

GENTA INC DE/  
Form 10-Q  
May 16, 2011  
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2011

OR

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

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

Commission File Number 0-19635

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

Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

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

07922  
(Zip Code)

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

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

\  
Yes X No

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

Yes No

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

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
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 May 16, 2011 the registrant had 167,763,185 shares of common stock outstanding.

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Genta Incorporated  
INDEX TO FORM 10-Q

| PART I.    | FINANCIAL INFORMATION   | Page |
|------------|---|------|
| Item 1.    | Consolidated Financial Statements:  |      |
|            | Consolidated Balance Sheets at March 31, 2011 (unaudited)<br>and December 31, 2010                      | 3    |
|            | Consolidated Statements of Operations for the Three Months<br>Ended March 31, 2011 and 2010 (unaudited) | 4    |
|            | Consolidated Statements of Cash Flows for the Three Months<br>Ended March 31, 2011 and 2010 (unaudited) | 5    |
|            | Notes to Consolidated Financial Statements  | 6    |
| Item 2.    | Management's Discussion and Analysis of Financial<br>Condition<br>and Results of Operations             | 15   |
| Item 3.    | Quantitative and Qualitative Disclosures about Market Risk  | 22   |
| Item 4.    | Controls and Procedures   | 23   |
| PART II.   | OTHER INFORMATION   |      |
| Item 1.    | Legal Proceedings   | 23   |
| Item 1A.   | Risk Factors  | 24   |
| Item 2.    | Unregistered Sales of Equity Securities and Use of Proceeds   | 37   |
| Item 3.    | Defaults Upon Senior Securities   | 37   |
| Item 4.    | (Removed and Reserved)  | 37   |
| Item 5.    | Other Information   | 37   |
| Item 6.    | Exhibits  | 38   |
| SIGNATURES |   | 39   |

GENTA INCORPORATED  
CONSOLIDATED BALANCE SHEETS

(In thousands, except par value data)

| ASSETS   | March 31,<br>2011<br>(unaudited) | December 31,<br>2010 |
|--|----------------------------------|----------------------|
| Current assets:  |                                  |                      |
| Cash and cash equivalents  | \$ 8,893                         | \$ 12,835            |
| Inventory (Note 4)   | 25                               | 31                   |
| Prepaid expenses and other current assets  | 618                              | 890                  |
| <b>Total current assets</b>  | <b>9,536</b>                     | <b>13,756</b>        |
| Property and equipment, net  | 320                              | 334                  |
| Deferred financing costs (Note 6)  | 968                              | 1,459                |
| <b>Total assets</b>  | <b>\$ 10,824</b>                 | <b>\$ 15,549</b>     |
| <b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>   |                                  |                      |
| Current liabilities:   |                                  |                      |
| Accounts payable and accrued expenses  | \$ 4,717                         | \$ 5,813             |
| Note payable   | 241                              | 421                  |
| Convertible notes due July 7, 2011, \$34 outstanding, net of debt discount of (\$28) at March 31, 2011 and \$36 outstanding, net of debt discount of (\$36) at December 31, 2010 (Note 6)                  | 6                                | -                    |
| Convertible notes due September 4, 2011, \$3,767 outstanding, net of debt discount of (\$3,339) at March 31, 2011 and \$4,386 outstanding, net of debt discount of (\$4,386) at December 31, 2010 (Note 6) | 428                              | -                    |
| <b>Total current liabilities</b>   | <b>5,392</b>                     | <b>6,234</b>         |
| Long-term liabilities:   |                                  |                      |
| Office lease settlement obligation (Note 5)  | 1,850                            | 1,872                |
| Convertible notes due April 2, 2012, \$234 outstanding, net of debt discount of (\$222) at March 31, 2011 and \$229 outstanding, net of debt discount of (\$229) at December 31, 2010 (Note 6)             | 12                               | -                    |
| Convertible notes due March 9, 2013, \$27,695 outstanding, net of debt discount of (\$26,869) at March 31, 2011 and \$25,130 outstanding, net of debt discount of (\$25,130) at December 31, 2010 (Note 6) | 826                              | -                    |
| Warrant liability (Note 6)   | 6,057                            | 18,738               |
| <b>Total long-term liabilities</b>   | <b>8,745</b>                     | <b>20,610</b>        |



GENTA INCORPORATED  
CONSOLIDATED STATEMENTS OF OPERATIONS  
(Unaudited)

| (In thousands, except per share data)   | Three Months Ended March 31, |              |
|---|------------------------------|--------------|
|   | 2011                         | 2010         |
| Product sales - net   | \$53                         | \$34         |
| Cost of goods sold  | 6                            | 12           |
| Gross margin  | 47                           | 22           |
| Operating expenses:   |                              |              |
| Research and development  | 2,348                        | 2,443        |
| Selling, general and administrative   | 1,629                        | 3,773        |
| Total operating expenses  | 3,977                        | 6,216        |
| Other income/(expense):   |                              |              |
| Interest and other income, net  | 5                            | 8            |
| Interest expense  | (862)                        | (517)        |
| Amortization of deferred financing costs and debt discount (Note 6)             | (7,381)                      | (6,092)      |
| Fair value - conversion feature liability (Note 6)                              | -                            | (97,297)     |
| Fair value - warrant liability (Note 6)   | 12,681                       | (56,526)     |
| Total other income/(expense), net   | 4,443                        | (160,424)    |
| Net income/(loss)   | \$513                        | \$(166,618)  |
| Net income/(loss) per basic share (Note 1), (Note 8)                            | \$0.03                       | \$(3,820.46) |
| Net income/(loss) per diluted share (Note 1), (Note 8)                          | \$0.00                       | \$(3,820.46) |
| Shares used in computing net income/(loss) per basic share (Note 1), (Note 8)   | 16,401                       | 44           |
| Shares used in computing net income/(loss) per diluted share (Note 1), (Note 8) | 3,292,227                    | 44           |

