

GENTA INC DE/  
Form 10-K  
March 29, 2010

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

**FORM 10-K**

x      **Annual Report Pursuant to SECTION 13 or 15(d)  
of the Securities Exchange Act of 1934**

**For the fiscal year ended December 31, 2009**

o      **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 000-19635**

**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 No.)

GENTA INCORPORATED

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

07922  
(Zip Code)

**(908) 286-9800**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Name of each exchange on which registered:
Common Stock, \$.001 par value	
Series G Participating Cumulative	Over-the-Counter Bulletin Board
Preferred Stock Purchase Rights	

Securities registered pursuant to Section 12(g) of the Act: **NONE**

Indicate by check mark if a registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☒

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer <input type="radio"/>	Accelerated filer <input type="radio"/>
Non-accelerated filer <input type="radio"/>	Smaller reporting company <input checked="" type="radio"/>

(Do not check if a smaller reporting company)

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

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was \$41,404,787 as of June 30, 2009 (the last business day of the registrant's most recently completed second fiscal quarter).

As of March 29, 2010, the registrant had 327,237,118 shares of Common Stock outstanding.

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The statements contained in this Annual Report on Form 10-K that are not historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. Such forward-looking statements include those which express plan, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. The words potentially, anticipate, expect, could, calls for and similar expressions also identify forward-looking statements. We intend that all forward-looking statements be subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect our views as of the date they are made with respect to future events and financial performance, but are subject to many risks and uncertainties, which could cause actual results to differ materially from any future results expressed or implied by such forward-looking statements. Factors that could affect actual results include risks associated with:

- the Company's financial projections;
  - the Company's projected cash flow requirements and estimated timing of sufficient cash flow;
  - the Company's current and future license agreements, collaboration agreements, and other strategic alliances;
  - the Company's ability to obtain necessary regulatory approval for Genasense® (oblimersen sodium) Injection from the U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA);
  - the safety and efficacy of the Company's products;
  - the commencement and completion of clinical trials;
  - the Company's ability to develop, manufacture, license and sell its products or product candidates;
  - the Company's ability to enter into and successfully execute license and collaborative agreements, if any;
  - the adequacy of the Company's capital resources and cash flow projections, and the Company's ability to obtain sufficient financing to maintain the Company's planned operations, 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 Certain Risks and Uncertainties Related to the Company's Business.
- 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 our 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-K.

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## PART I

### Item 1. Business

#### Overview

Genta Incorporated, also referred to herein as us, we, our, Genta or the Company, was incorporated in Delaware February 4, 1988. Genta is a biopharmaceutical company engaged in pharmaceutical (drug) research and development. We are dedicated to the identification, development and commercialization of novel drugs for the treatment of cancer and related diseases. Our research portfolio consists of two major programs: DNA/RNA Medicines (which includes our lead oncology drug, Genasense®); and Small Molecules (which includes our marketed product, Ganite®, and tesetaxel and oral gallium-containing compounds).

The DNA/RNA Medicines program includes drugs that are based on using modifications of either DNA or RNA as drugs that can be used to treat disease. These technologies include antisense, decoys, and small interfering or micro RNAs. Our lead drug from this program is an investigational antisense compound known as Genasense® (oblimersen sodium injection). Genasense® is designed to disrupt a specific mRNA, which then block the production of a protein known as Bcl-2. Current science suggests that Bcl-2 is a fundamental (although not sole) cause of the inherent resistance of cancer cells to anticancer treatments, such as chemotherapy, radiation, and monoclonal antibodies. While Genasense® has displayed some anticancer activity when used alone, we are developing the drug primarily as a means of amplifying the cytotoxic effects of other anticancer treatments. We are also developing tesetaxel as an oral agent that targets tubulin in cancer cells, an extremely well-validated cancer target. Oral gallium compounds employ the same active ingredient in our marketed product, Ganite®, that has demonstrated clinical activity in a range of diseases associated with accelerated bone loss.

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

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

The design of AGENDA was based on data obtained from a similarly designed Phase 3 trial that was published in 2006. Results from this antecedent study showed that treatment with Genasense® plus dacarbazine compared with dacarbazine alone was associated with a statistically significant increase in overall response, complete response, durable response, and progression-free survival (PFS). However, the primary endpoint of overall survival approached but did not quite reach statistical significance ( $P=0.077$ ) in the entire intent-to-treat population. Our further analysis of this trial showed that there was a significant treatment interaction effect related to levels of a blood enzyme known as LDH. When this effect was analyzed by treatment arm, survival was shown to be significantly superior for patients

with a non-elevated LDH who received Genasense® (P=0.018; n=508). Moreover, this benefit was particularly noteworthy for patients whose baseline LDH did not exceed 80% of the upper limit of normal for this lab value. LDH had also been previously described by others as the single most important prognostic factor in advanced melanoma. Thus, the AGENDA trial sought to confirm the observations that were previously observed in the antecedent trial in a biomarker-defined patient population.



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

Overall survival, the other co-primary endpoint in AGENDA, is too early to evaluate, as prospectively specified. An analysis for futility, which was defined as greater than 50% conditional power to observe a statistically significant benefit of Genasense® under the prospectively assumed hazard ratio of 0.69, was conducted for the co-primary endpoint of overall survival. AGENDA passed this futility analysis, and an Independent Data Monitoring Committee has recommended that the trial continue to completion for the determination of the overall survival endpoint. The safety profile of Genasense® in AGENDA was consistent with prior studies. We have indicated our intention to continue patient follow-up in the AGENDA trial to determine whether Genasense® will yield a statistically significant improvement in its co-primary endpoint of overall survival. We currently project that this information may be available in the first quarter of 2011. If the final analysis for overall survival is statistically significant, we plan to resubmit our New Drug Application (NDA) to the FDA and seek approval for treatment of patients with advanced melanoma with Genasense®. We anticipate that such a filing would take place in 2011.

