

GENTA INC DE/  
Form 10-Q  
November 12, 2010

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010

OR

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

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

Commission File Number 0-19635

GENTA INCORPORATED

(Exact name of Registrant as specified in its charter)

Delaware 33-0326866  
(State or (I.R.S.  
other Employer  
jurisdiction of  
incorporation Identification  
or Number)  
organization)

200 Connell  
Drive  
Berkeley 07922  
Heights, NJ  
(Address of (Zip Code)  
principal  
executive  
offices)

(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

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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

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 November 11, 2010 the registrant had 110,776,005 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)

ASSETS	September 30, 2010 (unaudited)	December 31, 2009
<b>Current assets:</b>		
Cash and cash equivalents	\$ 11,681	\$ 1,216
Accounts receivable - net of allowances of \$39 at September 30, 2010 and \$23 at December 31, 2009, respectively	2	2
Receivable on sale of New Jersey tax losses	-	2,873
Inventory (Note 4)	38	81
Prepaid expenses and other current assets	505	971
<b>Total current assets</b>	<b>12,226</b>	<b>5,143</b>
Property and equipment, net	171	205
Deferred financing costs on sale of convertible notes, warrants and common stock (Note 6)	2,013	6,881
Restricted cash account	5,005	-
<b>Total assets</b>	<b>\$ 19,415</b>	<b>\$ 12,229</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 5,387	\$ 8,829
Convertible notes due June 9, 2011, \$1,890 outstanding, net of debt discount of (\$967) at September 30, 2010 (Note 6)	923	-
Convertible notes due June 9, 2010, \$1,787 outstanding, net of debt discount of (\$115) at December 31, 2009 (Note 6)	-	1,672
Convertible notes due July 7, 2011, \$291 outstanding, net of debt discount of (\$133) at September 30, 2010 (Note 6)	158	-
Convertible notes due September 4, 2011, \$3,768 outstanding, net of debt discount of (\$2,132) at September 30, 2010 (Note 6)	1,636	-
<b>Total current liabilities</b>	<b>8,104</b>	<b>10,501</b>
<b>Long-term liabilities:</b>		
Office lease settlement obligation (Note 5)	1,893	1,979
Convertible notes due April 2, 2012, \$251 outstanding, net of debt discount of (\$94) at September 30, 2010 and \$4,452 outstanding,	157	1,302

net of debt discount of (\$3,150) at December 31, 2009 (Note 6)

Convertible notes due July 7, 2011, \$751 outstanding, net of debt discount of (\$570) at December 31, 2009 (Note 6)

Convertible notes due July 7, 2011, \$751 outstanding, net of debt discount of (\$570) at December 31, 2009 (Note 6)	-	181
Convertible notes due September 4, 2011, \$7,000 outstanding, net of debt discount of (\$5,872) at December 31, 2009 (Note 6)	-	1,128

Convertible notes due March 9, 2013, \$25,949 outstanding, net of debt discount of (\$19,859) at September 30, 2010 (Note 6)

Convertible notes due March 9, 2013, \$25,949 outstanding, net of debt discount of (\$19,859) at September 30, 2010 (Note 6)	6,090	-
<b>Total long-term liabilities</b>	<b>8,140</b>	<b>4,590</b>

#### Commitments and contingencies (Note 9)

#### Stockholders' equity/(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 September 30, 2010 and December 31, 2009, respectively

Series G participating cumulative preferred stock, \$.001 par value; 0 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively

Common stock, \$.001 par value; 6,000,000 and 6,000,000 shares authorized, 12,899 and 1,928 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively (Note 1)

Series A convertible preferred stock, \$.001 par value; 8 shares issued and outstanding, liquidation value of \$385 at September 30, 2010 and December 31, 2009, respectively	-	-
Series G participating cumulative preferred stock, \$.001 par value; 0 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	-	-
Common stock, \$.001 par value; 6,000,000 and 6,000,000 shares authorized, 12,899 and 1,928 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively (Note 1)	13	2
Additional paid-in capital	1,167,018	1,027,563
Accumulated deficit	(1,163,860 )	(1,030,427 )
<b>Total stockholders' equity/(deficit)</b>	<b>3,171</b>	<b>(2,862 )</b>

<b>Total liabilities and stockholders' equity/(deficit)</b>	<b>\$ 19,415</b>	<b>\$ 12,229</b>
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See accompanying notes to consolidated financial statements.

GENTA INCORPORATED  
CONSOLIDATED STATEMENTS OF OPERATIONS  
(Unaudited)

(In thousands, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Product sales - net	\$ 82	\$ 49	\$ 192	\$ 180
Cost of goods sold	13	10	40	12
Gross margin	69	39	152	168
Operating expenses:				
Research and development	2,395	5,874	7,255	11,846
Selling, general and administrative	2,239	8,869	7,845	13,008
Total operating expenses	4,634	14,743	15,100	24,854
Other income/(expense):				
Interest income and other income/(expense), net	12	(12 )	47	4
Interest expense	(973 )	(265 )	(2,456 )	(841 )
Amortization of deferred financing costs and debt discount (Note 6)	(7,758 )	(5,450 )	(24,363 )	(22,362 )
Fair value - conversion feature liability (Note 6)	14,625	-	(55,813 )	(19,040 )
Fair value - warrant liability (Note 6)	6,401	-	(35,900 )	(7,655 )
Total other income/(expense)	12,307	(5,727 )	(118,485 )	(49,894 )
Net income/(loss)	\$ 7,742	\$ (20,431 )	\$ (133,433 )	\$ (74,580 )
Net income/(loss) per basic share (Note 8)	\$ 0.88	\$ (14.66 )	\$ (22.29 )	\$ (98.32 )
Net income/(loss) per diluted share (Note 8)	\$ 0.16	\$ (14.66 )	\$ (22.29 )	\$ (98.32 )
Shares used in computing net income/(loss) per basic share (Note 8)	8,757	1,393	5,986	759
Shares used in computing net income/(loss) per diluted share (Note 8)	53,151	1,393	5,986	759

See accompanying notes to consolidated financial statements.





GENTA INCORPORATED  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)

(In thousands)	Nine Months Ended September 30,	
	2010	2009
<b>Operating activities:</b>		
Net loss	\$(133,433 )	\$(74,580 )
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	97	112
Amortization of deferred financing costs and debt discount (Note 6)	24,363	22,362
Share-based compensation (Note 7)	3,997	9,624
Change in fair value - conversion feature liability (Note 6)	55,813	19,040
Change in fair value - warrant liability (Note 6)	35,900	7,655
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	-	1
Receivable on sale of New Jersey tax losses	2,873	-
Inventory	43	12
Prepaid expenses and other current assets	466	463
Accounts payable and accrued expenses	(370 )	257
Net cash used in operating activities	(10,251 )	(15,054 )
<b>Investing activities:</b>		
Purchase of property and equipment	(63 )	(51 )
Interest on restricted cash	(5 )	-
Net cash used in investing activities	(68 )	(51 )
<b>Financing activities:</b>		
Sale of convertible notes net of financing costs (Note 6)	25,784	17,580
Deposits in restricted cash account	(5,000 )	-
Net cash provided by financing activities	20,784	17,580
Increase in cash and cash equivalents	10,465	2,475
Cash and cash equivalents at beginning of period	1,216	4,908
Cash and cash equivalents at end of period	\$11,681	\$7,383

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
September 30, 2010  
(Unaudited)

1. Reverse Stock Split

At the Annual Meeting of Stockholders of Genta Incorporated (“Genta” or the “Company”) held on June 15, 2010, the Company’s stockholders authorized its Board of Directors to effect a reverse stock split of all outstanding shares of common stock. The Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of 1-for-100 shares and the reverse stock split became effective on August 2, 2010. All common share and per common 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 the reverse stock split.

2. Organization and Liquidity

Genta 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 and negative cash flows from operations since its inception. The Company expects that such losses will continue at least until one or more of its product candidates are approved by one or more regulatory authorities for commercial sale in one or more indications. As of September 30, 2010, the Company had an accumulated deficit of \$1,163.9 million. Cash and cash equivalents as of September 30, 2010 were \$11.7 million. The Company has historically financed its activities from the sale of shares of common stock, convertible notes, warrants and proceeds from partnerships with other companies.

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

On March 9, 2010, the Company issued \$25 million of units consisting of \$20 million of various senior unsecured convertible notes and \$5 million of senior secured convertible notes. In connection with the sale of the units, the Company also agreed to issue warrants in an amount equal to 40% of the purchase price paid for each such unit. The Company had direct access to \$20 million of the proceeds, and the remaining \$5 million of the proceeds were placed in a blocked account as collateral security for the \$5 million secured notes. In March 2010 and April 2010, four investors who had participated in the Company’s April 2009 financing exercised their rights under the April 2009 securities purchase agreement and the April 2009 consent agreement to acquire convertible notes of \$1.0 million.