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Unaudited)

| (In thousands)   | Three Months Ended March 31, |              |
|--|------------------------------|--------------|
|  | 2011                         | 2010         |
| Operating activities:  |                              |              |
| Net income/(loss)  | \$513                        | \$(166,618 ) |
| Adjustments to reconcile net income/(loss) to net cash used in operating activities: |                              |              |
| Depreciation and amortization  | 46                           | 35           |
| Amortization of deferred financing costs and debt discount                           | 7,382                        | 6,092        |
| Share-based compensation   | 197                          | 2,602        |
| Proceeds from sale of New Jersey tax losses received in 2010                         | -                            | 2,873        |
| Change in fair value - conversion feature liability (Note 6)                         | -                            | 97,297       |
| Change in fair value - warrant liability (Note 6)                                    | (12,681 )                    | 56,526       |
| Changes in operating assets and liabilities:   |                              |              |
| Inventory  | 6                            | 15           |
| Prepaid expenses and other current assets  | 271                          | 300          |
| Accounts payable and accrued expenses  | 536                          | (1,394 )     |
| Net cash used in operating activities  | (3,730 )                     | (2,272 )     |
| Investing activities:  |                              |              |
| Purchase of property and equipment   | (32 )                        | -            |
| Net cash used in investing activities  | (32 )                        | -            |
| Financing activities:  |                              |              |
| Repayments of note payable   | (180 )                       | -            |
| Sale of convertible notes net of financing costs                                     | -                            | 25,629       |
| Deposits in blocked cash account   | -                            | (5,000 )     |
| Net cash provided by/(used in) financing activities                                  | (180 )                       | 20,629       |
| Increase/(decrease) in cash and cash equivalents                                     | (3,942 )                     | 18,357       |
| Cash and cash equivalents at beginning of period                                     | 12,835                       | 1,216        |
| Cash and cash equivalents at end of period   | \$8,893                      | \$19,573     |

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2011

(Unaudited)

Reverse Stock Split

1.

At a Special Meeting of Stockholders of the Company on December 29, 2010, the Company's stockholders authorized its Board of Directors to effect up to two reverse stock splits of all outstanding shares of common stock before December 31, 2011, with each reverse stock split having an exchange ratio from 1-for-2 up to 1-for-100. The Board of Directors subsequently approved the implementation of one reverse stock split at a ratio of 1-for-50 shares and the reverse stock split became effective on February 18, 2011. 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 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 March 31, 2011, the Company had an accumulated deficit of \$1,197.2 million. Cash and cash equivalents as of March 31, 2011 were \$8.9 million. In recent years, the Company has financed its operations from the sale of convertible notes, shares of common stock and warrants.

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.

In March 2010 and April 2010, the Company raised \$25.6 million from the sale of various convertible notes and debt warrants. Presently, with no further financing, the Company projects that it will run out of funds in the third quarter of 2011. As of March 31, 2011, the Company had convertible notes with face value of \$3.8 million maturing in September 2011. The terms of the convertible notes issued in April 2009, referred to as the April 2009 Notes, enable those noteholders, at their option, to purchase certain additional notes with similar terms. The Company currently does not have any additional financing in place. If it is unable to raise additional funds, the Company 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, or raise such additional funds, on terms acceptable to it.

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



Accounting Standards Updates not effective until after March 31, 2011 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 March 31, 2011 and the results of operations and cash flows for the three months ended March 31, 2011 and 2010 have been made in conformity with United States generally accepted accounting principles. The results of operations for the three months ended March 31, 2011 may not be indicative of expected results of operations for the year ended December 31, 2011, or any other period. 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, 2010.

### Use of Estimates

The preparation of financial statements in conformity with United States 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.

### 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 three months ended March 31, 2011 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.

7

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## 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. 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 convertible notes issued in 2008, April 2009, July 2009, September 2009 and March 2010 (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 their respective maturity dates. 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 months ended March 31, 2011 and March 31, 2010 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 months ended March 31, 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 March 31, 2011, the potentially dilutive securities include 3,275.8 million shares reserved for the conversion of convertible notes, convertible preferred stock, vesting of outstanding RSUs, exercise of outstanding warrants and 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 (\$ in thousands):

|                | March 31,<br>2011 | December 31,<br>2010 |
|----------------|-------------------|----------------------|
| Raw materials  | \$ 24             | \$ 24                |
| Finished goods | 1                 | 7                    |
|                | \$ 25             | \$ 31                |

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

## 5. Office Lease Settlement Obligation

In March 2010, the Company entered into an amendment of its lease for office space with its landlord, whereby the lease for its office space in Berkeley Heights, New Jersey was extended until August 2015. In addition, as part of the amendment, the Company is due to pay an office settlement lease obligation over the life of the lease with a final payment of \$1.6 million due in August 2015.