We have been conducting other trials of Genasense® in melanoma, including a Phase 2 trial of Genasense® plus chemotherapy consisting of Abraxane® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus temozolomide (Temodar®). We also expect to examine whether different dosing regimens would improve efficacy and dosing convenience of Genasense®.

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 (Flu/Cy) with or without Genasense®. The trial achieved its primary endpoint: a statistically significant increase (17% vs. 7%;  $P=0.025$ ) in the proportion of patients who achieved a complete response (CR), defined as a complete or nodular partial response. Patients who achieved this level of response also experienced disappearance of predefined disease symptoms. A key secondary endpoint, duration of CR, was also significantly longer for patients treated with Genasense® (median exceeding 36+ months in the Genasense® group, versus 22 months in the chemotherapy-only group).

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

We received a non-approvable notice from the FDA in December 2006 for our NDA that proposed the use of Genasense® in combination with Flu/Cy for the treatment of patients with relapsed or refractory CLL who had previously received fludarabine. We appealed this decision with FDA's Center for Drug Evaluation and Research (CDER) using the agency's Formal Dispute Resolution process. In June 2008, we announced results from 5 years of follow-up on patients who had been accrued to our completed Phase 3 trial. These data showed that patients treated with Genasense® plus chemotherapy who achieved either a complete response (CR) or a partial response (PR) also achieved a statistically significant increase in survival compared with patients treated with chemotherapy alone.

(median = 56 months vs. 38 months, respectively). After 5 years of follow-up, 22 of 49 (45%) responders in the Genasense® group were alive compared with 13 of 54 (24%) responders in the chemotherapy-only group (hazard ratio = 0.6; P = 0.038). Moreover, with 5 years of follow-up, 12 of 20 patients (60%) in the Genasense® group who achieved CR were alive, 5 of these patients remained in continuous CR without relapse, and 2 additional patients had relapsed but had not required additional therapy. By contrast, only 3 of 8 CR patients in the chemotherapy-only group were alive, all 3 had relapsed, and all 3 had required additional anti-leukemic treatment. However, in March 2009, CDER decided

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that available data were still insufficient to support approval of Genasense® in CLL, and the Agency recommended conducting another clinical trial. In the absence of a co-development partner to share expenses, we have determined that we will not conduct the recommended study in the CLL indication until the survival results of the AGENDA trial are known. We have made no decision whether to conduct this study or whether to pursue the current application for regulatory approval in other territories.

As with melanoma, we have believed the clinical activity in CLL, as well as in NHL and other types of cancer, should be explored with additional clinical research. We are currently assessing whether to proceed with such studies in advance of the final survival results in AGENDA.

In March 2008, we obtained an exclusive worldwide license for tesetaxel from Daiichi Sankyo Company Ltd. Maintenance of the license from Daiichi Sankyo requires certain milestone payments. If such payments are not made, Daiichi Sankyo may elect to terminate the license. Tesetaxel is a novel taxane compound that is taken by mouth.

Tesetaxel has completed Phase 2 trials in a number of cancer types, and the drug has shown definite evidence of antitumor activity in gastric cancer and breast cancer. Tesetaxel also appears to be associated with a lower incidence of peripheral nerve damage, a common side effect of taxanes that limits the maximum amount of these drugs that can be given to patients. At the time we obtained the license, tesetaxel was on clinical hold by FDA due to the occurrence of several fatalities in the setting of severe neutropenia. In the second quarter of 2008, we filed a response to the FDA requesting a lift of the clinical hold, which was granted in June 2008. In January 2009, we initiated of a new clinical trial with tesetaxel to examine the clinical pharmacology of the drug over a narrow dosing range around the established Phase 2 dose. That trial has now been completed and its results have been submitted for presentation at the June 2010 annual meeting of the American Society of Clinical Oncology (ASCO). We plan to initiate several new clinical trials with tesetaxel during 2010.

We have also submitted applications to FDA for designation of tesetaxel as an Orphan Drug for treatment of patients with advanced gastric cancer and for patients with advanced melanoma. Both of these designations were granted. Our current priorities for clinical testing of tesetaxel include the evaluation of safety and efficacy in patients with advanced gastric cancer, advanced melanoma and prostate cancer. Other disease priorities for clinical research include cancers of the bladder and breast, among other disorders.

Our third pipeline project consists of several formulations of an oral gallium-containing compound. One of these formulations is known as G4544, which was developed in collaboration with Emisphere Technologies, Inc. We completed a single-dose Phase 1 study of an initial formulation of this new drug known as G4544(a), the results of which were presented in the second quarter of 2008. We are currently contemplating whether a modified formulation, known as G4544(b), will prove more clinically acceptable.

If we are able to identify a clinically and commercially acceptable formulation of an oral gallium-containing compound, we currently intend to evaluate whether an expedited regulatory approval may be possible. We believe a drug of this class may also be broadly useful for treatment of other diseases associated with accelerated bone loss, such as bone metastases, Paget's disease and osteoporosis. In addition, new uses of gallium-containing compounds have been identified for treatment of certain infectious diseases. While we have no current plans to begin clinical development in the area of infectious disease, we intend to support research conducted by certain academic institutions by providing clinical supplies of our gallium-containing drugs for patients with cystic fibrosis.

We are currently marketing Ganite® in the U.S., which is an intravenous formulation of gallium, for treatment of cancer-related hypercalcemia that is resistant to hydration. Sales of Ganite® have been low relative to original expectations in part due to our under-investment in its marketing for a small indication. Since Ganite® has now lost patent protection, we do not plan to substantially increase our investment in the drug, but we believe the product has

strategic importance for our franchise of gallium-containing compounds and we currently intend for Ganite® to remain on the market.

