notes with certain institutional and accredited investors. The 2008 Notes bear interest at an annual rate of 15% payable at quarterly intervals in other senior secured convertible promissory notes to the holder, and are presently convertible into shares of Genta common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal.

On April 2, 2009, we closed on approximately \$6 million of April 2009 notes and warrants. The April 2009 Notes bear interest at an annual rate of 8% payable semi-annually in other senior secured convertible promissory notes to the holder, and are convertible into shares of our common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal amount outstanding.

On July 7, 2009, we entered into a securities purchase agreement with certain accredited institutional investors to place up to \$10 million in aggregate principal amount of units consisting of (i) 70% unsecured subordinated convertible notes, or the July 2009 Notes, and (ii) 30% common stock. In connection with the sale of the units, we also issued to the investors two-year warrants to purchase common stock in an amount equal to 25% of the number of shares of common stock issuable upon conversion of the Notes purchased by each investor. We closed on \$3 million of such July 2009 Notes, common stock and warrants on July 7, 2009.

On August 6, 2009, we entered into an amendment whereby, among other things, the certain accredited institutional investors who were parties to the July 2009 securities purchase agreement agreed to purchase \$10 million of additional notes and warrants having the same terms of the July 2009 Notes as well as shares of common stock, increasing their aggregate investment to \$13 million.

During the first six months of 2009, cash used in operating activities was \$9.5 million compared with \$14.4 million for the same period in 2008, reflecting the reduced size of our company.

Presently, with no further financing, we project that we will run out of funds in September 2009. The terms of the July 2009 financing, as amended, commit those investors to purchase \$10 million of additional notes and warrants having the same terms of the July 2009 Notes as well as shares of common stock. If that additional financing is consummated, we project that we will run out of funds in January 2010. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase additional notes with similar terms. We currently do not have any additional financing in place. If we are unable to raise additional funds, we could be required to reduce our spending plans, reduce our workforce, license one or more of our products or technologies that we would otherwise seek to commercialize ourselves, or sell certain assets. There can be no assurance that we can obtain financing, if at all, on terms acceptable to us.

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

We 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; and (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.

#### Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting. SFAS 168 represents the last numbered standard to be issued by FASB under the old (pre-Codification) numbering system, and amends the GAAP hierarchy. On July 1, 2009, FASB will launch new FASB's Codification (full name: the FASB Accounting Standards Codification TM.) The Codification will supersede existing GAAP for nongovernmental entities; governmental entities will continue to follow standards issued by FASB's sister organization, the Governmental Accounting Standards Board (GASB). This pronouncement has no effect on Company's financial statements.

In May 2009, the FASB issued SFAS 165, Subsequent Events. SFAS 165 incorporates into authoritative accounting literature certain guidance that already existed within generally accepted auditing standards, but the rules concerning recognition and disclosure of subsequent events will remain essentially unchanged. Subsequent events guidance addresses events which occur after the balance sheet date but before the issuance of financial statements. Under Statement No. 165 as under current practice, an entity must record the effects of subsequent events that provide evidence about conditions that existed at the balance sheet date and must disclose but not record the effects of subsequent events which provide evidence about conditions that did not exist at the balance sheet date. We adopted SFAS 165 and it did not have an impact on our consolidated financial statements. There were no recognized or nonrecognized subsequent events occurring after June 30, 2009 that required accounting or disclosure in accordance

with SFAS 165. Subsequent events were evaluated to August 14, 2009, the date the financial statements of the Company were issued.

In April 2009, the FASB issued FASB Staff Position SFAS 141(R)-1, Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies, to amend and clarify the initial recognition and measurement, subsequent measurement and accounting, and related disclosures arising from contingencies in a business combination under SFAS 141(R). Under the new guidance, assets acquired and liabilities assumed in a business combination that arise from contingencies should be recognized at fair value on the acquisition date if fair value can be determined during the measurement period. If fair value can not be determined, companies should typically account for the acquired contingencies using existing guidance. The implementation of this standard did not have a material effect on our consolidated financial statements.