## 6. Convertible Notes and Warrants

On March 9, 2010, the Company issued \$10 million of a senior unsecured convertible note (the “B Notes”), \$10 million of a senior unsecured convertible note (the “C Notes”) and \$5 million of a senior unsecured convertible note (the “D Notes”). In connection with the sale of the notes, the Company also issued warrants (the “Debt Warrants”) to purchase \$10 million of senior unsecured convertible notes (the “E Notes”). In March and April 2010, four investors who had participated in the Company’s April 2009 financing, described below, exercised their rights under the April 2009 securities purchase agreement and the April 2009 consent agreement to acquire \$1.0 million of senior unsecured convertible notes (the “F Notes”). In May 2010, two holders of Debt Warrants totaling \$1.3 million exercised their warrants using a cashless exercise procedure and received, in total, \$1.1 million of E Notes. In October 2010, two investors exercised Debt Warrants totaling \$4.0 million using a cashless exercise procedure and received \$3.6 million of E Notes. In January 2011, two investors exercised Debt Warrants totaling \$2.7 million using a cashless exercise procedure and received \$2.4 million of E Notes. 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, and as of March 31, 2011, were convertible into shares of Genta common stock at a conversion rate of \$0.0142.

Concurrent with the sale of the March 2010 Notes, 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. Subsequently, the maturity of the outstanding 2008 Notes was extended to September 4, 2011, as discussed below.

Prior to the approval of a 1-for-100 reverse stock split that was implemented in August 2010, 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, then 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 were 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 were classified as liabilities and measured at fair value on the balance sheet. The conversion feature liabilities and the warrant liabilities were accounted for using mark-to-market accounting at each reporting date until all the criteria for permanent equity were met.

In connection with the March 2010 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 is being amortized over the life of the notes through their maturity dates. Similarly, in March 2010, in connection with a \$0.9 million exercise 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 \$4.5 million. The Company recorded an initial discount of \$0.9 million equal to the face value of the F Notes, which is being amortized over the life of the notes through their maturity dates.



On March 31, 2010, based on the revised fair-market valuation of the conversion feature liability related to the March 2010 transaction, the liability was valued at \$119.0 million, resulting in a net expense on the Consolidated Statements of Operations for the first quarter of 2010 of \$94.0 million. Similarly, based on the revised fair-market valuation of the conversion feature liability related to the \$0.9 million F note transactions, the conversion feature liability was valued at \$4.2 million, resulting in a net expense on the Consolidated Statements of Operations for the first quarter of 2010 of \$3.3 million.

The conversion feature liability for the \$25 million transaction was valued at March 9, 2010 and March 31, 2010 and the \$0.9 million transactions were valued at March 17, 2010 and March 22, 2010 and March 31, 2010 using the Black-Scholes valuation model with the following assumptions:

|                                      | March 31, 2010 | March 17/22,<br>2010 | March 9, 2010 |
|--------------------------------------|----------------|----------------------|---------------|
| Price of share of Genta common stock | \$ 240.00      | \$ 310.00            | \$ 530.00     |
| Volatility                           | 268%           | 267%                 | 266%          |
| Risk-free interest rate              | 1.60%          | 1.47%                | 1.43%         |
| Remaining contractual lives          | 2.9            | 3.0                  | 3.0           |

Pursuant to the terms of the Amendment and Consent Agreement dated December 14, 2010 between the Company and certain investors, the conversion prices of the B Notes and E Notes were adjusted to \$0.0142 effective March 12, 2011. In accordance with the terms of all of the Company's other convertible notes, Debt Warrants, March 2010 Warrants and December 2010 Warrants, described below, the conversion prices of all of the Company's other notes, Debt Warrants, March 2010 Warrants and December 2010 Warrants were also adjusted to \$0.0142 effective March 12, 2011. The Company valued this change in the conversion rate on March 12, 2011; the aggregate intrinsic value of the difference in conversion rates was in excess of the face value of each of its convertible notes. Thus, a full debt discount was recorded in an amount equal to the face value of each of its convertible notes on March 12, 2011 and the Company began amortizing the resultant debt discount over the remaining term of the convertible notes.

From January 1, 2011 through March 31, 2011, holders of the B Notes voluntarily converted \$0.7 million, resulting in an issuance of 16.7 million shares of common stock, holders of C Notes voluntarily converted \$0.5 million, resulting in an issuance of 11.5 million shares of common stock, holders of D Notes voluntarily converted \$0.1 million, resulting in an issuance of 4.0 million shares of common stock and holders of F Notes voluntarily converted \$0.1 million, resulting in an issuance of 3.7 million shares of common stock. At March 31, 2011, the face value outstanding of the B Notes were \$6.9 million, the C Notes were \$7.6 million, the D Notes were \$5.6 million, the E Notes were \$7.5 million and the F Notes were \$0.1 million.

The Company recorded the liability for the Debt Warrants at a fair value of \$105.6 million on March 9, 2010, based upon a Black-Scholes calculation. The debt warrant liability was marked-to-market and charged/credited to expense in a manner similar to the conversion feature at each reporting date until all the criteria for permanent equity were met. At March 31, 2010, based on the revised fair-market valuation of the warrant liability of \$47.7 million, the liability was reduced by \$57.9 million, resulting in a net expense on the Consolidated Statements of Operations for the first quarter of 2010 of \$47.7 million.