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## Summary of Business and Research and Development Programs

Our goal is to establish Genta as a biopharmaceutical leader and preferred partner in the oncology market and eventually, as direct marketers of our products in the United States. Our key strategies in this regard are:

*Build on our core competitive strength of oncology development expertise to establish a leadership position in providing biopharmaceutical products for the treatment of cancer;*

*Expand our pipeline of products in two therapeutic categories, DNA/RNA Medicines and Small Molecules, through internal development, licensing and acquisitions;*

*Establish our lead antisense compound, Genasense®, as the preferred chemosensitizing drug for use in combination with other cancer therapies in melanoma and other cancers; and*

*Establish a sales and marketing presence in the U.S. oncology market.*

### Research and Development Programs

#### DNA/RNA Medicines

A number of technologies have been developed using modifications of DNA or RNA. These agents have been used as scientific tools for laboratory use to identify gene function, as diagnostic probes to evaluate diseases, and more recently as potential drugs to treat human diseases. Collectively, these technologies include methods known as antisense, RNA interference, micro-RNA, decoys and gene therapy. Founded in 1988, Genta was one of the first companies established to exploit these new technologies for use as potential drugs and we remain broadly committed to research and development of these compounds with a specific focus on cancer medicine, commonly known as oncology. Our most advanced drugs in our DNA/RNA Medicines program involve the use of antisense technology.

#### Antisense Technology

Most cellular functions, including whether cells live or die, are carried out by proteins. The genetic code for a protein is contained in DNA, which is made up of bases known as nucleotides that are arranged in a specific sequence. The specificity of the sequence accounts for the production of a specific protein. In order for DNA to produce a protein, an intermediate step is required. In this step, DNA is transcribed into messenger RNA (mRNA). The sequence of mRNA that encodes a protein is oriented in only one direction, which is known as the sense orientation.

Antisense drugs are short sequences of chemically modified DNA bases that are called oligonucleotides, or oligos. The oligos are engineered in a sequence that is exactly opposite (hence anti) to the sense coding orientation of mRNA. Because antisense drugs bind only short regions of the mRNA (rather than the whole message itself), they contain far fewer nucleotides than the whole gene. Moreover, since they are engineered to bind only to the matching sequence on a specific mRNA, antisense drugs have both high selectivity and specificity, which can be used to attack production of a single, disease-causing protein. Genasense® is an antisense oligo that is designed to block the production of Bcl-2.

We have devoted significant resources towards the development of antisense oligos that contain a phosphorothioate backbone, which is the nucleotide chain comprised of ribose and phosphate groups. However, we also have patents and technologies covering later generation technologies that involve mixed backbone structures, as well as sterically fixed chemical bonds, that may further enhance the molecule's ability to bind to the intended target. Moreover, we have developed certain formulations that can be used to more efficiently increase the uptake of oligos into cells. Some

of these advanced technologies may be incorporated into future products from our DNA/RNA Medicines program.

### **Genasense® as a Regulator of Apoptosis ( Programmed Cell Death )**

The programmed death of cells, also known as apoptosis, is necessary to accommodate the billions of new cells that are produced daily and also to eliminate aged or damaged cells. However, abnormal regulation of the apoptotic process can result in disease.

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Cancer is commonly associated with the over- or under-production of many types of proteins. These proteins may be directly cancer-causing (i.e., oncogenic ) or they may contribute to the malignant nature of cancer (for instance, by increasing the longevity of cancer cells or making them more likely to spread throughout the body). The ability to selectively halt the production of certain proteins may make the treatment of certain diseases more effective. Apoptosis is regulated by a large number of proteins, particularly members of the Bcl-2 protein family. In an effort to make existing cancer therapy more effective, we are developing Genasense® to target and block the production of Bcl-2, a protein that is central to the process of apoptosis.

### **Bcl-2 as an Inhibitor of Programmed Cell Death**

Normally, when a cancer cell is exposed to treatment, such as with chemotherapy, radiation or immunotherapy, a death signal is sent to an organelle within the cell called the mitochondrion. The mitochondrion then releases a factor known as cytochrome C that activates a series of enzymes called caspases. These enzymes cause widespread fragmentation of cellular proteins and DNA, which ultimately causes cell death.

Bcl-2 is normally found in the mitochondrial membrane where it regulates the release of cytochrome C. High levels of Bcl-2 are associated with most types of human cancer, including major hematologic cancers such as lymphomas, myeloma, and leukemia, and solid tumors such as melanoma and cancers of the lung, colon, breast and prostate. In these diseases, Bcl-2 inhibits the release of cytochrome C that would ordinarily be triggered by cancer therapy. Thus, Bcl-2 appears to be a major contributor to both inherent and acquired resistance to cancer treatments. Overcoming resistance to chemotherapy poses a major challenge for cancer treatment.

In cancer cells, Bcl-2 inhibits the process of programmed cell death, thereby allowing cells to survive for much longer than normal cells. Genasense® has been developed as a chemosensitizing drug to block production of Bcl-2, thereby dramatically increasing the sensitivity of cancer cells to standard cancer treatment.

### **Genasense®**

Genasense® has been designed to block the production of Bcl-2. Current science suggests that Bcl-2 is a fundamental although not sole cause of the inherent resistance of cancer cells to most types of existing anticancer treatments, such as chemotherapy, radiation or monoclonal antibodies. Blocking Bcl-2, therefore, may enable cancer treatments to be more effective. While Genasense® has displayed some anticancer activity when used by itself, we believe the drug can be optimally used as a means of amplifying the effectiveness of other cancer therapies, most of which function by triggering apoptosis, which as noted is relatively blocked in cancer cells due to over-production of Bcl-2.