#### Critical Accounting Policies and Estimates

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements. In preparing our financial statements in accordance with accounting principles generally accepted in the United States of America, management is required to make estimates and assumptions that, among other things, affect the reported amounts of assets and liabilities and reported amounts of revenues and expenses. These estimates are most significant in connection with our critical accounting policies, namely those of our accounting policies that are most important to the portrayal of our financial condition and results and require management's most difficult, subjective or complex judgments. These judgments often result from the need to make estimates about the effects of matters that are inherently uncertain. Actual results may differ from those estimates under different assumptions or conditions. We believe that the following represents our critical accounting policies:

- **Going concern.** Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statement for the year ended December 31, 2008 with respect to this uncertainty. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.
- **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.
  - **Research and development costs.** All such costs are expensed as incurred, including raw material costs required to manufacture drugs for clinical trials.
- **Estimate of fair value of convertible notes and warrant.** We use a Black-Scholes model to estimate the fair value of our convertible notes and warrant.

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

Our carrying values of cash, marketable securities, accounts payable, accrued expenses and debt are a reasonable approximation of their fair value. The estimated fair values of financial instruments have been determined by us using available market information and appropriate valuation methodologies. 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 June 30, 2009. Therefore, there will be no ongoing exposure to a potential material adverse effect on our business, financial condition or results of operation for sensitivity to changes in interest rates or to changes in currency exchange rates.

### Item 4T. 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 Principal Accounting and 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 Principal Accounting and 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 September 2008, several shareholders of our Company, on behalf of themselves and all others similarly situated, filed a class action complaint against our Company, our Board of Directors, and certain of our executive officers in Superior Court of New Jersey, captioned *Collins v. Warrell*, Docket No. L-3046-08. The complaint alleged that in issuing convertible notes, our Board of Directors, and certain officers breached their fiduciary duties, and our Company aided and abetted the breach of fiduciary duty. On March 20, 2009, the Superior Court of New Jersey granted the motion of our Company to dismiss the class action complaint and dismissed the complaint with prejudice. On April 30, 2009, the plaintiffs filed a notice of appeal with the Appellate Division. On May 13, 2009, the plaintiffs filed a motion for relief from judgment based on a claim of new evidence, which was denied on June 12, 2009. The plaintiffs also asked the Appellate Division for a temporary remand to permit the Superior Court judge to resolve the issues of the new evidence plaintiffs sought to raise. By order dated June 25, 2009, and filed on July 6, 2009, the Appellate Division granted the motion for temporary remand, and directed the issues on remand to be resolved in 30 days. A hearing on the plaintiffs' motion was held on July 31, 2009, at which time the Court permitted letter briefing on the issues raised during that hearing. The plaintiffs submitted a letter brief on August 3, 2009, and the Company submitted a letter brief on August 5, 2009. No ruling has yet issued. The Company strongly denies the allegations of this complaint and intends to vigorously defend this lawsuit.

In November 2008, a complaint against our Company and its transfer agent, BNY Mellon Shareholder Services, was filed in the Supreme Court of the State of New York by an individual stockholder. The complaint alleges that our Company and our transfer agent caused or contributed to losses suffered by the stockholder. Our Company denies the allegations of this 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, 2008 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.

If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In such case, the market price of our common stock would likely decline due to the occurrence of any of these risks, and you may lose all or part of your investment.

#### Risks Related to Our Business

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.

On June 9, 2008, we placed \$20 million of senior secured convertible notes, or the 2008 Notes, with certain institutional and accredited investors. The 2008 Notes bear interest at an annual rate of 15% payable at quarterly intervals in other senior secured convertible promissory notes to the holder, and are presently convertible into shares

of Genta common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal.



On April 2, 2009, we entered into a securities purchase agreement with certain accredited institutional investors to place up to \$12 million of senior secured convertible notes, or the April 2009 Notes, and corresponding warrants to purchase common stock. We closed on approximately \$6 million of such notes and warrants on April 2, 2009. The April 2009 Notes bear interest at an annual rate of 8% payable semi-annually in other senior secured convertible promissory notes to the holder, and are convertible into shares of our common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal amount outstanding.