Presently, with no further financing, the Company projects that it will run out of funds in the second quarter of 2011. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase additional notes with similar terms. The Company is only able to access \$5 million held in a blocked account as collateral security for the March 2010 D Notes (as defined in Note 6 of the Consolidated Financial Statements), if certain stock price and daily trading volume targets are met, as noteholders convert their March 2010 D Notes, or upon the approval of holders of 2/3 of the March 2010 D Notes. There is no guarantee that the Company will be able to access these funds. The Company currently does not have any additional financing in place. If it is unable to raise additional funds, it could be required to reduce its spending plans, reduce its workforce, license one or more of its products or technologies that it would otherwise seek to commercialize itself, or sell certain assets. There can be no assurance that the Company can obtain

financing, if at all, on terms acceptable to it.

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A special meeting of the Company's stockholders is planned for December 29, 2010. The Company has recommended to its stockholders that they provide authorization to the Company's Board of Directors to effect up to two reverse stock splits by December 31, 2011, with each reverse stock split in the ratio of 1-for-2 up to 1-for-100, and to approve the Company's Restated Certificate of Incorporation, as amended, to increase the total number of authorized shares of capital stock available for issuance from 6,005,000,000, consisting of 6,000,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock to 100,000,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock.

The Company's historical operating results cannot be relied on to be an indicator of future performance, and management cannot predict whether the Company will obtain or sustain positive operating cash flow or generate net income in the future.

### 3. Summary of Significant Accounting Policies

#### Accounting Standards Updates

In January 2010, the FASB issued ASU 2010-06- Improving Disclosures about Fair Value Measurements. ASU 2010-06 requires additional disclosures about fair value measurements including transfers in and out of Levels 1 and 2 and a higher level of disaggregation for the different types of financial instruments. For the reconciliation of Level 3 fair value measurements, information about purchases, sales, issuances and settlements should be presented separately. This ASU is effective for annual and interim reporting periods beginning after December 15, 2009 for most of the new disclosures and for periods beginning after December 15, 2010 for the new Level 3 disclosures. Comparative disclosures are not required in the first year the disclosures are required.

Other Accounting Standards Updates not effective until after September 30, 2010 are not expected to have a significant effect on the Company's consolidated financial position or results of operations.

#### Basis of Presentation

The foregoing consolidated financial statements are unaudited and have been prepared from the books and records of the Company. In the Company's opinion, all normal and recurring adjustments necessary for a fair presentation of the financial position of the Company as of September 30, 2010 and the results of operations and cash flows for the three and nine months ended September 30, 2010 and 2009 have been made in conformity with generally accepted accounting principles. The results of operations for the three and nine months ended September 30, 2010 may not be indicative of expected results of operations for the year ended December 31, 2010. These interim financial statements and notes are condensed as permitted by the instructions to Form 10-Q and should be read in conjunction with the audited Consolidated Financial Statements of the Company included in its Form 10-K for the year ended December 31, 2009.

#### 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 consists 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.



### Restricted Cash

Restricted cash represents funds received from the March 2010 financing that have been placed in a blocked account as collateral security for the D Notes (as defined in Note 6 to the Consolidated Financial Statements). The security interest of the holders of the D Notes will be released, and restrictions on the Company's use of the \$5 million held in the blocked account will terminate if, at any time after six months and ten weeks from the closing of the transaction: (i) the Company files a Form 8-K with the United States Securities and Exchange Commission showing that the daily trading volume of the Company's common stock for each of the 10 trading days prior to the date on which such filing is made, equals or exceeds one-tenth of the number of shares underlying the D Notes on the date such filing is made; and (ii) the daily closing price on each trading day (each such trading day, a "Test Date") during the 10 trading day period prior to the date on which such filing is made is greater than the conversion price then in effect for the D Notes on such Test Date by an amount equal to or greater than 200% of the conversion price on such Test Date. The security interest will also be released (i) dollar for dollar upon conversion of any part of the D Notes or (ii) in its entirety upon the approval of the holders of two-thirds of the then outstanding principal amount of D Notes.

### 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 12 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 nine months ended September 30, 2010, 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 have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended, or 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 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.

## Restricted Stock Units and Stock Options

Restricted stock units (“RSUs”) and stock options are recognized in the Consolidated Statements 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. During 2009, with the implementation of two Equity Award Exchange programs, outstanding stock option awards granted under the 1998 Non-Employee Directors Plan, as amended, and 1998 Stock Incentive Plan, as amended, were exchanged for grants of new RSUs under the Company’s 2009 Stock Incentive Plan. The incremental compensation cost for the new RSUs was measured as the excess of the fair value of the RSUs over the fair value of the exchanged stock option awards on the date of exchange. The incremental compensation cost of the RSUs is being recognized over the vesting period of the RSUs. The Company utilizes a Black-Scholes option-pricing model to measure the fair value of stock options granted to employees. See Note 7 to the Consolidated Financial Statements for a further discussion on share-based compensation.

## Deferred Financing Costs

In conjunction with the issuance of the 2008 Notes, the April 2009 Notes, the July 2009 Notes, the September 2009 Notes and March 2010 Notes (as described in Note 6 to the Consolidated Financial Statements), the Company incurred certain financing costs, including, for several of the financings, the issuance of warrants to purchase the Company’s common stock. This additional consideration is being amortized over the term of the notes through the earliest maturity date using the effective interest method. If the maturity of the notes is accelerated because of conversions or defaults, then the amortization is accelerated. The fair value of the warrants issued as placement fees in connection with these financings are calculated utilizing the Black-Scholes option-pricing model.

## Net Income/(Loss) Per Common Share

Net income/(loss) per common share for the three and nine months ended September 30, 2010 and 2009, respectively, are based on the weighted average number of shares of common stock outstanding during the periods. There is no difference between the basic and diluted net loss per share for the three and nine months ended September 30, 2009 and for the nine months ended September 30, 2010 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 September 30, 2010 and 2009, respectively, the potentially dilutive securities include 57.4 million and 2.5 million shares, respectively, reserved for the conversion of convertible notes, convertible preferred stock, issuance and vesting of RSUs, the exercise of outstanding warrants and the shares issuable upon the exercise of purchase rights of our noteholders.

## 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):

	September 30, 2010	December 31, 2009
Raw materials	\$ 24	\$ 24
Finished goods	14	57
	\$ 38	\$ 81

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

On April 5, 2010, the Company, entered into an Amendment of its Lease Agreement with The Connell Company, a corporation based in New Jersey, whereby the Company extended its lease of office space in Berkeley Heights, New Jersey for an additional five years until August 31, 2015. In addition, the Amendment extends the payment of \$1.9 million owed by the Company to Connell that had been due on January 1, 2011, to the earlier of 1) August 31, 2015, 2) the date that the company receives an up-front cash payment totaling at least \$15.0 million from a business development deal or 3) the date which is 6 months after the date that the Company receives approval from the U.S. Food and Drug Administration (“FDA”) for either Genasense® or tsetaxel.

## 6. Convertible Notes and Warrants

On March 9, 2010, the Company issued \$25 million of units (the “2010 Units”), each 2010 Unit consisting of (i) 40% of a senior unsecured convertible note (the “B Notes”), (ii) 40% of a senior unsecured convertible note (the “C Notes”) and (iii) 20% of a senior secured convertible note (the “D Notes”). In connection with the sale of the 2010 Units, the Company also issued warrants (the “Debt Warrants”) to purchase senior unsecured convertible notes (the “E Notes”) in an amount equal to 40% of the purchase price paid for each such 2010 Unit. The Company had direct access to \$20 million of the proceeds, and the remaining \$5 million of the proceeds were placed in a blocked account as collateral security for the \$5 million in principal amount of the D Notes. On March 17, 2010, March 22, 2010 and April 9, 2010, four investors who had participated in the Company’s April 2009 financing, exercised their rights under the April 2009 securities purchase agreement and the April 2009 consent agreement to acquire convertible notes (the “F Notes”) of \$1.0 million. On May 6, 2010 and May 10, 2010, two holders of Debt Warrants totaling \$1.3 million exercised their warrants using a cashless exercise procedure and received, in total, E Notes for \$1.1 million. The notes in all of the above transactions, (“the March 2010 Notes”), bear interest at an annual rate of 12% payable semiannually in cash or in other convertible notes to the holder, and as of September 30, 2010 were convertible into shares of Genta common stock at a conversion rate of 1,000 shares of common stock for every \$1,000.00 of principal.

Concurrent with the issuance of the 2010 units, the Company also extended the maturity date of the outstanding 2008 Notes from June 9, 2010 to June 9, 2011 in exchange for three-year warrants (“March 2010 Warrants”) to purchase the same number of shares of the Company’s Common Stock issuable upon conversion of such 2008 Notes.