## **Overview of Preclinical and Clinical studies of Genasense®**

### **Preclinical Studies**

A number of preclinical studies in cell lines and in animals have shown enhancement of tumor cell killing when Bcl-2 antisense was used in combination with standard cancer therapies, including anti-metabolites, alkylating agents, corticosteroids, other cytotoxic chemotherapy, radiation and monoclonal antibodies. Several studies have demonstrated enhanced antitumor activity and durable tumor regression in animals engrafted with human cancers that were treated with Bcl-2 antisense followed by antitumor agents that induce programmed cell death. These studies include human lymphoma, melanoma, breast cancer and prostate cancers, which were treated with Genasense® in

combination with cyclophosphamide, dacarbazine, docetaxel and paclitaxel, respectively.

## Clinical Studies

Genasense® has been in clinical trials since 1995. We currently have efficacy and safety data on over 2,500 patients in Phase 1, Phase 2 and Phase 3 clinical trials that have been conducted in the U.S., Europe, South America and Australia. These studies have included patients with a wide variety of tumor types, including advanced melanoma, several types of acute and chronic leukemia, NHL, multiple myeloma and cancers of the prostate, colon, lung, breast and other tumor types. Results of these clinical trials suggest that Genasense® can be administered to cancer patients with acceptable side-effects and that such treatment may reduce the level of Bcl-2 protein in cancer cells.



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Based on work accomplished to date, we have focused on three indications for Genasense®: melanoma; CLL; and NHL. In addition, we have sought to develop treatment methods for Genasense® that do not involve the use of continuous intravenous (IV) infusions.

In 2007, we began a new Phase 1 trial of Genasense® administered as an IV infusion over 1–2 hours. This trial showed that the maximally tolerable dose was 900 mg, and we have now advanced that study into a trial at that dose administered twice per week. We have also continued to escalate the single dose of Genasense® up to a total of 1200 mg over 2 hours. The pharmacokinetic and pharmacodynamic data from these trials may be useful for determining whether the prior requirement for treatment by continuous IV infusion can ultimately be eliminated by these more convenient dosing regimens.

For additional background information on the drug application process and clinical trials, see Government Regulation.

## **Ganite®**

### **Ganite® as a Treatment for Cancer-Related Hypercalcemia**

On October 6, 2003, we began marketing Ganite® for the treatment of cancer-related hypercalcemia. Ganite® is our first drug to receive marketing approval. The principal patent covering the use of Ganite® for its approved indication, including potential extensions under Hatch-Waxman provisions in the U.S., expired in April 2005.

Hypercalcemia is a life-threatening condition caused by excessive buildup of calcium in the bloodstream, which may occur in up to 20% of cancer patients. Gallium nitrate was originally studied by the National Cancer Institute (NCI) as a new type of cancer chemotherapy. More than 1,000 patients were treated in Phase 1 and Phase 2 trials, and the drug showed promising antitumor activity against NHL, bladder cancer and other diseases. In the course of these studies, gallium nitrate was also shown to strongly inhibit bone resorption. Gallium nitrate underwent additional clinical testing and was approved by the FDA in 1991 as a treatment for cancer-related hypercalcemia. Lower doses of Ganite® were also tested in patients with less severe bone loss, including bone metastases, a cancer that has spread to bone, Paget's disease, an affliction of older patients that causes pain and disability, and osteoporosis.

Side effects of Ganite® include nausea, diarrhea and kidney damage. (A complete listing of Ganite®'s side effects is contained in the product's Package Insert that has been reviewed and approved by the FDA.)

## **Other Pipeline Products and Technology Platforms**

### **Oral Gallium-Containing Compounds**

We have sought to develop novel formulations of gallium-containing compounds that can be taken orally and that will have extended patent protection. Such formulations might be useful for diseases in which long-term low-dose therapy is deemed desirable, such as bone metastases, Paget's disease and osteoporosis. In March 2006, Genta and Emisphere Technologies, Inc. announced that the two companies had entered into an exclusive worldwide licensing agreement to develop an oral formulation of a gallium-containing compound. A number of candidate formulations have been developed in this collaboration. In August 2007, we announced submission of an Investigational New Drug Application, or IND, to the Endocrinologic and Metabolic Drugs Division of the FDA for a new drug known as G4544. G4544 is a new tablet formulation that enables oral absorption of the active ingredient contained in Ganite®. Results of the initial clinical trial were presented at a scientific meeting in the second quarter of 2008. In January

2009, we announced that two new patents related to our franchise in gallium-containing products have issued in the United States. Applications similar to these patents are pending worldwide, and several additional applications that address other compositions and uses have been filed in the U.S. and other territories. These patents and filings provide for claims of compositions and uses of gallium compounds that can be taken by mouth over extended periods for treatment of skeletal diseases as well as other indications.

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## **Patents and Proprietary Technology**

It is our policy to protect our technology by filing patent applications with respect to technologies important to our business development. To maintain our competitive position, we also rely upon trade secrets, unpatented know-how, continuing technological innovation, licensing opportunities and certain regulatory approvals (such as orphan drug designations).

We own or have licensed several patents and applications to numerous aspects of oligonucleotide technology, including novel compositions of matter, methods of large-scale synthesis, methods of controlling gene expression and methods of treating disease. Genta's patent portfolio includes approximately 65 granted patents and 66 pending applications in the U.S. and foreign countries. We endeavor to seek appropriate U.S. and foreign patent protection on our oligonucleotide technology.