On July 7, 2009, we entered into a securities purchase agreement with certain accredited institutional investors to place up to \$10 million in aggregate principal amount of units consisting of (i) 70% unsecured subordinated convertible notes, or the July 2009 Notes, and (ii) 30% common stock. In connection with the sale of the units, we also issued to the investors two-year warrants to purchase common stock in an amount equal to 25% of the number of shares of common stock issuable upon conversion of the Notes purchased by each investor. We closed on \$3.0 million of such July 2009 Notes, common stock and warrants on July 7, 2009.

On August 6, 2009, we entered into an amendment whereby, among other things, the certain accredited institutional investors who were parties to the July 2009 securities purchase agreement agreed to purchase \$10 million of additional notes and warrants having the same terms of the July 2009 Notes as well as shares of common stock, increasing their aggregate investment to \$13 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 one or more of our products or technologies that we would otherwise seek to commercialize ourselves;
  - attempt to sell our company or sell certain assets;
    - cease operations; or
    - declare bankruptcy.

Presently, with no further financing, we will run out of funds in September 2009. The terms of the July 2009 financing, as amended, commit those investors to purchase \$10 million of additional notes and warrants having the same terms of the July 2009 Notes, as well as shares of common stock. If that additional financing is consummated, we project that we will run out of funds in January 2010. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase additional notes with similar terms. We currently do not have any additional financing in place. There can be no assurance that we can obtain financing, if at all, on terms acceptable to us.

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. For example, the NDA for Genasense® in melanoma was withdrawn in 2004 after an advisory committee to the FDA failed to recommend approval. A negative decision was also received for a similar application in melanoma from the EMEA in 2007. Our NDA for Genasense® plus chemotherapy in patients with relapsed or refractory CLL was also unsuccessful.

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 outcomes with respect to FDA and/or EMEA approvals could negatively impact our ability to obtain additional funding or identify potential partners.

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

Recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and we may not be able to continue as a going concern.

Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statement for the year ended December 31, 2008 with

respect to this uncertainty. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of the common shares of our stock and we may have a more difficult time obtaining financing.

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

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 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 June 30, 2009, we have incurred a cumulative net deficit of \$998.3 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. If Genasense® is not approved, if approval is significantly delayed, or if in the event of approval the product is commercially unsuccessful, then 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.

Genta's patent portfolio includes approximately 65 granted patents and 66 pending applications in the U.S. and foreign countries. We endeavor to seek appropriate U.S. and foreign patent protection on our oligonucleotide technology.

We have licensed ten U.S. patents relating to Genasense® and its backbone chemistry that expire between 2008 and 2015. Corresponding patent applications have been filed in three foreign countries. We also own five U.S. patent applications relating to methods of using Genasense® expected to expire in 2020 and 2026, with approximately 50 corresponding foreign patent applications and granted patents.

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.

Between 2004 and 2007, we reported that randomized trials of Genasense® in patients with myeloma, acute myeloid leukemia, (AML), hormone-refractory prostate cancer, small cell lung cancer and non small cell lung cancer were not sufficiently positive to warrant further investigation on the dose-schedules that were examined or with the chemotherapy that was employed in these trials. Data from these trials have been presented at various scientific meetings.

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.

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 and taxanes, 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 to 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 litigation are uncertain.

In November 2008, a complaint against us and our transfer agent, BNY Mellon Shareholder Services, was filed in the Supreme Court of the State of New York by an individual stockholder. The complaint alleges that we and our transfer agent caused or contributed to losses suffered by the stockholder. We deny the allegations of the complaint and intend to vigorously defend this lawsuit.