The debt warrant liability was valued at March 9, 2010 and March 31, 2010 using the Black-Scholes valuation model with the following assumptions:

|                                      | March 31, 2010 | March 9, 2010 |
|--------------------------------------|----------------|---------------|
| Price of share of Genta common stock | \$ 240.00      | \$ 530.00     |
| Volatility                           | 228%           | 225%          |



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|                             |       |       |
|-----------------------------|-------|-------|
| Risk-free interest rate     | 2.35% | 2.15% |
| Remaining contractual lives | 4.5   | 4.6   |

10

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In December 2010, the Company extended the maturity date of its outstanding 2008 Notes from June 9, 2011 to September 4, 2011 in exchange for December 2010 Warrants. The December 2010 Warrants allow the holder to purchase 10% of the number of shares of common stock issuable upon conversion of 2008 Notes and have the same expiration date as the March 2010 Warrants. Both the March 2010 Warrants and the December 2010 Warrants have anti-dilution protection; warrants with anti-dilution protection are accounted for as liabilities and marked-to-market over their lives. The March 2010 Warrants and December 2010 Warrants will be marked-to-market over the lives of the warrants, and based upon a Black-Scholes valuation model, a liability of \$18.7 million was recorded at December 31, 2010. At March 31, 2011, the March 2010 Warrants and December 2010 Warrants were valued at \$6.1 million based upon a Black-Scholes valuation model, resulting in income on the Consolidated Statements of Operations for the first quarter of 2011 of \$12.7 million.

The liability for the March 2010 Warrants and December 2010 Warrants were valued at March 31, 2011 and December 31, 2010 using a Black-Scholes valuation model with the following assumptions:

|                                      | March 31,<br>2011 |   | December<br>31,<br>2010 |   |
|--------------------------------------|-------------------|---|-------------------------|---|
| Price of share of Genta common stock | \$ 0.057          |   | \$ 1.475                |   |
| Volatility                           | 246               | % | 316                     | % |
| Risk-free interest rate              | 0.80              | % | 0.70                    | % |
| Remaining contractual lives          | 2.0               |   | 2.2                     |   |

The Company recorded the fair value of the March 2010 Warrants at \$19.5 million on March 9, 2010, based upon a Black-Scholes calculation. At March 31, 2010, based on the revised fair-market valuation of the warrant liability of \$8.8 million, the liability was reduced by \$10.7 million, resulting in a net expense on the Consolidated Statement of Operations for the first quarter of 2010 of \$8.8 million. The warrant liability was valued at March 9, 2010 and March 31, 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 September 4, 2009, the Company issued \$7 million of additional July 2009 Notes (defined below), 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 with the conversion price reset on March 12, 2011 noted above, are convertible into shares of common stock at a conversion rate of \$0.0142.

From January 1, 2011 through March 31, 2011, holders of the September 2009 Notes and July 2009 Notes issued on September 4, 2009, voluntarily converted \$0.7 million, resulting in an issuance of 12.7 million shares of common stock. At March 31, 2011, \$1.9 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 1,200 shares of common stock at an exercise price of \$5,000.00 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 March 31, 2011, the unamortized balances of the financing fee were \$0.2 million and the warrants were \$0.5 million.

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 with the conversion price reset on March 12, 2011 noted above, are convertible into shares of common stock at a conversion rate of \$0.0142. At March 31, 2011, \$34 thousand of the July 2009 Notes were outstanding.

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 with the conversion price reset on March 12, 2011 noted above, are convertible into shares of common stock at a conversion rate of \$0.0142. As of March 31, 2011, 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. At March 31, 2011, \$0.2 million of the April 2009 Notes were outstanding.

On June 9, 2008, the Company placed \$20 million of 2008 Notes. 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 with the conversion price reset on March 12, 2011 noted above, are convertible into shares of common stock at a conversion rate of \$0.0142.

From January 1, 2011 through March 31, 2011, holders of the 2008 Notes voluntarily converted \$0.1 million, resulting in an issuance of 3.0 million shares of common stock. At March 31, 2011, \$1.8 million of the 2008 Notes were outstanding.

The Company is in compliance with all debt-related covenants at March 31, 2011. Upon the occurrence of an event of default, holders of the Company's notes have the right to require the Company to prepay all or a portion of their notes.

All of the Company's convertible notes contain various provisions regarding the adjustment of their applicable conversion prices. As noted above, conversion price resets were effected on December 31, 2010 and March 12, 2011. There are no other scheduled adjustments to the conversion prices of the Company's convertible notes.

The conversion rate of all of the Company's convertible notes will be reduced if the Company issues 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 the convertible notes) is adjusted or modified to a price less than the then applicable conversion price.

At March 31, 2011, the maturities of the Company's convertible notes are as follows:

| (\$ in thousands, face value amounts)                             | 2011     | 2012   | 2013      |
|---|----------|--------|-----------|
| 2008 Notes  | \$ 1,845 | \$ -   | \$ -      |
| April 2009 Notes  | -        | 234    | -         |
| July 2009 Notes   | 34       | -      | -         |
| September 2009 Notes and July 2009 Notes issued in September 2009 | 1,922    | -      | -         |
| March 2010 Notes  | -        | -      | 27,695    |
| Total   | \$ 3,801 | \$ 234 | \$ 27,695 |

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

During 2009, the Company established the 2009 Stock Incentive Plan (“2009 Plan”). The following table summarizes the RSU activity under the 2009 Plan for the three months ended March 31, 2011:

| Restricted Stock Units                        | Number of Shares<br>(in thousands) | Weighted Average Grant Date Fair Value per Share |
|---|------------------------------------|--|
| Outstanding nonvested RSUs at January 1, 2011 | 192                                | \$67.21  |
| Granted                                       | 3,425                              | \$0.057  |
| Vested  | -                                  | -  |
| Forfeited or expired                          | -                                  | -  |
| Outstanding nonvested RSUs at March 31, 2011  | 3,617                              | \$3.81   |

Based on the closing price of Genta common stock of \$0.057 per share on March 31, 2011, the fair value of the nonvested RSUs at March 31, 2011 is \$0.2 million. As of March 31, 2011, there was approximately \$0.2 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 1.1 years.