We have licensed 10 U.S. patents relating to the composition of Genasense®. We acquired exclusive rights from the University of Pennsylvania to antisense oligonucleotides directed against the Bcl-2 mRNA, as well as methods of their use for the treatment of cancer. The claims of the University of Pennsylvania patents cover our proprietary antisense oligonucleotide molecules, which target the Bcl-2 mRNA, including Genasense®, and methods of using them. Related U.S. and corresponding foreign patent applications have issued or are pending. The most important of these composition of matter patents in the U.S. expires in 2015. We believe this patent may be eligible for up to 5 years of extension under Waxman-Hatch provisions, (i.e., to 2020). We also own 5 U.S. patent applications relating to methods of using Genasense® expected to expire in 2020 and 2026, with approximately 50 corresponding foreign patent applications and granted patents.

We have also licensed certain rights licensed from the U.S. NIH that cover phosphorothioate antisense oligonucleotides. This patent will expire in 2010, and we do not expect to owe royalty payments related to this patent. We do not believe the expiration of this patent will have a material adverse impact on our overall intellectual property position for Genasense®.

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

The principal patent covering the use of Ganite® for its approved indication, including extensions expired in April 2005.

The patent positions of biopharmaceutical and biotechnology firms, including Genta, can be uncertain and can involve complex legal and factual questions. Consequently, even though we are currently pursuing our patent applications with the United States and foreign patent offices, we do not know whether any of our applications will result in the issuance of any patents, or if any issued patents will provide significant proprietary protection, or even if successful that these patents will not be circumvented or invalidated. Even if issued, patents may be circumvented or challenged and invalidated in the courts. Because some applications in the United States are kept in secrecy until an actual patent is issued, we cannot be certain that others have not filed patent applications directed at inventions covered by our pending patent applications, or that we were the first to file patent applications for such inventions. Thus, we may become involved in interference proceedings declared by the U.S. Patent and Trademark Office (or comparable foreign office or process) in connection with one or more of our patents or patent applications to determine priority of invention, which could result in substantial costs to us, as well as an adverse decision as to priority of invention of the

patent or patent application involved.

Competitors or potential competitors may have filed applications for, or have received patents and may obtain additional patents and proprietary rights relating to, compounds or processes competitive with those of ours. Accordingly, there can be no assurances that our patent applications will result in issued patents or that, if issued, the patents will afford protection against competitors with similar technology. We cannot provide assurance that any patents issued to Genta will not be infringed or circumvented by others, nor can there be any assurance that we will obtain necessary patents or technologies or the rights to use such technologies.

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In addition, there may be patents which are unknown to us and which may block our ability to make, use or sell our products. We may be forced to defend ourselves against charges of infringement or we may need to obtain expensive licenses to continue our business. See the Risk Factor below, entitled "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."

We also rely upon unpatented trade secrets. No assurances can be given as to whether third parties will independently develop substantially equivalent proprietary information and techniques, or gain access to our trade secrets, or disclose such technologies to the public, or that we can meaningfully maintain and protect unpatented trade secrets.

We require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements with us. These agreements generally provide that all confidential information developed or made known to an individual during the course of the individual's relationship with Genta shall be kept confidential and shall not be disclosed to third parties except in specific circumstances. In the case of employees, the agreement generally provides that all inventions conceived by the individual shall be assigned to, and made the exclusive property of Genta. There can be no assurance, however, that these agreements will provide meaningful protection for our trade secrets, or guarantee adequate remedies in the event of unauthorized use or disclosure of confidential proprietary information or in the event of an employee's refusal to assign any patents to Genta in spite of his/her contractual obligation.

## **License Agreements**

Our license agreement with the University of Pennsylvania, dated August 1, 1991, as most recently amended on October 23, 2003, has a term for the duration of our royalty obligations to the University of Pennsylvania. We are required to pay royalties to the University of Pennsylvania until the later of 12 years from (i) the date of first commercial sale of licensed product (which has not yet occurred) or (ii) the date of expiration of the last to expire licensed patent with a valid claim covering the licensed product (which is currently scheduled to expire in 2015). We may terminate this agreement upon notice to the University of Pennsylvania. The University of Pennsylvania may terminate this agreement upon an event of default that we have not cured. The royalty rate that we may be obligated to pay to the University of Pennsylvania ranges from 2% to 4% of the net sales price, with an additional royalty for compensation we receive from any sublicense of our rights under this agreement. We also may be required to pay certain aggregate milestone payments and certain additional fees in the aggregate of \$4,770,000 contingent upon certain preclinical, clinical and regulatory events. The aggregate payments we made to the University of Pennsylvania under this agreement from the date of execution of the agreement through December 31, 2009 are approximately \$1.3 million.

Our license agreement with Emisphere Technologies, Inc., dated March 22, 2006, has a term until the later of (a) the term of the development program, or (b) the term of the clinical program, or (c) the expiration of all royalty and payment obligations. The term of the development program continues for the term of the clinical program, unless the parties agree to perform additional research and development activities under this agreement, and if so, the term of the development program continues until such additional activities are completed. The term of the clinical program continues until we obtain initial regulatory approval of the licensed product in a specified field, unless the parties agree to extend the term to pursue additional indications, which we currently estimate may be completed in 2015. We are required to pay royalties to Emisphere on a product-by-product and country-by-country basis until the later of (i) 10 years after the first commercial launch of such product (which has not yet occurred) and (ii) the expiration of the last-to-expire valid claim in such country of sale that would be infringed, in the absence of the license granted under

this agreement, by the manufacture, use or sale of such product in such country of sale (which is currently scheduled to expire in 2026). We may terminate this license agreement upon notice to Emisphere. Emisphere may terminate this agreement upon a breach of any material provision. The royalty rate that we may be obligated to pay to Emisphere range in the low to mid teens of worldwide net sales, on a sliding scale depending on sales volume. We also may be required to pay certain milestone payments in the aggregate of

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\$24,250,000 contingent upon certain regulatory approvals. The aggregate payments we made to Emisphere for services performed under this agreement from the date of execution of the agreement through December 31, 2009 are approximately \$1.5 million.