In September 2008, several shareholders of the Company, on behalf of themselves and all others similarly situated, filed a class action complaint against the Company, the Board of Directors, and certain of its executive officers in Superior Court of New Jersey, captioned *Collins v. Warrell*, Docket No. L-3046-08. The complaint alleged that in issuing convertible notes, the Board of Directors, and certain officers breached their fiduciary duties, and the Company aided and abetted the breach of fiduciary duty. On March 20, 2009, the Superior Court of New Jersey granted the motion of the Company to dismiss the class action complaint and dismissed the complaint with prejudice. On April 30, 2009, the plaintiffs filed a notice of appeal with the Appellate Division. On May 13, 2009, the plaintiffs filed a motion for relief from judgment based on a claim of new evidence, which was denied on June 12, 2009. The plaintiffs also asked the Appellate Division for a temporary remand to permit the Superior Court judge to resolve the issues of the new evidence plaintiffs sought to raise. By order dated June 25, 2009, and filed on July 6, 2009, the Appellate Division granted the motion for temporary remand, and directed the issues on remand to be resolved in 30 days. A hearing on the plaintiffs' motion was held on July 31, 2009, at which time the Court permitted letter briefing on the issues raised during that hearing. The plaintiffs submitted a letter brief on August 3, 2009, and the Company submitted a letter brief on August 5, 2009. No ruling has yet issued. We strongly deny the allegations of this complaint and intend 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.

In September 2005, 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. 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 competitors, including litigation;
  - fluctuations in our operating results; and
- market conditions for biopharmaceutical stocks in general.



At June 30, 2009, our outstanding convertible notes were convertible into 88 million shares of common stock. On July 7, 2009, we sold \$3.0 million of notes, common stock and warrants. Future sales of shares of our common stock by existing stockholders, holders of convertible notes who might convert such convertible notes into common stock and warrant holders who may exercise their 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.

As our convertible noteholders convert their notes into shares of our common stock, our stockholders will be diluted.

On June 9, 2008, we placed \$20 million of the 2008 Notes, with certain institutional and accredited investors. The 2008 Notes are presently convertible, after adjusting for the April 2009 note offering and the 1:50 reverse stock split, into shares of our common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal. At June 30, 2009, our outstanding 2008 Notes were convertible into approximately 28.3 million shares of our common stock.

On April 2, 2009, we closed on approximately \$6 million of the April 2009 Notes. The April 2009 Notes are convertible into shares of our common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal amount outstanding, adjusting for the 1:50 reverse stock split. At June 30, 2009, our outstanding April 2009 Notes were convertible into approximately 59.5 million shares of our common stock.

On July 7, 2009, we entered into a securities purchase agreement with certain accredited institutional investors to place up to \$10 million in aggregate principal amount of units consisting of (i) 70% unsecured subordinated convertible notes, or the Notes, and (ii) 30% common stock. In connection with the sale of the units, we also issued to the investors two-year warrants to purchase common stock in an amount equal to 25% of the number of shares of common stock issuable upon conversion of the Notes purchased by each investor. We closed on \$3.0 million of such Notes, common stock and warrants on July 7, 2009.

On August 6, 2009, we entered into an amendment whereby, among other things, the certain accredited institutional investors who were parties to the July 2009 securities purchase agreement agreed to purchase \$10 million of additional notes and warrants having the same terms of the July 2009 Notes as well as shares of common stock, increasing their aggregate investment to \$13 million.

The conversion of some or all of our notes dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon conversion of the notes could adversely affect prevailing market prices of our common stock. In addition, the existence of the notes may encourage short selling by market participants because the conversion of the notes could depress the price of our common stock.

If holders of our notes elect to convert their notes and sell material amounts of our common stock in the market, such sales could cause the price of our common stock to decline, and such downward pressure on the price of our common stock may encourage short selling of our common stock by holders of our notes or others.

If there is significant downward pressure on the price of our common stock, it may encourage holders of notes or others to sell shares by means of short sales to the extent permitted under the U.S. securities laws. Short sales involve the sale by a holder of notes, usually with a future delivery date, of common stock the seller does not own. Covered short sales are sales made in an amount not greater than the number of shares subject to the short seller's right to acquire common stock, such as upon conversion of notes. A holder of notes may close out any covered short position by converting its notes or purchasing shares in the open market. In determining the source of shares to close out the covered short position, a holder of notes will likely consider, among other things, the price of common stock available for purchase in the open market as compared to the conversion price of the notes. The existence of a significant number of short sales generally causes the price of common stock to decline, in part because it indicates that a number of market participants are taking a position that will be profitable only if the price of the common stock declines.

Our common stock is considered a "penny stock" and does not qualify for exemption from the "penny stock" restrictions, which may make it more difficult for you to sell your shares.