Share-based compensation expense recognized for the three months ended March 31, 2011 and 2010, respectively, was comprised as follows:

| (\$ in thousands, except per share data)                   | Three months ended<br>March 31 |          |
|--|--------------------------------|----------|
|  | 2011                           | 2010     |
| Research and development expenses                          | \$ 84                          | \$ 653   |
| Selling, general and administrative                        | 113                            | 1,949    |
| Total share-based compensation expense                     | \$ 197                         | \$ 2,602 |
| Share-based compensation expense, per basic common share   | \$ 0.01                        | \$ 59.65 |
| Share-based compensation expense, per diluted common share | \$ 0.00                        | \$ 59.65 |

## 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<br>March 31, |               |
|--|---------------------------------|---------------|
|  | 2011                            | 2010          |
| Numerator:   |                                 |               |
| Net income/(loss)  | \$ 513                          | \$ (166,618 ) |
| Plus: income impact of assumed conversion interest on convertible debt | 944                             | -             |
| Net income/(loss) plus assumed conversion                              | \$ 1,457                        | \$ (166,618 ) |

## Denominator:

## Weighted average shares outstanding:

|   |           |    |
|---|-----------|----|
| Basic   | 16,401    | 44 |
| Effect of dilutive convertible notes                                      | 2,234,533 | -  |
| Effect of dilutive warrants/rights  | 1,037,676 | -  |
| Effect of dilutive restricted stock units and convertible preferred stock | 3,617     | -  |
| Diluted   | 3,292,227 | 44 |

## Net income/(loss) per share:

|         |         |                |
|---------|---------|----------------|
| Basic   | \$ 0.03 | \$ (3,820.46 ) |
| Diluted | \$ 0.00 | \$ (3,820.46 ) |

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 three months ended March 31, 2011 and March 31, 2010. On January 4, 2011, the Company issued \$0.1 million of September 2009 Notes in lieu of interest due on its September 2009 Notes. On January 7, 2011, the Company issued \$1 thousand in July 2009 Notes in lieu of interest due on its July 2009 Notes. On March 2, 2011, the Company issued \$9 thousand in April 2009 Notes in lieu of interest due on its April 2009 Notes. On March 9, 2011, the Company issued \$68 thousand of 2008 Notes in lieu of interest due on its 2008 Notes. On March 9, 2011 the Company issued B Notes, C Notes, D Notes, E Notes and F Notes totaling \$1.5 million in lieu of interest due on the B Notes, C Notes, D Notes, E Notes and F Notes. 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 \$163 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 March 9, 2010, the Company issued approximately \$386 thousand of 2008 Notes in lieu of interest due on its 2008 Notes.

From January 1, 2011 through March 31, 2011, holders of the Company's convertible notes voluntarily converted approximately \$2.1 million, resulting in an issuance of 51.6 million shares of common stock. From January 1, 2010 through March 31, 2010, holders of the Company's convertible notes voluntarily converted approximately \$2.5 million, resulting in an issuance of 34 thousand shares of common stock.

From January 1, 2011 through March 31, 2011, holders of the Company's March 2010 Warrants voluntarily exercised a portion of their warrants, resulting in an issuance of 2.1 million shares.

11. Subsequent Events

From April 1, 2011 through May 16, 2011, holders of convertible notes have voluntarily converted approximately \$1.6 million of their notes, resulting in an issuance of 109.2 million shares of common stock.





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 plans, 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, or FDA or European Medicines Agency, or EMA;
  - the safety and efficacy of the Company's products;
  - the timing of 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.

The Company has had recurring annual operating losses since its inception and we expect to incur substantial operating losses due to continued requirements for ongoing and planned research and development activities, pre-clinical and clinical testing, manufacturing activities, regulatory activities and establishment of a sales and marketing organization. From our inception to March 31, 2011, we have incurred a cumulative net deficit of \$1,197.2 million. 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.

Our principal goal is to secure regulatory approval for the marketing of our products. One of our lead drugs, 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 various diseases. We have been especially interested in the development of Genasense® in three specific diseases: melanoma, chronic lymphocytic leukemia, referred to herein as CLL, and non-Hodgkin's lymphoma, referred to herein as NHL.

Our major recent initiative with Genasense® related 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 a tumor biomarker, (lactate dehydrogenase, or LDH) to identify patients who were most likely to respond to Genasense®. This selection was based on data we obtained from our preceding trial in melanoma. The co-primary endpoints of AGENDA were progression-free survival, or PFS, and overall survival.

As noted, AGENDA was designed based on data obtained from a similarly designed Phase 3 trial that was published in 2006. Results from that study showed that treatment with Genasense® plus dacarbazine compared with dacarbazine alone was associated with a statistically significant increase in the secondary endpoints of overall response, a complete response, or CR, durable response and PFS. However, the primary endpoint of overall survival approached but did not reach statistical significance ( $P=0.077$ ) in the entire "intent-to-treat" population. Further analysis of this trial showed that there was a significant treatment interaction effect related to blood levels of LDH. 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. LDH had also been previously described by others as the single most important prognostic factor in advanced melanoma. Thus, the AGENDA trial sought to prospectively confirm these observations of potentially improved survival in this 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 increase in its co-primary endpoint of PFS or for secondary endpoints of overall response rate and disease control rate (which includes complete and partial responses, plus stable disease greater than 3 months duration). However, the differences in PFS, overall response and disease control all numerically favored the group that received Genasense®.