Our license agreement with Daiichi Sankyo Company, Limited, dated March 7, 2008, has a term that continues until when we have no remaining royalty payment obligations to Daiichi Sankyo. Either party may terminate the agreement as a result of a material breach by the other party. The royalty rate that we may be obligated to pay to Daiichi Sankyo ranges in the low to mid teens of aggregate annual net sales, on a sliding scale depending on sales volume. We are required to pay royalties to Daiichi Sankyo on a country-by-country basis until the later of (i) 10 years from the first commercial sale of such product in such country (which has not yet occurred) or (ii) expiration of the last to expire issued patent (or pending patent application) within the Daiichi Sankyo patents with a valid claim covering such product in such country (which is currently scheduled to expire in 2020). We also may be required to pay certain milestone payments in the aggregate of \$68,000,000 contingent upon certain clinical thresholds and a number of regulatory approvals. The aggregate payments we made to Daiichi Sankyo under the agreement from the date of execution of the agreement through December 31, 2009 were \$2.5 million, and the aggregate payments that we are required to make to Daiichi Sankyo in the near term are set forth in this report under Contractual Obligations in Management's Discussion & Analysis.

We do not believe that we will commercialize any product subject to the patent licensed from the National Institute of Health prior to the expiration of the patent on November 23, 2010.

## **Research and Development**

In addition to our current focus in the areas described above, we continually evaluate our programs in light of the latest market information and conditions, the availability of third party funding, technological advances, financial liquidity and other factors. As a result of such evaluations, we change our product development plans from time to time and anticipate that we will continue to do so. We recorded research and development expenses of \$15.1 million and \$20.0 million during the years ended December 31, 2009 and 2008, respectively.

## **Sales and Marketing**

Currently we do not have a sales force. At the present time, we do not contemplate rebuilding a sales and marketing infrastructure in the United States absent favorable regulatory decisions on at least one of our products. For international product sales, we may distribute our products through collaborations with third parties.

On March 6, 2007, we entered into a distribution and supply agreement with IDIS Limited (a privately owned company based in the United Kingdom). The term of the agreement lasts for three years with automatic one-year renewals unless adequate notice of intent not to renew is provided by either party. The agreement will continue on a product-by-product and country-by-country basis until that product has been granted a marketing authorization for an indication within that country of the territory and we have provided written notice of termination for such product in that country. We may terminate this agreement upon notice to IDIS. Either party may terminate the agreement (i) as a result of a material breach by the other party, (ii) upon the other party's bankruptcy, insolvency, liquidation, or similar events, (iii) upon any distraint, execution or other process levied or enforced against the property of the other party, or (iv) in the event the other party ceases, or threatens to cease to carry on its business. There are no minimum purchase requirements, but we pay IDIS certain scheduled pricing for product that we order. The amount we pay to IDIS is reflected in our results of operations for each respective period.

## **Manufacturing and Raw Materials**

Our ability to conduct clinical trials on a timely basis, to obtain regulatory approvals and to commercialize our products will depend in part upon our ability to manufacture our products, either directly or through third parties, at a competitive cost and in accordance with applicable FDA and other regulatory requirements, including current Good Manufacturing Practice regulations.



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We currently rely on third parties to manufacture our products. We have a manufacturing and supply agreement with Avecia Biotechnology, Inc., or Avecia, a leading multinational manufacturer of pharmaceutical products, to supply quantities of Genasense®. This agreement renews automatically at the end of each year, unless either party gives one-year notice. We are not obligated to purchase further drug substance from Avecia prior to approval of Genasense®. We believe this agreement is sufficient for our production needs with respect to Genasense®.

For Ganite® we have a manufacturing and supply agreement with Johnson Matthey Inc. that renews automatically at the end of each year, unless either party gives one-year notice. Under the agreement, we will purchase a minimum of 80% of our requirements for quantities of Ganite®; however, there are no minimum purchase requirements.

For tasetaxel, we are currently evaluating new suppliers of both bulk drug substance and finished goods with the intent of completely replacing the supply chain that was previously used to manufacture this compound. Until the new supply chain is established, we will continue to use investigational supplies of the compound that were manufactured by Daiichi Sankyo Company, Ltd.

The raw materials that we require to manufacture our drugs are available only from a few suppliers. Under the terms of our manufacturing and supply agreement, Avecia is responsible for procuring the raw materials needed to manufacture Genasense®. We believe that we have adequately addressed our needs for suppliers of raw materials to manufacture Genasense® and Ganite® and meet future customer demand.

## **Human Resources**

As of December 31, 2009, we had 16 employees, 6 of whom hold doctoral degrees. As of that date, there were 10 employees engaged in research, development and other technical activities and 6 in administration. None of our employees are represented by a union. Most of our management and professional employees have had prior experience and positions with pharmaceutical and biotechnology companies. We believe we maintain satisfactory relations with our employees and have not experienced interruptions of operations due to employee relations issues.

## **Government Regulation**

Regulation by governmental authorities in the United States and foreign countries is a significant factor in our ongoing research and product development activities and in the manufacture and marketing of our proposed products. All of our therapeutic products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical testing and pre-market approval procedures by the FDA and similar authorities in foreign countries. Various federal, and in some cases, state statutes and regulations, also govern or affect the development, testing, manufacturing, safety, labeling, storage, recordkeeping and marketing of such products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable federal and, in some cases, state statutes and regulations, require substantial expenditures. Any failure by us, our collaborators or our licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the marketing of our products and our ability to receive products or royalty revenue.