Prior to the implementation of the reverse stock split, described in Note 1 to the Consolidated Financial Statements, there were not enough shares of Common Stock authorized under the Company’s certificate of incorporation to cover the shares underlying all of the March 2010 Notes. The Company accounted for the conversion options embedded in the March 2010 Notes in accordance with “Accounting for Derivative Instruments and Hedging Activities”, FASB ASC 815-10, and “Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock” (FASB ASC 815-40). FASB ASC 815-10 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 FASB ASC 815-40. FASB ASC 815-40 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, the holder of each March 2010 Note has the right to require the Company to repay 100% of the outstanding principal and accrued interest on each note in cash on the second anniversary of the closing date of the March 2010 financing.

In accordance with FASB ASC 815-40, when there are insufficient authorized shares to permit exercise of all of the issued convertible notes, the debt warrants and warrants, the conversion obligation for the notes and the warrant obligations will be classified as liabilities and measured at fair value on the balance sheet. The conversion feature liabilities and the warrant liabilities will be accounted for using mark-to-market accounting at each reporting date until all the criteria for permanent equity have been met.



On March 9, 2010, in connection with the \$25 million financing, the convertible features of the B, C and D Notes were recorded as derivative liabilities of \$263.5 million, resulting in an expense of \$238.5 million. The Company recorded an initial discount of \$25.0 million, equal to the face value of the notes, which will be amortized over the term of the notes through their maturity date. On March 17, 2010, March 22, 2010 and April 9, 2010, in connection with the \$1.0 million exercises of purchase rights/options, the convertible features of the F Notes were recorded as a derivative liability of \$5.4 million, resulting in an expense of \$4.4 million. The Company recorded an initial discount of \$1.0 million, equal to the face value of the F Notes, which will be amortized over the term of the notes through their maturity date. On May 6, 2010 and May 10, 2010, in connection with the \$1.1 million issuance of E Notes, the convertible features of the E Notes were recorded as a derivative liability of \$7.5 million, resulting in an expense of \$6.4 million. The Company recorded an initial discount of \$1.1 million, equal to the face value of the E Notes, which will be amortized over the term of the notes through their maturity date.

From March 9, 2010 through September 30, 2010, holders of the March 2010 B Notes and March 2010 C Notes voluntarily converted \$1.4 million and \$1.4 million, respectively, resulting in an issuance of 1.4 million and 1.4 million shares of common stock, respectively. At September 30, 2010, the approximate balances of the March 2010 B Notes, March 2010 C Notes, March 2010 D Notes, March 2010 E Notes and March 2010 F Notes were \$9.2 million, \$9.2 million, \$5.3 million, \$1.2 million and \$1.0 million, respectively.

In connection with the placement of the March 2010 Notes, the Company incurred financing fees of \$0.2 million. The financing fees are being amortized over the term of the March 2010 Notes. At September 30, 2010 the unamortized balances of the financing fee was \$0.2 million.

At the Annual Meeting of Stockholders of Genta Incorporated held on June 15, 2010, the Company's stockholders authorized its Board of Directors to effect a reverse stock split of all outstanding shares of common stock. The Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of 1-for-100 shares on July 9, 2010 and the reverse stock split became effective on August 2, 2010. The approval of the reverse stock split resulted in the Company having enough shares to accommodate the potential number of shares underlying the March 2010 Notes and Debt Warrants. The fair value of the conversion feature liability of the March 2010 Notes was re-measured at July 9, 2010 at \$81.8 million and credited to permanent equity, resulting in income for the three months ended September 30, 2010 of \$14.6 million.

The conversion feature liability for the March 2010 Notes was valued at July 9, 2010 and the date of the transactions using the Black-Scholes valuation model with the following assumptions:

	July 9, 2010	May 6/10, 2010	April 9, 2010	March 17/22, 2010	March 9, 2010
Price of share of Genta common stock	\$ 3.05	\$ 6.44	\$ 1.56	\$ 6.20	\$ 10.60
Volatility	287 %	278 %	272 %	267 %	266 %
Risk-free interest rate	0.89 %	1.34 %	1.68 %	1.47 %	1.43 %
Remaining contractual lives	2.7	2.8	2.9	3.0	3.0

On March 9, 2010, the Company recorded the liability for the Debt Warrants at a fair value of \$105.6 million and the March 2010 Warrants at a fair value of \$19.5 million, based upon a Black-Scholes valuation model. The warrant liabilities were marked-to-market and charged/credited to expense in a manner similar to the conversion feature liability at each reporting date until July 9, 2010. The Debt Warrants and March 2010 Warrants were re-measured at July 9, 2010 at \$30.3 million and \$5.6 million, respectively and credited to permanent equity, resulting in income for the three months ended September 30, 2010 of \$6.4 million.

The liability for the Debt Warrants was valued at July 9, 2010 and March 9, 2010 using the Black-Scholes valuation model with the following assumptions:

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	July 9, 2010		March 9, 2010	
Price of share of Genta common stock	\$ 3.05		\$ 10.60	
Volatility	237	%	225	%
Risk-free interest rate	1.54	%	2.15	%
Remaining contractual lives	4.3		4.6	

The liability for the March 2010 warrants was valued at July 9, 2010 and March 9, 2010 using the Black-Scholes valuation model with the same assumptions used for the valuation of the conversion feature liability of the March 2010 Notes.

On June 9, 2008, the Company placed \$20 million of 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 20 shares of common stock for every \$1,000.00 of principal, (adjusted for the reverse stock splits effected on June 26, 2009 and August 2, 2010). As a consequence of the April 2009 Note financing, the conversion rate was reset to 100 shares of common stock for every \$1,000.00 of principal. As a result of the March 2010 financing, (see above), the conversion rate for the 2008 Notes that were convertible into shares of common stock at a conversion rate of 100 shares of common stock for every \$1,000.00 of principal were adjusted to be convertible into shares of common stock at a conversion rate of 1,000 shares of common stock for every \$1,000.00 of principal. The Company valued this change in the conversion rate on March 9, 2010; the aggregate intrinsic value of the difference in conversion rates was in excess of the \$1.9 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 on March 9, 2010, and the Company is amortizing the resultant debt discount over the remaining term of the 2008 Notes.

From January 1, 2010 through September 30, 2010, holders of the 2008 Notes voluntarily converted \$0.1 million, resulting in an issuance of 0.1 million shares of common stock. At September 30, 2010, \$1.9 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.

In connection with the placement of the 2008 Notes, the Company issued a warrant to its private placement agent to purchase 8,000 shares of common stock at an exercise price of \$100.00 per share and incurred a financing fee of \$1.2 million. The financing fees and the initial value of the warrant are being amortized over the term of the 2008 Notes. At September 30, 2010 and December 31, 2009, the unamortized balances of the financing fee were \$32 thousand and \$0.1 million, respectively, and the warrants were \$0.2 million and \$0.7 million, respectively.

On April 2, 2009, the Company issued \$6 million of April 2009 Notes and corresponding warrants to purchase common stock. 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 were convertible into shares of the Company's common stock at a conversion rate of 100 shares of common stock for every \$1,000.00 of principal amount outstanding. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase up to \$13.2 million of additional notes with similar terms. As a result of the March 2010 financing, the conversion rate for the April 2009 Notes that were convertible into shares of common stock at a conversion rate of 100 shares of common stock for every \$1,000.00 of principal were adjusted to be convertible into shares of common stock at a conversion rate of 1,000 shares of common stock for every \$1,000.00 of principal. The Company valued this change in the conversion rate on March 9, 2010; the aggregate intrinsic value of the difference in conversion rates was in excess of the \$4.3 million face value of the April

2009 Notes. Thus, a full debt discount was recorded in an amount equal to the face value of the April 2009 Notes on March 9, 2010, and the Company is amortizing the resultant debt discount over the remaining term of the April 2009 Notes.

From January 1, 2010 through September 30, 2010, holders of the April 2009 Notes voluntarily converted \$4.4 million, resulting in an issuance of 4.1 million shares of common stock. At September 30, 2010, \$0.3 million of the April 2009 Notes were outstanding.

In connection with the placement of the April 2009 Notes, the Company issued a warrant to its private placement agent to purchase 36 thousand shares of common stock at an exercise price of \$50.00 per share and incurred financing fees of \$0.6 million. The financing fees and the initial value of the warrant are being amortized over the term of the April 2009 Notes. At September 30, 2010 and December 31, 2009, the unamortized balances of the financing fee were \$28 thousand and \$0.5 million, respectively, and the warrants were \$0.2 million and \$3.0 million, respectively.