As prospectively specified, AGENDA was statistically powered to detect an improvement in overall survival, which is a late endpoint. At the time the early endpoints of the study were released (i.e. PFS, response rate), the data on late endpoints of survival and durable response were too early to analyze. An analysis for futility, which was defined as greater than 50% conditional power to observe a statistically significant increase 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 recommended that the trial continue to completion for the determination of the overall survival endpoint. The safety profile in patients who received Genasense® plus dacarbazine in AGENDA was consistent with prior studies. Followup of all patients for survival terminated on March 31, 2011. We currently project that the survival information will be available in May 2011. 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, regarding approval for treatment of patients with advanced melanoma.

We have conducted other trials of Genasense® in melanoma, including a Phase 2 trial of Genasense® plus chemotherapy consisting of Abraxane® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus temozolomide (Temodar®). In this trial, we examined whether different dosing regimens could be used to improve convenience. We project that final data from that trial, including overall survival information will be presented in the second quarter of 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 in the proportion of patients who achieved a CR, defined as a complete or nodular partial response (17% vs. 7%; P=0.025). Patients who achieved this level of response also experienced disappearance of predefined disease symptoms. A key secondary endpoint, duration of CR, was also significantly longer for patients treated with Genasense® (median exceeding 36+ months in the Genasense® group, versus 22 months in the chemotherapy-only group).

Several secondary endpoints were not improved by the addition of Genasense®. The percentage of patients who experienced serious adverse events was increased in the Genasense® arm; however, the percentages of patients who discontinued treatment due to adverse events were equal in the treatment arms. The incidence of certain serious adverse reactions, including but not limited to nausea, fever and catheter-related complications, was increased in patients treated with Genasense®.

We submitted a NDA to the FDA 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. However, we received a “non-approvable” notice from the FDA in December 2006 for this NDA. Our appeals of this decision to the FDA were unsuccessful.

In June 2008, we announced results from 5 years of follow-up on patients who had been accrued to the Phase 3 CLL trial. These data showed that patients treated with Genasense® plus chemotherapy who achieved either a CR or a partial response, also know 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. In the absence of a co-development partner to share expenses, we will not conduct a new study in CLL unless the survival results of the AGENDA trial are positive.



In March 2008, we obtained an exclusive worldwide license for tesetaxel from Daiichi Sankyo Company Limited. 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.

We have initiated several new clinical trials with tesetaxel, including Phase 2 trials of tesetaxel in patients with advanced gastric cancer, breast cancer, bladder cancer, prostate cancer and melanoma. These trials are currently open to enrollment at major cancer centers around the world.

The FDA has granted our 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.

The FDA has also designated tesetaxel as an Orphan Drug for treatment of patients with advanced gastric cancer and for patients with advanced melanoma. Orphan Drug designation for tesetaxel in gastric cancer was also granted by the EMA. Orphan Drug designation is designed to facilitate the development of new drugs that are intended to treat diseases that affect a small number of patients. We routinely file for both Fast Track and Orphan Drug designations, or similar designations in applicable territories, for diseases that fulfill regulatory requirements for such designation.

Our third pipeline project consists of the development of an oral gallium-containing compound. We believe such compounds may have broad utility to treat diseases associated with accelerated bone loss. These illnesses include hypercalcemia, bone metastases, Paget’s disease and osteoporosis. In addition, new uses of gallium-containing compounds have been identified for treatment of certain infectious diseases. We have supported research conducted by certain academic institutions by providing clinical supplies of our gallium-containing drugs for patients with cystic fibrosis who have severe infections.

We completed a single-dose Phase 1 clinical study of one such compound (known as G4544[a]). We have developed additional experimental compounds of this class with the goal of identifying a potential lead compound for further clinical testing. Some of these compounds are currently being tested in animals to evaluate their oral absorption.

If we are able to identify a clinically and commercially acceptable formulation of an oral gallium-containing compound, we will evaluate whether an expedited regulatory approval may be possible.

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. 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.

## Results of Operations for the Three Months Ended March 31, 2011 and March 31, 2010

| (\$ in thousands)  | 2011     | 2010          |
|--|----------|---------------|
| Product sales – net  | \$ 53    | \$ 34         |
| Cost of goods sold   | 6        | 12            |
| Gross margin   | 47       | 22            |
| Operating expenses:  |          |               |
| Research and development                                   | 2,348    | 2,443         |
| Selling, general and administrative                        | 1,629    | 3,773         |
| Total operating expenses                                   | 3,977    | 6,216         |
| Other (expense)/income:                                    |          |               |
| Interest and other income                                  | 5        | 8             |
| Interest expense   | (862 )   | (517 )        |
| Amortization of deferred financing costs and debt discount | (7,381 ) | (6,092 )      |
| Fair value – conversion feature liability                  | -        | (97,297 )     |
| Fair value – warrant liability                             | 12,681   | (56,526 )     |
| Total other income/(expense), net                          | 4,443    | (160,424 )    |
| Net income/(loss)  | \$ 513   | \$ (166,618 ) |

## Product sales-net

Product sales-net were \$53 thousand for the first quarter of 2011, compared with \$34 thousand for the first quarter of 2010. Net sales increased in the first quarter of 2011 due to a significant decline in the level of product returns.

## Cost of goods sold

Cost of goods sold for the first quarter of 2011 declined 50% from the prior-year quarter due to the decline in unit sales. As a percent of sales, cost of goods sold declined due to the significant decline in the level of product returns.