Our common stock is classified as a "penny stock" by the SEC and is subject to rules adopted by the SEC regulating broker-dealer practices in connection with transactions in "penny stocks." The SEC has adopted regulations which define a "penny stock" to be any equity security that has a market price of less than \$5.00 per share, or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, these rules require delivery, prior to any transaction in a penny stock, of a disclosure schedule relating to the penny stock market. Disclosure is also required to be made about current quotations for the securities and commissions payable to both the broker-dealer and the registered representative. Finally, broker-dealers must send monthly statements to purchasers of penny stocks disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. As a result of our shares of common stock being subject to the rules on penny stocks, the liquidity of our common stock may be adversely affected.

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

As previously disclosed on Current Reports on Forms 8-K filed by the Company on April 6, 2009 and July 8, 2009, the Company has issued unregistered equity securities.

Item 3. Defaults Upon Senior Securities

None.

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

- a) The Company held a Special Meeting of Stockholders, herein after referred to as the Special Meeting, on June 26, 2009.
  - b) Proxies for the meeting were solicited pursuant to Regulation 14A of the Exchange Act. There was no solicitation in opposition to the definitive proxy statement dated as of May 28, 2009.
  - c) At the Special Meeting, stockholders voted to approve the resolution that was proposed in the proxy statement. Briefly described below is the resolution voted upon at the Special Meeting and the corresponding results.
- 1) To authorize the Board of Directors to effect a reverse stock split of the outstanding Common Stock at any exchange ratio up to 1-for-100. The result of the voting, on a pre-split basis was as follows:

For:	2,725,320,481
Against:	648,253,338
Abstained:	6,386,610

Item 5. Other Information

On August 29, 2008, the Company filed a Form S-1 Registration Statement with the Securities and Exchange Commission for the offer and sale of the Company's common stock. On March 9, 2009, the Company amended its filing to be for the offer and sale of the Company's convertible debt securities and warrants. On July 30, 2009, the Company amended its filing to be for the offer and sale of the Company's common stock, convertible debt securities and warrants. The Form S-1/A is not effective and does not relate to any pending or specific future financing.

## Item 6. Exhibits.

## (a) Exhibits

Exhibit Number	Description of Document
4.1	Form of Senior Secured Convertible Promissory Note (Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, as filed with the SEC on April 6, 2009).
4.2	Form of Warrant (Incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K, as filed with the SEC on April 6, 2009)
4.3	Form of Unsecured Subordinated Convertible Promissory Note (Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, as filed with the SEC on July 8, 2009).
4.4	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K, as filed with the SEC on July 8, 2009).
10.1	Form of Securities Purchase Agreement, dated April 2, 2009, by and among the Company and certain accredited investors set forth therein (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 6, 2009)
10.2	Form of Amended and Restated General Security Agreement, dated April 2, 2009, by and among the Company and certain accredited investors set forth therein (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on April 6, 2009).
10.3	Form of Securities Purchase Agreement, dated July 7, 2009, by and among the Company and certain accredited investors set forth therein (Incorporated by reference to Exhibit 10.1 of the company's Current Report on Form 8-K, as filed with the SEC on July 8, 2009).
10.4	Form of Consent Agreement, dated April 2, 2009, by and among the Company and certain accredited investors set forth therein (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on April 6, 2009).
10.5	Form of Registration Rights Agreement, dated July 7, 2009, by and among the Company and certain accredited investors set forth therein (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on July 8, 2009).
10.6	Form of Consent Agreement, dated July 7, 2009, by and among the Company and certain accredited investors set forth therein (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on July 8, 2009).
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification by Vice President, Finance 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 Vice President, Finance 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: August 14, 2009

/s/ RAYMOND P. WARRELL, JR., M.D.  
Raymond P. Warrell, Jr., M.D.  
Chairman and Chief Executive Officer  
(principal executive officer)

Date: August 14, 2009

/s/ GARY SIEGEL  
Gary Siegel  
Vice President, Finance  
(principal financial and accounting officer)

## Exhibit Index

Exhibit Number	Description of Document
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