On July 7, 2009, the Company issued \$3 million of July 2009 Notes, common stock and July 2009 Warrants. The July 2009 Notes bear interest at an annual rate of 8% payable semi-annually in other senior secured convertible promissory notes to the holder, and were convertible into shares of the Company's common stock at a conversion rate of 100 shares of common stock for every \$1,000.00 of principal amount outstanding. As a result of the March 2010 financing, the conversion rate for the July 2009 Notes that were convertible into shares of common stock at a conversion rate of 100 shares of common stock for every \$1,000.00 of principal were adjusted to be convertible into shares of common stock at a conversion rate of 1,000 shares of common stock for every \$1,000.00 of principal. The Company valued this change in the conversion rate on March 9, 2010; the aggregate intrinsic value of the difference in conversion rates was in excess of the \$0.7 million face value of the July 2009 Notes. Thus, a full debt discount was recorded in an amount equal to the face value of the July 2009 Notes on March 9, 2010, and the Company is amortizing the resultant debt discount over the remaining term of the July 2009 Notes.

From January 1, 2010 through September 30, 2010, holders of the July 2009 Notes voluntarily converted \$0.5 million, resulting in an issuance of 0.4 million shares of common stock. At September 30, 2010, \$0.3 million of the July 2009 Notes were outstanding.

In connection with the placement of the July 2009 Notes, the Company issued a warrant to its private placement agent to purchase 18 thousand shares of common stock at an exercise price of \$100.00 per share and incurred financing fees of \$0.1 million. The financing fees and the initial value of the warrant are being amortized over the term of the July 2009 Notes. At September 30, 2010 and December 31, 2009, the unamortized balances of the warrants were \$65 thousand and \$0.2 million, respectively.

On September 4, 2009, the Company issued \$7 million of additional July 2009 Notes, common stock and July 2009 Warrants. Also on September 4, 2009, the Company issued \$3 million of September 2009 Notes, common stock and September 2009 Warrants to certain accredited institutional investors. The September 2009 Notes bear interest at an annual rate of 8% payable semi-annually in other senior secured convertible promissory notes to the holder, and were convertible into shares of the Company's common stock at a conversion rate of 100 shares of common stock for every \$1,000.00 of principal amount outstanding. As a result of the March 2010 financing, the conversion rate for the September 2009 Notes and the July 2009 Notes that were issued in September, previously convertible into shares of common stock at a conversion rate of 100 shares of common stock for every \$1,000.00 of principal were adjusted to be convertible into shares of common stock at a conversion rate of 1,000 shares of common stock for every \$1,000.00 of principal. The Company valued this change in the conversion rate on March 9, 2010; the aggregate intrinsic value of the difference in conversion rates was in excess of the \$6.8 million face value of the September 2009 and July 2009 Notes. Thus, a full debt discount was recorded in an amount equal to the face value of the September 2009 and July 2009 Notes on March 9, 2010, and the Company is amortizing the resultant debt discount over the remaining term of the September 2009 and July 2009 Notes.

From January 1, 2010 through September 30, 2010, holders of the September 2009 Notes and July 2009 Notes issued on September 4, 2009, voluntarily converted \$3.6 million, resulting in an issuance of 3.3 million shares of common

stock. At September 30, 2010, \$3.8 million of the September 2009 Notes and July 2009 Notes issued on September 4, 2009 were outstanding.



In connection with the placement of the September 2009 Notes and July 2009 Notes on September 4, 2009, the Company issued warrants to its private placement agent to purchase 60 thousand shares of common stock at an exercise price of \$100.00 per share and incurred financing fees of \$0.6 million. The financing fees and the initial value of the warrants of \$2.2 million are being amortized over the term of the September 2009 and July 2009 Notes. At September 30, 2010 and December 31, 2009, the unamortized balances of the financing fee were \$0.3 million and \$0.5 million, respectively, and the warrants were \$1.0 million and \$1.9 million, respectively.

The Company is in compliance with all debt-related covenants at September 30, 2010.

## 7. Stock Incentive Plans and Share-Based Compensation

During 2009, the Company established the 2009 Stock Incentive Plan (“2009 Plan”) and implemented an Equity Award Exchange Offer Program for non-employee Directors, whereby each eligible non-employee Director exchanged their outstanding stock options that had been granted under the Company’s 1998 Non-Employee Directors’ Plan, as amended, and were granted restricted stock units (“RSUs”) under the 2009 Plan. The Company also implemented an Equity Award Exchange Offer Program for all U.S. employees, whereby each employee exchanged their outstanding stock options that had been granted under the Company’s 1998 Stock Incentive Plan, as amended (“1998 Plan”), for new replacement RSUs under the 2009 Plan. The RSUs vest in accordance with the terms set forth in the 2009 Stock Incentive Plan. Approximately 75% of the total awards granted as new replacement RSUs vest over time between the date of issuance and August 31, 2012 and the remaining 25% vest based on certain performance conditions. The surrender of the options was accounted for as a modification of an award. The Company determined the compensation cost of the modification as the difference in the fair value of the options immediately before the modification and the fair value of the RSUs immediately after the modification. The incremental cost for awards that were not vested as of the modification date are being expensed over the remaining vesting period of the RSUs.

The following table summarizes the RSU activity under the 2009 Plan for the nine months ended September 30, 2010:

Restricted Stock Units	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value per Share
Outstanding nonvested RSUs at January 1, 2010	444	\$ 39.50
Granted	250	\$ 1.20
Vested	(327 )	\$ 10.23
Forfeited or expired	(41 )	\$ 39.50
Outstanding nonvested RSUs at September 30, 2010	326	\$ 39.50

Based on the closing price of Genta common stock of \$0.41 per share on September 30, 2010, the fair value of the nonvested RSUs at September 30, 2010 is \$0.1 million. As of September 30, 2010, there was approximately \$0.5 million of total unrecognized compensation cost related to non-vested share-based compensation granted under the 2009 Plan, which is expected to be recognized over a weighted-average period of 0.8 years.

Share-based compensation expense recognized for the three and nine months ended September 30, 2010 and 2009, respectively, was comprised as follows:

(\$ thousands, except per share data)	Three months ended September		Nine months ended September	
	2010	2009	2010	2009

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Research and development expenses	\$ 287	\$ 2,918	\$ 1,506	\$ 2,950
Selling, general and administrative	405	6,599	2,491	6,674
Total share-based compensation expense	\$ 692	\$ 9,517	\$ 3,997	\$ 9,624
Share-based compensation expense, per basic and diluted common share	\$ 0.08	\$ 6.83	\$ 0.67	\$ 12.69

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## 8. Net Income/(Loss) per Share

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

(\$ in thousands, except per share amounts)	Three months ended September		Nine months ended September 30,	
	2010	30, 2009	2010	2009
Numerator:				
Net income/(loss)	\$ 7,742	\$ (20,431 )	\$ (133,433 )	\$ (74,580 )
Plus: income impact of assumed conversion interest on convertible debt	935	-	-	-
Net income/(loss) plus assumed conversion	\$ 8,677	\$ (20,431 )	\$ (133,433 )	\$ (74,580 )
Denominator:				
Weighted average shares outstanding:				
Basic	8,757	1,393	5,986	759
Effect of dilutive convertible notes	32,149	-	-	-
Effect of dilutive warrants/rights	11,887	-	-	-
Effect of dilutive restricted stock units and convertible preferred stock	358	-	-	-
Diluted	53,151	1,393	5,986	759
Net income/(loss) per share:				
Basic	\$ 0.88	\$ (14.66 )	\$ (22.29 )	\$ (98.32 )
Diluted	\$ 0.16	\$ (14.66 )	\$ (22.29 )	\$ (98.32 )

## 9. Commitments and Contingencies

## Litigation and Potential Claims

In September 2008, several stockholders, 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 in June 2008, 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 Company's motion 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 and the Appellate Division granted the motion for temporary remand. Following the briefing and a hearing, the Superior Court denied the motion for relief from judgment on August 28, 2009. Thus, this matter proceeded in the Appellate Division. Plaintiffs' brief before the Appellate Division was filed on October 28, 2009, and our responsive brief was filed on January 27, 2010. The plaintiffs' reply brief was filed on March 15, 2010. The Company is currently awaiting a decision from the Appellate Division on this matter. At this time, the Company cannot estimate when the Appellate Division will rule on the appeal. The Company, Board of Directors and Officers deny these allegations and intend 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 nine months ended September 30, 2010 and 2009, respectively. On January 4, 2010, the Company issued \$187 thousand of September 2009 Notes in lieu of interest due on its September 2009 Notes. On January 7, 2010, the Company issued \$30 thousand in July 2009 Notes in lieu of interest due on its July 2009 Notes. On March 2, 2010, the Company issued \$162 thousand in April 2009 Notes in lieu of interest due on its April 2009 Notes. On March 9, 2010, the Company issued \$67 thousand in 2008 Notes in lieu of interest due on its 2008 Notes. On June 9, 2010, the Company issued \$66 thousand of 2008 Notes in lieu of interest due on its 2008 Notes. On July 4, 2010, the Company issued \$193 thousand of September 2009 Notes in lieu of interest due on its September 2009 Notes. On September 2, 2010, the Company issued \$10 thousand of April 2009 Notes in lieu of interest due on its April 2009 Notes. On September 9, 2010, the Company issued \$68 thousand of 2008 Notes in lieu of interest due on its 2008 Notes. On September 9, 2010, the Company issued notes for \$600 thousand, \$600 thousand, \$300 thousand, \$66 thousand and \$57 thousand for March 2010 B Notes, March 2010 C Notes, March 2010 D Notes, March 2010 E Notes and March 2010 F Notes, respectively, in lieu of interest due on September 9, 2010.