## Research and development expenses

Research and development expenses were \$2.3 million for the three months ended March 31, 2011, virtually unchanged with \$2.4 million recognized for the three months ended March 31, 2010. Research and development expenses incurred on the tesetaxel project during the first quarter of 2011 were approximately \$1.3 million, or 56% of research and development expenses during the first quarter of 2011 and research and development expenses incurred on the Genasense® project for the first quarter of 2011 were approximately \$0.7 million, representing 31% of research and development expenses during the first quarter of 2011. In the prior-year quarter, research and development expenses incurred on the tesetaxel project (including purchased drug supply for tesetaxel) during the three months ended March 31, 2010 were approximately \$1.4 million, representing 58% of research and development expenses and research and development expenses incurred on the Genasense® project were approximately \$0.8 million, or 31% of research and development expenses.

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are subject to wide

variability. Results from clinical trials may not be favorable. Data from clinical trials are subject to varying interpretation and may be deemed insufficient by the regulatory bodies that review applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

#### Selling, general and administrative expenses

Selling, general and administrative expenses were \$1.6 million for the three months ended March 31, 2011, compared with \$3.8 million for the three months ended March 31, 2010. This decline was primarily due to lower share-based compensation expense, as share-based compensation expense recognized for the three months ended March 31, 2011 was \$0.1 million and for the three months ended March 31, 2010 was \$1.9 million.

#### Interest and other income

##### Interest expense

On March 9, 2010, we issued a series of convertible notes totaling \$25 million. In connection with the sale of the notes, we also issued warrants, referred to as Debt Warrants, to purchase \$10 million of senior unsecured convertible notes. In March and April 2010, four investors who had participated in our April 2009 financing, exercised their rights under that financing to acquire senior unsecured convertible notes of \$1.0 million. In May 2010, two holders of Debt Warrants totaling \$1.3 million exercised their warrants using a cashless exercise procedure and received notes of \$1.1 million. In October 2010, two holders of Debt Warrants totaling \$4.0 million exercised their warrants using a cashless exercise procedure and received notes of \$3.6 million. In January 2011, two holders exercised Debt Warrants of \$2.7 million using a cashless exercise procedure and received notes of \$2.4 million. The notes in all of the above transactions, referred to as 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 March 31, 2011, were convertible into shares of Genta common stock at a conversion rate of \$0.0142.

Concurrent with the sale of the March 2010 Notes, we also extended the maturity date of our outstanding convertible notes from a financing in 2008, referred to as 2008 Notes, from June 9, 2010 to June 9, 2011 in exchange for three-year warrants, referred to as March 2010 Warrants, to purchase the same number of shares of our common stock issuable upon conversion of such 2008 Notes. In December 2010, we extended the maturity date of our outstanding 2008 Notes from June 9, 2011 to September 4, 2011 in exchange for December 2010 Warrants. The December 2010 Warrants allow the holder to purchase 10% of the number of shares of common stock issuable upon conversion of 2008 Notes and have the same expiration date as the March 2010 Warrants.

The total of interest and other income and interest expense resulted in expense, net of \$(0.9) million for the three months ended March 31, 2011, compared to \$(0.5) million for the prior-year quarter. The increase is primarily attributable to the inclusion of a full three months of interest expense on our March 2010 Notes during the first quarter of 2011.

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

Amortization of deferred financing costs and debt discount increased to \$7.4 million for the three months ended March 31, 2011 compared with \$6.1 million for the prior-year quarter. The increase is primarily attributable to the inclusion of a full three months of amortization related to our March 2010 Notes during the first quarter of 2011.

##### Fair value – conversion feature liability

On the date 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. Similarly, in March 2010, in connection with the issuance of \$0.9 million in March 2010 Notes, the convertible features of the notes were recorded as a derivative liability of \$5.4 million, resulting in an expense of \$4.5 million.

At March 31, 2010, based on the revised fair-market valuation of the conversion feature liabilities related to the March 2010 transactions, the liabilities were valued at \$123.2 million, resulting in a net expense on the Consolidated Statements of Operations for the first quarter of 2010 of \$97.3 million.

#### Fair value – warrant liability

At March 31, 2011, the March 2010 Warrants and December 2010 Warrants were valued at \$6.1 million based upon a Black-Scholes valuation model, resulting in income on the Consolidated Statements of Operations for the first quarter of 2011 of \$12.7 million.

In the prior-year period, 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 were initially recorded at a fair value of \$125.1 million based upon a Black-Scholes valuation model and re-measured at March 31, 2010, resulting in a net expense of \$56.5 million for the three months ended March 31, 2010.

#### Net income/(loss)

Genta recorded net income of \$0.5 million, or \$0.03 net income per basic share and \$0.00 net income per diluted share, for the three months ended March 31, 2011 and reported a net loss of \$166.6 million, or net loss per basic and diluted share of \$(3,820.46) per share, for the three months ended March 31, 2010. The improvement in net income was primarily due to the recognition of the conversion feature liability in the prior quarter plus the income recorded in this year's quarter as a result of marking-to-market the warrant liabilities.

#### Liquidity and Capital Resources

At March 31, 2011, we had cash and cash equivalents totaling \$8.9 million, compared with \$12.8 million at December 31, 2010, reflecting funds used in operating our company.

Net cash used in operating activities for the three months ended March 31, 2011 was \$3.7 million compared with \$2.3 million for the same period in 2010. The prior-year period included the receipt of funds of \$2.9 million from the sale of portions of New Jersey net operating losses and research and development credits.

In March 2010 and April 2010, we raised \$25.6 million from the sale of various convertible notes and debt warrants. Presently, with no further financing, we project that the Company will run out of funds in the third quarter of 2011. As of March 31, 2011, we had convertible notes with face value of \$3.8 million maturing in September 2011. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase additional notes with similar terms. We currently do not have any additional financing in place. If we are unable to raise additional funds, we could be required to reduce our spending plans, reduce our workforce, license one or more of our products or technologies that we would otherwise seek to commercialize ourselves, or sell certain assets. There can be no assurance that we can obtain financing, if at all, or raise such additional funds, on terms acceptable to us.