The activities required before a new pharmaceutical agent may be marketed in the United States begin with preclinical testing. Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of the product and its formulations. The results of these studies must be submitted to the FDA as part of an IND. An IND becomes effective within 30 days of filing with the FDA unless the FDA imposes a clinical hold on the IND. In addition, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence, as the case may be, without prior FDA

authorization, and then only under terms authorized by the FDA.

Clinical trials are generally categorized into four phases.

Phase 1 trials are initial safety trials on a new medicine in which investigators attempt to establish the dose range tolerated by a small group of patients using single or multiple doses, and to determine the pattern of drug distribution and metabolism.

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Phase 2 trials are clinical trials to evaluate efficacy and safety in patients afflicted with a specific disease. Typically, Phase 2 trials in oncology comprise 14 to 50 patients. Objectives may focus on dose-response, type of patient, frequency of dosing or any of a number of other issues involved in safety and efficacy.

In the case of products for life-threatening diseases, the initial human testing is generally done in patients rather than in healthy volunteers. Since these patients are already afflicted with the target disease, it is possible that such studies may provide results traditionally obtained in Phase 2 trials.

Phase 3 trials are usually multi-center, comparative studies that involve larger populations. These trials are generally intended to be pivotal in importance for the approval of a new drug. In oncology, Phase 3 trials typically involve 100 to 1,000 patients for whom the medicine is eventually intended. Trials are also conducted in special groups of patients or under special conditions dictated by the nature of the particular medicine and/or disease. Phase 3 trials often provide much of the information needed for the package insert and labeling of the medicine. A trial is fully enrolled when it has a sufficient number of patients to provide enough data for the statistical proof of efficacy and safety required by the FDA and others. After a sufficient period of follow-up has elapsed to satisfactorily evaluate safety and efficacy, the trials' results can then be analyzed. Those results are then commonly reported at a scientific meeting, in a medical journal and to the public.

Depending upon the nature of the trial results, a company may then elect to discuss the results with regulatory authorities such as the FDA. If the company believes the data may warrant consideration for marketing approval of the drug, the results of the preclinical and clinical testing, together with chemistry, manufacturing and control information, are then submitted to the FDA for a pharmaceutical product in the form of an NDA. In responding to an NDA, biologics license application or premarket approval application, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not satisfy its regulatory approval criteria. There can be no assurance that the approvals that are being sought or may be sought by us in the future will be granted on a timely basis, if at all, or if granted will cover all the clinical indications for which we are seeking approval or will not contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use. Phase 3b trials are conducted after submission of a NDA, but before the product's approval for market launch. Phase 3b trials may supplement or complete earlier trials, or they may seek different kinds of information, such as quality of life or marketing. Phase 3b is the period between submission for approval and receipt of marketing authorization.

After a medicine is marketed, Phase 4 trials provide additional details about the product's safety and efficacy.

In circumstances where a company intends to develop and introduce a novel formulation of an active drug ingredient already approved by the FDA, clinical and preclinical testing requirements may not be as extensive. Limited additional data about the safety and/or effectiveness of the proposed new drug formulation, along with chemistry and manufacturing information and public information about the active ingredient, may be satisfactory for product approval. Consequently, the new product formulation may receive marketing approval more rapidly than a traditional full new drug application; although no assurance can be given that a product will be granted such treatment by the FDA.

Under European Union regulatory systems, we may submit requests for marketing authorizations either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

We and our third-party manufacturers are also subject to various foreign, federal, state and local laws and regulations relating to health and safety, laboratory and manufacturing practices, the experimental use of animals and the use, manufacture, storage, handling and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our

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research and development work and manufacturing processes. We currently incur costs to comply with laws and regulations and these costs may become more significant.

## **Competition**

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 substantially more 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.

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

*You should carefully consider the following risks and all of the other information set forth in this Form 10-K before deciding to invest in shares of our common stock. The risks described below are not the only ones facing us. 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 occurs, our business, financial condition or results of operations would likely suffer. In such case, the market price of our common stock would likely decline due to the occurrence of any of these risks, and you may lose all or part of your investment.*

## **Risks Related to Our Business**

**We may be unsuccessful in our efforts to obtain approval from the FDA or EMEA and commercialize Genasense® or our other pharmaceutical products.**

The commercialization of our pharmaceutical products involves a number of significant challenges. In particular, our ability to commercialize products, such as Ganite®, Genasense® and tesetaxel, 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;

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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 EMEA approval. For example, the recent results in the Phase 3 AGENDA trial of Genasense® in advanced melanoma were not sufficient to apply for a NDA in the U.S. If extended followup of the AGENDA trial shows a statistically significant benefit for patients, we may be able to submit a NDA after that result is known. However, our prior regulatory applications for Genasense® in melanoma were unsuccessful. Our NDA for Genasense® plus chemotherapy in patients with relapsed or refractory CLL was also unsuccessful.

Our financial condition and results of operations have been and will continue to be significantly affected by FDA and EMEA action with respect to Genasense®. Any adverse events with respect to FDA and/or EMEA approvals could negatively impact our ability to obtain additional funding or identify potential partners.

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

### **Our business may suffer if we fail to obtain timely funding in the future.**

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.