On March 9, 2009, the Company issued approximately \$386 thousand of 2008 Notes in lieu of interest due on its 2008 Notes. On June 9, 2009, the Company issued approximately \$125 thousand of 2008 Notes in lieu of interest due on its 2008 Notes. On September 2, 2009, the Company issued approximately \$175 thousand of April 2009 Notes in lieu of interest due on its April 2009 Notes. On September 9, 2009, the Company issued approximately \$81 thousand of 2008 Notes in lieu of interest due on its 2008 Notes.

From January 1, 2010 through September 30, 2010, holders of the Company's convertible notes voluntarily converted approximately \$11.4 million, resulting in an issuance of 10.6 million shares of common stock.

On May 5, 2010, a holder of a Debt Warrant of \$1.0 million exercised his warrant using a cashless exercise procedure and received an E Note for \$0.9 million. On May 10, 2010, a holder of a Debt Warrant of \$0.3 million exercised his warrant using a cashless exercise procedure and received an E Note for \$0.2 million.

## 11. Subsequent Events

From October 1, 2010 through November 11, 2010, holders of convertible notes have voluntarily converted approximately \$3.9 million of their notes, resulting in an issuance of 97.9 million shares of common stock.

Based on the terms of the March 2010 B Note, March 2010 E Note and March 2010 F Note, the conversion price of the March 2010 B Note, March 2010 E Note, and March 2010 F Note were adjusted to \$0.0396 effective October 9, 2010. In accordance with the terms of the Notes, the conversion prices of all of the Notes were also adjusted to \$0.0396 effective October 9, 2010. The Company valued this change in the conversion rate; the aggregate intrinsic value of the difference in conversion rates was in excess of the face value of each of the Notes. Thus, a full debt discount was recorded in an amount equal to the face value of each of the Notes on October 9, 2010, and the Company will amortize the resultant debt discount over the remaining term of the Notes.

On October 11, 2010, two holders of Debt Warrants totaling \$4.0 million exercised their warrants using a cashless exercise procedure and received, in total, E Notes in the amount of \$3.6 million.

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 approvals for its products 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, or the Company’s risk of bankruptcy;
  - 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”.

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 amended, 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 tesetaxel and oral gallium-containing compounds). 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. Additionally, we expect that such losses will continue at least until one or more of our product candidates are approved by one or more regulatory authorities for commercial sale in one or more indications. From our inception to September 30, 2010, we have incurred a cumulative net deficit of \$1,163.9 million. We have experienced significant quarterly fluctuations in operating results, and we expect that these fluctuations in revenues, expenses and losses will continue.

Our principal goal is to secure worldwide regulatory approvals for the marketing of our products. Our lead product, 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.

Our major current initiative with Genasense® relates to its potential use in patients with advanced melanoma. In 2009, we completed accrual to a Phase 3 trial of Genasense® plus chemotherapy in advanced melanoma. This trial, known as AGENDA, was a randomized, double-blind, placebo-controlled study in which patients were randomly assigned to receive Genasense® plus dacarbazine or dacarbazine alone. The study used LDH as a biomarker to identify patients who were most likely to respond to Genasense®, based on data obtained from our preceding trial in melanoma. The co-primary endpoints of AGENDA were progression-free survival, or PFS, and overall survival.

The design of AGENDA was based on data obtained from a similarly designed Phase 3 trial that was published in 2006. Results from this antecedent study showed that treatment with Genasense® plus dacarbazine compared with dacarbazine alone was associated with a statistically significant increase in overall response, complete response, durable response and PFS. However, the primary endpoint of overall survival approached but did not quite reach statistical significance ( $P=0.077$ ) in the entire “intent-to-treat” population. Our further 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. Thus, the AGENDA trial sought to confirm the observations that were previously observed in the antecedent trial in a biomarker-defined patient population.

A total of 315 patients were enrolled into AGENDA. In October 2009, we announced that AGENDA did not show a statistically significant benefit for its co-primary endpoint of PFS. Secondary endpoints of overall response rate and disease control rate (which includes complete and partial responses, plus stable disease greater than 3 months duration) also did not show a statistically significant benefit. According to the prespecified analysis plan, the statistical significance of durable response, (a secondary endpoint that measures the proportion of patients who achieved a complete or partial response that lasts greater than 6 months), was too early to evaluate. However, the observed

differences in PFS, overall response, disease control and durable response all numerically favored the group that received Genasense®.



Overall survival, the other co-primary endpoint in AGENDA, was also too early to evaluate, as prospectively specified. An analysis for futility, which was defined as greater than 50% conditional power to observe a statistically significant benefit of Genasense® under the prospectively assumed hazard ratio of 0.69, was conducted for the co-primary endpoint of overall survival. AGENDA passed this futility analysis, and an Independent Data Monitoring Committee has recommended that the trial continue to completion for the determination of the overall survival endpoint. The safety profile of Genasense® in AGENDA was consistent with prior studies. We have indicated our intention to continue patient follow-up in the AGENDA trial to determine whether Genasense® will yield a statistically significant improvement in its co-primary endpoint of overall survival. Followup of all patients for survival is scheduled to terminate on March 31, 2011, and we currently project that the survival information will be available shortly thereafter. If the final analysis for overall survival is statistically significant, we believe that Genasense® could receive regulatory approval for marketing in this indication. Under such circumstance, we would confer with the FDA regarding resubmission of our New Drug Application, or NDA, and seek approval for treatment of patients with advanced melanoma with Genasense®. We anticipate that such submission would take place in 2011.

We have also conducted extensive trials in patients with advanced CLL. We completed a randomized Phase 3 trial in 241 patients with relapsed or refractory CLL who were treated with fludarabine and cyclophosphamide, also known as 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, or 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 received a “non-approvable” notice from the FDA in December 2006 for our NDA that proposed the use of Genasense® in combination with Flu/Cy for the treatment of patients with relapsed or refractory CLL who had previously received fludarabine. We appealed this decision with FDA’s Center for Drug Evaluation and Research, or CDER, using the agency’s Formal Dispute Resolution process. 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 CR or a partial response, also known as 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. However, 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. In the absence of a co-development partner to share expenses, we have determined that we will not conduct the recommended study in the CLL indication until the survival results of the AGENDA trial are known. We have made no decision whether to conduct this study or whether to pursue the current application for regulatory approval in other territories.



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 initiated our first clinical trial with tesetaxel.

We initiated several new clinical trials with tesetaxel during 2010. In February, we initiated a Phase 2a trial of tesetaxel in patients with advanced gastric cancer. The trial is currently open to enrollment at Northwestern University, Chicago, IL, and M.D. Anderson Cancer Center in Houston, TX. In September, we initiated a new Phase 2a trial of tesetaxel in advanced bladder cancer. Similarly designed trials are planned in prostate and breast cancer. Endpoints of these studies include response rate, durable response, disease control, PFS and safety.

In April 2010, the FDA granted the Company’s request for “Fast Track” designation of tesetaxel for treatment of patients with advanced gastric cancer. Fast Track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The designation typically enables a company to submit a NDA on a “rolling” basis with ongoing FDA review during the submission process. NDAs with Fast Track designation are also usually granted priority review by FDA at the time of submission.

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. Orphan Drug designation for tesetaxel in gastric cancer was approved by the European Medicines Authority, or EMA, in October 2010. We routinely file for both Fast Track and Orphan Drug designations, or similar designations in applicable territories and for diseases that fulfill regulatory requirements for such designation.

Our third pipeline project consists of the development of an oral gallium-containing compound. One formulation, known as G4544, was 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 whether a modified formulation, known as “G4544(b)”, or some alternative formulation will prove more clinically acceptable.

If we are able to identify a clinically and commercially acceptable formulation of an oral gallium-containing compound, we currently intend to evaluate whether an expedited regulatory approval may be possible. We believe a drug of this class 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 for patients with cystic fibrosis.

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. Sales of Ganite® have been low relative to original expectations in part due to our under-investment in its marketing for a small indication. Since Ganite® has now lost patent protection, we do not plan to substantially increase our investment in the drug, but we believe the product has strategic importance for our franchise of gallium-containing compounds and we currently intend for Ganite® to remain on the market. A trial of Ganite® has been initiated in patients with advanced cystic fibrosis and serious infections, for which the Company is supplying drug at no charge to participants. This trial is currently ongoing at the University of Washington and at the University of Iowa.