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

### Critical Accounting Policies and Estimates

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

- **Going concern.** Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and as a result, our independent registered public accounting firm included an explanatory paragraph in their report on our consolidated financial statements for the year ended December 31, 2010 with respect to this uncertainty. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

**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.

**Valuation of RSUs.** RSUs 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.

### 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 March 31, 2011. Therefore, there will be no ongoing exposure to a potential material adverse effect on our business, financial condition or results of operation for sensitivity to changes in interest rates or to changes in currency exchange rates.

#### Item 4. Controls and Procedures

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

As required by Rule 13a-15(b), Genta's Chief Executive Officer and 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.

## 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, 2010. 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.

### 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 third quarter of 2011. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase additional notes with similar terms. We currently do not have any additional financing in place. If we are unable to raise additional funds, we could be required to reduce our spending plans, reduce our workforce, license one or more of our products or technologies that we would otherwise seek to commercialize ourselves, or sell certain assets. There can be no assurance that we can obtain financing, if at all, or raise such additional funds, 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 tesetaxel, 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 re-submit a NDA in the U.S., and our prior regulatory applications for Genasense® in melanoma and CLL were 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.

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

Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements for the year ended December 31, 2010 with respect to this uncertainty. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of the common shares of our stock and we may have a more difficult time obtaining financing.

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

We 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 increase in its co-primary endpoint of PFS, or for secondary endpoints of overall response rate and disease control rate (which includes complete and partial responses, plus stable disease greater than 3 months duration).

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 March 31, 2011, we had a face amount of debt outstanding of \$31.7 million, consisting of the face value of 2008 Notes of \$1.8 million, the face value of April 2009 Notes of \$0.2 million, the face value of July 2009 Notes issued in July 2009 of \$34 thousand, the face value of the September 2009 Notes and July 2009 Notes issued in September 2009 of \$1.9 million and the face value of March 2010 Notes of \$27.7 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;
- 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.

Any of the above-listed factors could have an adverse effect on our business, financial condition and results of operations and our ability to meet our payment obligations under the notes and our other debt.

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. Conversion price resets went into effect on October 9, 2010, January 1, 2011 and March 12, 2011. There are no other scheduled adjustments to the conversion prices of our convertible notes.

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 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.

Our substantial amount of 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.

Our business could suffer if we are not able to enter into suitable contractual collaborative arrangements with research institutions and corporate partners for the development and commercialization of our products, or if our collaborative arrangements are not successful in developing and commercializing products.

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

We also seek strategic alliances with corporate partners, primarily pharmaceutical and biotechnology companies, to help us develop and commercialize drugs. Various problems can arise in strategic alliances. A partner responsible for conducting clinical trials and obtaining regulatory approval may fail to develop a marketable drug. A partner may decide to pursue an alternative strategy or focus its efforts on alliances or other arrangements with third parties. A partner that has been granted marketing rights for a certain drug within a geographic area may fail to market the drug successfully. Consequently, strategic alliances that we may enter into may not be scientifically or commercially successful.

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

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

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

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

We have never been profitable. We have incurred substantial annual operating losses associated with ongoing research and development activities, preclinical testing, clinical trials, regulatory submissions and manufacturing activities. From the period since our inception to March 31, 2011, we have incurred a cumulative net deficit of \$1,197.2 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 tesetaxel 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. Additionally, involvement in such proceedings could divert management attention from our operations.

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.

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 2 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 or in international markets.

The FDA in the United States and regulatory authorities in international markets impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve lengthy and detailed preclinical and clinical testing and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more depending upon the type, complexity and novelty of the product. We cannot apply for regulatory 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 or international regulatory authorities 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 tasetaxel (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 into our products and services;
  - additional expense associated with amortization of acquired assets;
  - maintenance of uniform standards, controls, procedures and policies; and
- impairment of existing relationships with employees, suppliers and customers as a result of the integration of new management personnel.

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

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

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

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

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

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

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



### Risks Related to Outstanding Litigation

The outcome of and costs relating to pending 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.

We may implement a reverse stock split prior to December 31, 2011.

At a Special Meeting of Stockholders held on December 29, 2010, our stockholders authorized our Board of Directors to implement two reverse stock splits prior to December 31, 2011, with each stock split having an exchange ratio from 1-for-2 up to 1-for-100. We implemented one reverse stock split having a ratio of 1-for-50 on February 18, 2011. Our Board may decide to implement an additional reverse stock split prior to December 31, 2011.

Our stock price is volatile.

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

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

At March 31, 2011, we had 57.1 million shares of common stock outstanding and 3,275.8 million shares reserved for the conversion of our outstanding convertible preferred stock, convertible notes, warrants, debt warrants, 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 about 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

Item 3. Defaults Upon Senior Securities

None.

Item 4. (Removed and Reserved)

Item 5. Other Information

None.

37

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Item 6. Exhibits.

(a) Exhibits

| Exhibit<br>Number | Description of Document   |
|-------------------|---|
| 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: May 16, 2011

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

Raymond P. Warrell, Jr., M.D.

Chairman and Chief Executive Officer

(principal executive officer)

Date: May 16, 2011

/s/ GARY SIEGEL

Gary Siegel

Vice President, Finance

(principal financial and accounting officer)

Exhibit Index

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