In April 2010, we presented results from the first human use of a gallium-containing compound to treat serious infection. In a patient with cystic fibrosis and a highly resistant lung infection, who had been treated with Ganite® over a 2-year period, high concentrations of gallium were achieved in sputum. Moreover, sputum concentrations were higher than simultaneous concentrations in blood and continued to rise even after treatment had been stopped. Measured concentrations in sputum equaled or exceeded concentrations that have been reported lethal to bacteria in laboratory tests. These results have now been confirmed in the initial presentation of results from the aforementioned cystic fibrosis trial in October 2010.

#### Results of Operations for the Three Months Ended September 30, 2010 and September 30, 2009

(\$ thousands)	2010	2009
Product sales – net	\$ 82	\$ 49
Cost of goods sold	13	10
Gross margin	69	39
Operating expenses:		
Research and development	2,395	5,874
Selling, general and administrative	2,239	8,869
Total operating expenses	4,634	14,743
Other (expense)/income:		
Interest income and other income/(expense), net	12	(12 )
Interest expense	(973 )	(265 )
Amortization of deferred financing costs and debt discount	(7,758 )	(5,450 )
Fair value – conversion feature liability	14,625	-
Fair value – warrant liability	6,401	-
Total other income/(expense), net	12,307	(5,727 )
Net income/(loss)	\$ 7,742	\$ (20,431 )

#### Product sales-net

Product sales-net of Ganite® were \$82 thousand for the three months ended September 30, 2010, compared with \$49 thousand for the three months ended September 30, 2009. Unit sales of Ganite® increased 25% from the third quarter of 2009 to the third quarter of 2010 with the remaining increase in net sales due to lower sales returns.

#### Cost of goods sold

Cost of goods sold increased due to the increase in unit sales, while cost of goods sold as a percentage of sales improved due to lower sales returns.

Research and development expenses

Research and development expenses were \$2.4 million for the three months ended September 30, 2010, compared with \$5.9 million for the three months ended September 30, 2009.

Research and development expenses declined as the prior-year period included higher expenses resulting from the AGENDA clinical trial and a decrease in share-based compensation expense for those employees categorized as research and development. Share-based compensation expense for the three months ended September 30, 2010 and 2009 was \$0.3 million and \$2.9 million, respectively.

Research and development expenses incurred on the tesetaxel project and Genasense® project during the three months ended September 30, 2010 were approximately \$1.2 million and \$0.9 million, representing 50% and 37% of research and development expenses, respectively.

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 \$ 2.2 million for the three months ended September 30, 2010, compared with \$8.9 million for the three months ended September 30, 2009, primarily attributable to lower share-based compensation expense for those employees categorized as selling, general and administrative. Share-based compensation expense for the three months ended September 30, 2010 and 2009 was \$0.4 million and \$6.6 million, respectively.

#### Interest income and other income/(expense), net Interest expense

The total of interest income and other income/(expense), net and interest expense resulted in net expense of \$(1.0) million for the three months ended September 30, 2010, compared to \$(0.3) million for the prior-year quarter, primarily due to the inclusion of interest expense on our March 2010 Notes.

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

Amortization of deferred financing costs and debt discount increased to \$7.8 million for the three months ended September 30, 2010 compared with \$5.5 million for the prior-year quarter. The increase is primarily attributable to the inclusion of amortization related to our March 2010 Notes and a full three months of amortization related to our September 2009 Notes, partially offset by lower amortization on the 2008 Notes, the April 2009 Notes and the July 2009 Notes due to the lower amount of notes outstanding.

#### Fair value – conversion feature liability

On March 9, 2010, we issued \$25 million of units, or the 2010 Units, each 2010 Unit consisting of (i) 40% of a senior unsecured convertible note, or the B Notes, (ii) 40% of a senior unsecured convertible note, or the C Notes and (iii) 20% of a senior secured convertible note, or the D Notes. In connection with the sale of the 2010 Units, we also issued warrants, or the Debt Warrants, to purchase senior unsecured convertible notes, or the E Notes, in an amount equal to 40% of the purchase price paid for each such 2010 Unit. On March 17, 2010, March 22, 2010 and April 9, 2010, four investors who had participated in our April 2009 financing, exercised their rights under the April 2009 securities purchase agreement and the April 2009 consent agreement to acquire F Notes of \$1.0 million. On May 6, 2010 and May 10, 2010, two holders of Debt Warrants totaling \$1.3 million exercised their warrants using a cashless

exercise procedure and received, in total, E Notes for \$1.1 million.

On the dates that we issued the March 2010 Notes, there were an insufficient number of authorized shares of common stock in order to permit conversion of all of the March 2010 Notes. When there are insufficient authorized shares to allow for settlement of convertible financial instruments, the conversion obligation for notes should be classified as a liability and measured at fair value on the balance sheet.

On March 9, 2010, based upon a Black-Scholes valuation model, we calculated a fair value of the conversion feature of the March 2010 Notes of \$263.5 million and expensed \$238.5 million, the amount that exceeded the proceeds of the \$25.0 million from the closing. On March 17, 2010, March 22, 2010 and April 9, 2010 in connection with the issuance of \$1.0 million in March 2010 F Notes, the convertible features of the F Notes were recorded as a derivative liability of \$5.4 million, resulting in an expense of \$4.4 million. On May 6, 2010 and May 10, 2010, in connection with the \$1.1 million issuance of E Notes, the convertible features of the E Notes were recorded as a derivative liability of \$7.5 million, resulting in an expense of \$6.4 million.

At the Annual Meeting of Stockholders of Genta Incorporated held on June 15, 2010, the Company's stockholders authorized its Board of Directors to effect a reverse stock split of all outstanding shares of common stock. The Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of 1-for-100 shares on July 9, 2010 and the reverse stock split became effective on August 2, 2010. The approval of the reverse stock split resulted in the Company having enough shares to accommodate the potential number of shares underlying the March 2010 Notes. The fair value of the conversion feature liability of the March 2010 Notes was re-measured at July 9, 2010 at \$81.8 million and credited to permanent equity, resulting in income on the Consolidated Statement of Operations of \$14.6 million for the three months ended September 30, 2010.

#### Fair value – warrant liability

In addition to issuing the Debt Warrants we also extended the maturity date of our outstanding 2008 Notes from June 9, 2010 to June 9, 2011 in exchange for three-year warrants, or the March 2010 Warrants to purchase the same number of shares of the Company's Common Stock issuable upon conversion of such 2008 Notes. The Debt Warrants and the March 2010 Warrants were also treated as liabilities, due to the insufficient number of authorized shares of common stock at the time that they were issued. The Debt Warrants and the March 2010 Warrants issued were initially recorded at a fair value of \$125.1 million based upon a Black-Scholes valuation model and re-measured at \$35.9 million on July 9, 2010 and credited to permanent equity, resulting in income on the Consolidated Statements of Operations of \$6.4 million for the three months ended September 30, 2010.

#### Net income/(loss)

Genta recorded net income of \$7.7 million, or net income per basic share of \$0.88 per share and net income per fully diluted share of \$0.16 per share, for the three months ended September 30, 2010 and reported a net loss of \$(20.4) million, or net loss per basic and diluted share of \$(14.66) per share, for the three months ended September 30, 2009.

Net income for the third quarter of 2010 compares favorably to the prior-year period primarily due to the mark-to-market income on the conversion feature liability and warrant liabilities of \$21.0 million and lower share-based compensation expense of \$8.8 million.



## Results of Operations for the Nine Months Ended September 30, 2010 and September 30, 2009

(\$ thousands)	2010	2009
Product sales – net	\$ 192	\$ 180
Cost of goods sold	40	12
Gross margin	152	168
Operating expenses:		
Research and development	7,255	11,846
Selling, general and administrative	7,845	13,008
Total operating expenses	15,100	24,854
Other (expense)/income:		
Interest income and other income/(expense), net	47	4
Interest expense	(2,456 )	(841 )
Amortization of deferred financing costs and debt discount	(24,363 )	(22,362 )
Fair value – conversion feature liability	(55,813 )	(19,040 )
Fair value – warrant liability	(35,900 )	(7,655 )
Total other income/(expense), net	(118,485 )	(49,894 )
Net loss	\$ (133,433 )	\$ (74,580 )

## Product sales-net

Product sales-net were \$192 thousand for the nine months ended September 30, 2010, compared with \$180 thousand for the nine months ended September 30, 2009. The average unit selling price of Ganite® was 15% higher in the nine months ended September 30, 2010 than in the comparison period for 2009 due to a May 2009 price increase. Unit sales of Ganite® increased 27% from the first nine months of 2009 to the first nine months of 2010. Net sales were negatively impacted due to a high level of sales returns earlier in 2010.

## Cost of goods sold

During the nine months ended September 30, 2009, most of the sales of Ganite® were from product that had been previously accounted for as excess inventory. This resulted in a lower cost of goods sold as a percentage of net sales in 2009.

## Research and development expenses

Research and development expenses were \$7.3 million for the nine months ended September 30, 2010, compared with \$11.8 million for the nine months ended September 30, 2009.

Research and development expenses declined due to lower expenses resulting from the AGENDA clinical trial. In addition, share-based compensation expense for those employees categorized as research and development declined from \$2.9 million in the prior-year period to \$1.5 million for the first nine months of 2010.

Research and development expenses incurred on the tesetaxel project and Genasense® project during the nine months ended September 30, 2010 were approximately \$3.3 million and \$3.2 million, representing 45% and 44% of research and development expenses, respectively.



#### Selling, general and administrative expenses

Selling, general and administrative expenses were \$7.8 million for the nine months ended September 30, 2010, compared with \$13.0 million for the nine months ended September 30, 2009, primarily due to lower share-based compensation expense of \$2.5 million recognized for those employees categorized as selling, general and administrative for the nine months ended September 30, 2010, compared to \$6.7 million in the prior-year period, as well as a net reduction in all other expenses in this category of \$1.0 million.

#### Interest income and other income/(expense), net Interest expense

The total of interest income and other income/(expense), net and interest expense resulted in net expense of \$(2.4) million for the nine months ended September 30, 2010, compared to \$(0.8) million for the prior-year period, primarily due to the inclusion of interest expense on our March 2010 Notes.

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

Amortization of deferred financing costs and debt discount of \$24.4 million for the nine months ended September 30, 2010 increased from \$22.4 million for the prior-year period. The inclusion of amortization related to our March 2010 Notes and a full nine months of amortization related to our September 2009 Notes was mostly offset by lower amortization on the 2008 Notes, the April 2009 Notes and the July 2009 Notes due to the lower amount of notes outstanding.

#### Fair value – conversion feature liability

The fair value of the conversion feature liability of the March 2010 Notes was re-measured at July 9, 2010 at \$81.8 million and credited to permanent equity, resulting in expense of \$55.8 million on the Consolidated Statement of Operations for the nine months ended September 30, 2010.

In the prior-year period, in April 2009, we issued approximately \$6 million of April 2009 Notes and corresponding warrants to purchase common stock. When we issued 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. The conversion feature liability of the April 2009 Notes was recorded on the Consolidated Statement of Operations and was marked-to-market until there were enough shares of common stock in order to permit conversion of all the April 2009 Notes, resulting in expense on the Consolidated Statement of Operations of \$19.0 million for the nine months ended September 30, 2009.

#### Fair value – warrant liability

The fair value of the warrant liabilities were re-measured at \$35.9 million on July 9, 2010 and credited to permanent equity, resulting in expense on the Consolidated Statement of Operations of \$35.9 million for the nine months ended September 30, 2010.

In the prior-year period, the warrants that were issued with 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. The warrant liability was marked-to-market until there were enough shares of common stock in order to permit conversion of all of the warrants issued with the April 2009 Notes, resulting in expense on the Consolidated Statement of Operations of \$7.7 million for the nine months ended September 30, 2009.



## Net loss

Genta recorded a net loss of \$(133.4) million, or net loss per basic and diluted share of \$(22.29) per share, for the nine months ended September 30, 2010 and reported a net loss of \$(74.6) million, or net loss per basic and diluted share of \$(98.32) per share, for the nine months ended September 30, 2009. The higher net loss was virtually all due to the higher expenses of \$65.0 million resulting from the re-measurement of the conversion feature liabilities and warrant liabilities, partially offset by lower share-based compensation expense of \$5.6 million.

## Liquidity and Capital Resources

At September 30, 2010, we had cash and cash equivalents totaling \$11.7 million, compared with \$1.2 million at December 31, 2009, reflecting our March 2010 financings offset by funds used in operations.

During the nine months ended September 30, 2010, cash used in operating activities was \$10.3 million compared with \$15.1 million for the same period in 2009, reflecting the receipt of \$2.9 million in February 2010 from the sale of portions of our New Jersey net operating losses and research and development credit carryforwards and lower expenses resulting from the AGENDA clinical trial.

Presently, with no further financing, we project that we will run out of funds in the second quarter of 2011. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase additional notes with similar terms. We are only able to access \$5 million held in a blocked account as collateral security for the March 2010 D Notes if certain stock price and daily trading volume targets are met, as noteholders convert their D Notes, or upon the approval of holders of 2/3 of D Notes. There is no guarantee that we will be able to access these funds. 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.

A special meeting of our stockholders is planned for December 29, 2010. We have recommended to our stockholders that they provide authorization to our Board of Directors to effect up to two reverse stock splits by December 31, 2011, with each reverse stock split in the ratio of 1-for-2 up to 1-for-100, and to approve our Restated Certificate of Incorporation, as amended, to increase the total number of authorized shares of capital stock available for issuance from 6,005,000,000, consisting of 6,000,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock to 100,000,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock.

We will require additional cash in order to maximize the commercial opportunity and continue clinical development of our product candidates. 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 funding will be available to us on favorable terms, if at all.

## 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:

- 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 warrants. We use a Black-Scholes model to estimate the fair value of our convertible notes and warrants.

### 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 September 30, 2010. 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 of our stockholders, on behalf of themselves and all others similarly situated, filed a class action complaint against us, 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 in June 2008, our Board of Directors, and certain officers breached their fiduciary duties, and we aided and abetted the breach of fiduciary duty. On March 20, 2009, the Superior Court of New Jersey granted our motion 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 and the Appellate Division granted the motion for temporary remand. Following the briefing and a hearing, the Superior Court denied the motion for relief from judgment on August 28, 2009. Thus, this matter proceeded in the Appellate Division. Plaintiffs' brief before the Appellate Division was filed on October 28, 2009, and our responsive brief was filed on January 27, 2010. The plaintiffs' reply brief was filed on March 15, 2010. We are currently awaiting a decision from the Appellate Division on this matter. At this time, we cannot estimate when the Appellate Division will rule on the appeal. We intend to continue our vigorous defense of this matter.

In November 2008, a complaint against us and our transfer agent, BNY Mellon Shareowner 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. On July 20, 2009, the stockholder moved for summary judgment. The summary judgment motion was fully briefed, and oral argument was heard on December 3, 2009. On May 18, 2010, the Court denied the stockholder's motion for summary judgment. A preliminary conference was held on June 24, 2010 and the case continued to proceed. Although we deny the allegations of this complaint, in order to hold down the cost of our legal expenses, on September 27, 2010, we settled this case with the individual stockholder for an amount that was not material to our Consolidated Financial Statements.



## 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, 2009 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. We have historically financed our activities from the sale of shares of common stock, convertible notes, warrants and proceeds from partnerships with other companies.

Presently, with no further financing, we project that we will run out of funds in the second quarter of 2011. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase additional notes with similar terms. We are only able to access \$5 million held in a blocked account as collateral security for the March 2010 D Notes if certain stock price and daily trading volume targets are met, as noteholders convert their D Notes, or upon the approval of holders of 2/3 of D Notes. There is no guarantee that we will be able to access these funds. 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.

We will require additional cash in order to maximize the commercial opportunity and continue clinical development of our product candidates. 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 funding will be available to us on favorable terms, if at all.

We may be unsuccessful in our efforts to obtain approval from the FDA or EMA and to commercialize our pharmaceutical product candidates.

The commercialization of our pharmaceutical products involves a number of significant challenges. In particular, our ability to commercialize products, such as tasetaxel, an oral gallium compound 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 our product candidates will receive FDA or EMA approval. For example, the recent results in the Phase 3 AGENDA trial of Genasense® in advanced melanoma were not sufficient to submit a NDA in the U.S. If extended followup of the AGENDA trial shows a statistically significant benefit for patients, we may be able to submit a NDA after that result is known. However, our prior regulatory applications for Genasense® in melanoma were unsuccessful. 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 EMA action with respect to Genasense®. Any adverse events with respect to FDA and/or EMA 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.

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.

In October 2009, we announced that AGENDA did not show a statistically significant benefit for its co-primary endpoint of PFS. Secondary endpoints of overall response rate and disease control rate (which includes complete and partial responses, plus stable disease greater than 3 months duration) also did not show a statistically significant benefit. According to the prespecified analysis plan, the statistical significance of durable response, (a secondary endpoint that measures the proportion of patients who achieved a complete or partial response that lasts greater than 6 months), is too early to evaluate. However, the observed differences in PFS, overall response, disease control and durable response all numerically favored the group that received Genasense®.

Overall survival, the other co-primary endpoint in AGENDA, is too early to evaluate, as prospectively specified. An analysis for futility, which was defined as greater than 50% conditional power to observe a statistically significant benefit of Genasense® ( $P < 0.05$ ) under the prospectively specified hazard ratio of 0.69, was conducted for the co-primary endpoint of overall survival. AGENDA passed this futility analysis, and an Independent Data Monitoring Committee has recommended that the trial continue to completion for the determination of the overall survival endpoint. The safety profile of Genasense® in AGENDA was consistent with prior studies. We currently intend to continue the AGENDA trial in order to determine whether the addition of Genasense® to dacarbazine is associated with a statistically significant increase in overall survival. If that association is demonstrated, we currently expect that Genta would submit regulatory applications for the marketing approval of Genasense® on a worldwide basis.

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.

We have a significant amount of debt. Our substantial indebtedness could adversely affect our business, financial condition and results of operations and our ability to meet our payment obligations under the notes and our other debt.

We have a significant amount of debt. As of September 30, 2010, we had a face amount of debt outstanding of \$32.2 million, consisting of the face value of 2008 Notes of \$1.9 million, the face value of April 2009 Notes of \$0.3 million, the face value of July 2009 Notes issued in July 2009 of \$0.3 million, the face value of the September 2009 Notes and July 2009 Notes issued in September 2009 of \$3.8 million and March 2010 Notes of \$25.9 million.

Our aggregate level of debt could have significant consequences on our future operations, including:

- making it more difficult for us to meet our payment and other obligations under our outstanding debt;
- resulting in an event of default if we fail to comply with the restrictive covenants contained in our debt agreements, which could result in all of our debt becoming due and payable and, in the case of an event of default under our secured debt, could permit the lenders to foreclose on our assets securing such debt;

- limiting our flexibility in planning for, or reacting to, and increasing our vulnerability to, changes in our business, the industry in which we operate and the general economy; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or are less leveraged.

Future adjustments to the conversion prices of our convertible notes may result in further dilution of our stockholders' ownership upon conversion of such notes.

Our convertible notes contain various provisions regarding the adjustment of their applicable conversion prices. If on the last trading day prior to December 31, 2010, or the December Adjustment Date, the volume weighted closing price of our common stock for the 10 consecutive trading day period ending on the last trading day prior to the December Adjustment Date, or the 10-Day December VWCP, is less than \$10.00 (as adjusted for any stock splits, combinations, recapitalizations or the like), the conversion price for the D Notes shall be reduced to a price equal to 10% of the 10-Day December VWCP. The adjustment of the conversion price of the D Notes in December would also result in the adjustment of the Company's other convertible notes pursuant to the anti-dilution provisions of such notes, as well as the March 2010 Warrants.

Additionally, the conversion rate of all of our convertible notes will be reduced if we issue additional shares of common stock or common stock equivalents for consideration that is less than the then applicable conversion price or if the conversion or exercise price of any common stock equivalent (including our convertible notes) is adjusted or modified to a price less than the then applicable conversion price.

If any of the foregoing adjustments occur, our convertible notes will be convertible into a greater number of shares and our current stockholders' ownership holdings will be further diluted upon exercise of such notes.

Future adjustments to the conversion prices of our convertible notes may result in us not having sufficient authorized shares to accommodate the conversion of all of our financial instruments, which would put us in default on our convertible notes.

As noted above, if the 10-Day December VWCP is less than \$10.00, the conversion price for our D Notes shall be reduced to a price equal to 10% of the 10-Day December VWCP. The adjustment of the conversion price of the D Notes in December would also result in the adjustment of the Company's other convertible notes pursuant to the anti-dilution provisions of such notes, as well as the March 2010 Warrants. The calculation of the 10-Day December VWCP may result in an adjusted conversion price low enough that we would not have enough authorized shares of common stock to accommodate all of our financial instruments, resulting in us being in technical default on all of our convertible notes. If we are in default under our convertible notes, the noteholders may deem the principal and all accrued interest on such convertible notes due and payable. If the noteholders demand payment of the principal and interest on the convertible notes, we may not have sufficient funds for our business operations.

Our substantial amount of secured debt may prevent us from obtaining additional financing in the future or make the terms of securing such additional financing more onerous to us.

While the terms or availability of additional capital is always uncertain, should we need to obtain additional financing in the future, because of our outstanding debt, it may be even more difficult for us to do so. If we are able to raise additional financing in the future, the terms of any such financing may be onerous to us. This potential inability to obtain borrowings or our obtaining borrowings on unfavorable terms could negatively impact our operations and impair our ability to maintain sufficient working capital.

Any future financings at a price per share below the conversion price of our outstanding convertible notes would reset the conversion price of the notes and result in greater dilution of current stockholders.

We may not have the ability to repay the principal on our convertible notes when due.

Our convertible notes mature on various dates in 2011, 2012 and 2013, and bear interest payable quarterly or semi-annually at rates of 8.0%, 12.0% or 15.0% per annum. Absent additional financing, we will likely not have sufficient funds to pay the principal upon maturity or upon any acceleration thereof. If we fail to pay principal on our convertible notes when due, we will be in default under our debt agreements which could have an adverse effect on our business, financial condition and results of operations.



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 September 30, 2010, we have incurred a cumulative net deficit of \$1,163.9 million. Achieving profitability is unlikely unless one or more of our product candidates is approved by the FDA or EMA 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® or tasetaxel 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, 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.

Tesetaxel, its potential uses, composition and methods of manufacturing are covered under a variety of patents licensed exclusively from Daiichi Sankyo, Inc. We believe that composition-of-matter claims on tesetaxel extend to at least 2020 in the U.S. and Europe and to 2022 in Japan. A number of other patents have been filed worldwide for this compound, including new applications for manufacturing processes and intermediates that were filed by us during 2010.

The principal patent covering the use of Ganite® for its approved indication 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 10 U.S. patents relating to the composition of Genasense®. We acquired exclusive rights from the University of Pennsylvania to antisense oligonucleotides directed against the Bcl-2 mRNA, as well as methods of their use for the treatment of cancer. The claims of the University of Pennsylvania patents cover our proprietary antisense oligonucleotide molecules, which target the Bcl-2 mRNA, including Genasense®, and methods of using them. Related U.S. and corresponding foreign patent applications have been issued or are pending. The most important of these "composition of matter" patents in the U.S. expires in 2015. We believe this patent may be eligible for up to 5 years of extension under Waxman-Hatch provisions, (i.e., to 2020). We also own 5 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.

We have also licensed certain rights from the U.S. NIH that cover phosphorothioate antisense oligonucleotides. This patent will expire in 2010, and the Company does not expect to owe royalty payments related to this patent.

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

We have devoted considerable resources to the development of potential antisense pharmaceutical products such as Genasense®, based upon oligonucleotide technology. Genasense® is our only antisense product to have been tested in humans. Tesetaxel has completed several clinical Phase 2a studies, and we plan to conduct additional clinical studies with the drug. 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 products obsolete or noncompetitive. Similar types of limitations apply to all our product candidates.

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®. We are currently seeking a third-party manufacturer for tasetaxel. 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 our product candidates are manufactured or tested for its ability to meet required specifications must be approved by the FDA and/or the EMA before a commercial product can be manufactured. Failure of such a facility to be approved could delay the approval of our product candidates.

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® and tesetaxel (if they obtain 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 September 2008, several of our stockholders, on behalf of themselves and all others similarly situated, filed a class action complaint against us, 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 in June 2008, our Board of Directors, and certain officers breached their fiduciary duties, and we aided and abetted the breach of fiduciary duty. On March 20, 2009, the Superior Court of New Jersey granted our motion 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 and the Appellate Division granted the motion for temporary remand. Following the briefing and a hearing, the Superior Court denied the motion for relief from judgment on August 28, 2009. Thus, this matter proceeded in the Appellate Division. Plaintiffs' brief before the Appellate Division was filed on October 28, 2009, and our responsive brief was filed on January 27, 2010. The plaintiffs' reply brief was filed on March 15, 2010. We are currently awaiting a decision from the Appellate Division on this matter. At this time, we cannot estimate when the Appellate Division will rule on the appeal. We intend to continue our vigorous defense of this matter.

#### 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 September 30, 2010, we had 12.9 million shares of common stock outstanding and 57.4 million shares reserved for the conversion of our outstanding convertible preferred stock, convertible notes, warrants, the issuance and vesting of outstanding restricted stock units and shares issuable upon the exercise of purchase rights of our noteholders. Future sales of shares of our common stock by existing stockholders, holders of preferred stock who might convert such preferred stock into common stock, holders of convertible notes who might convert such convertible notes into common stock and option and warrant holders who may exercise their options and warrants to purchase common stock also could adversely affect the market price of our common stock. Moreover, the perception that sales of substantial amounts of our common stock might occur could adversely affect the market price of our common stock.

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

The conversion of some or all of our notes and warrants dilutes 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 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

None that has not been otherwise publicly disclosed previously or otherwise disclosed in this report.

Item 3. Defaults Upon Senior Securities

None.

Item 4. (Removed and Reserved)

Item 5. Other Information

None.

Item 6. Exhibits.

(a) Exhibits

Exhibit Number	Description of Document
10.1	Genta Incorporated 2009 Stock Incentive Plan, as amended and restated (filed herewith).
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: November 11, 2010

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

Date: November 11, 2010

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

Exhibit Index

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