On March 9, 2010, we closed on a financing transaction whereby we issued \$25 million of units (the 2010 Units ), each 2010 Unit consisting of (i) 40% of a senior unsecured convertible note (the B Notes ), (ii) 40% of a senior unsecured convertible note (the C Notes ) and (iii) 20% of a senior secured convertible note (the D Notes ). In connection with the sale of the 2010 Units, we also issued warrants (the Debt Warrants ) to purchase senior unsecured convertible notes (the E Notes ) in an amount equal to 40% of the purchase price paid for each such 2010 Unit. In order to commercialize our products, seek new product candidates and continue our research and development programs, we will need to raise additional funds in the future until we are able to commercialize our products and maintain profits. We will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt and equity financing. We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. Future collaborations or similar arrangements may require us to license valuable intellectual property to, or to share substantial economic benefits with, our collaborators. If we raise additional capital by issuing additional equity or securities convertible into equity, our stockholders may experience dilution and our share price may decline. Any debt financing may result in restrictions on our spending.

**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



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and failures arise, our product candidates may never be approved for sale or become commercially viable. We do not believe that any of our product candidates have alternative uses if our current development activities are unsuccessful.

There are a number of difficulties and risks associated with clinical trials. These difficulties and risks may result in the failure to receive regulatory approval to sell our product candidates or the inability to commercialize any of our product candidates. The possibility exists that:

we may discover that a product candidate does not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude regulatory approval or limit commercial use if approved;

the results from early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;

institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;

subjects may drop out of our clinical trials;

our preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials; and

the cost of our clinical trials may be greater than we currently anticipate.

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

Overall survival, the other co-primary endpoint in AGENDA, is too early to evaluate, as prospectively specified. An analysis for futility, which was defined as greater than 50% conditional power to observe a statistically significant benefit of Genasense® ( $P < 0.05$ ) under the prospectively specified hazard ratio of 0.69, was conducted for the co-primary endpoint of overall survival. AGENDA passed this futility analysis, and an Independent Data Monitoring

Committee has recommended that the trial continue to completion for the determination of the overall survival endpoint. The safety profile of Genasense® in AGENDA was consistent with prior studies. Pending adequacy of financial resources and other contingencies noted herein, Genta currently intends to continue the AGENDA trial in order to determine whether the addition of Genasense® to dacarbazine is associated with a statistically significant increase in overall survival. If that association is demonstrated, we currently expect that Genta would submit regulatory applications for the marketing approval of Genasense® on a worldwide basis.

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

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**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 December 31, 2009, we had a face amount of debt outstanding of \$14.0 million, consisting of the face value of 2008 Notes of \$1.8 million, the face value of April 2009 Notes of \$4.5 million, the face value of July 2009 Notes issued in July 2009 of \$0.7 million and the face value of July 2009 Notes issued in September 2009 of \$4.9 million and September 2009 Notes of \$2.1 million. On March 9, 2010, we closed on a financing transaction whereby we issued \$25 million of units (the 2010 Units), each 2010 Unit consisting of (i) 40% of a senior unsecured convertible note (referred to as B Notes), (ii) 40% of a senior unsecured convertible note (referred to as C Notes) and (iii) 20% of a senior secured convertible note (referred to as D Notes). We have direct access to \$20 million of the proceeds, and the remaining \$5 million of the proceeds were placed in a blocked account as collateral security for \$5 million in the D notes. In connection with the sale of the 2010 Units, we also issued warrants to purchase senior unsecured convertible notes (referred to as E Notes) in an amount equal to 40% of the purchase price paid for each such 2010 Unit.

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.

**Our substantial amount of outstanding 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.

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

Our convertible notes mature on various dates beginning in June 2011 through 2013, and bear interest payable quarterly or semi-annually at rates of 8.00% or 15.00% 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

We have a significant amount of debt. Our substantial indebtedness could adversely affect our business, financial c

on our business, financial condition and results of operations.

**We have relied on and continue to rely on our contractual collaborative arrangements with research institutions and corporate partners for development and commercialization of our products. Our business could suffer if we are not able to enter into suitable arrangements, maintain existing relationships, or if our collaborative arrangements are not successful in developing and commercializing products.**

We have entered into collaborative relationships relating to the conduct of clinical research and other research activities in order to augment our internal research capabilities and to obtain access to specialized knowledge and expertise. Our business strategy depends in part on our continued ability to develop and maintain relationships with leading academic and research institutions and with independent researchers. The

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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 December 31, 2009, we have incurred a cumulative net deficit of \$1,030.4 million. Achieving profitability is unlikely unless one or more of our product candidates is approved by the FDA or EMEA for commercial sale in one or more indications.

### **Our business depends heavily on a small number of products.**

We currently market and sell one product, Ganite® and the principal patent covering its use for the approved indication expired in April 2005. If one or more of our pipeline products are not approved, if approval is significantly delayed, or if in the event of approval the product is commercially unsuccessful, sales of other products may not be sufficient to offset this loss of potential revenue.

We have relied on and continue to rely on our contractual collaborative arrangements with research institutions and

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;

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preserve trade secrets; and

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

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

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

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

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

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

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

The principal patent covering the use of Ganite® for its approved indication expired in April 2005.

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

We may be unable to obtain or enforce patents, other proprietary rights and licenses to protect our business, we could

We have licensed 10 U.S. patents relating to the composition of Genasense®. We acquired exclusive rights from the University of Pennsylvania to antisense oligonucleotides directed against the Bcl-2 mRNA, as well as methods of their use for the treatment of cancer. The claims of the University of Pennsylvania patents cover our proprietary antisense oligonucleotide molecules, which target the Bcl-2 mRNA, including Genasense®, and methods of using them. Related

U.S. and corresponding foreign patent applications have issued or are pending. The most important of these composition of matter patents in the U.S. expires in 2015. We believe this patent may be eligible for up to 5 years of extension under Waxman-Hatch provisions,

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(i.e., to 2020). We also own 5 U.S. patent applications relating to methods of using Genasense® expected to expire in 2020 and 2026, with approximately 50 corresponding foreign patent applications and granted patents.

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

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

Most of our resources have been dedicated to the research and development of potential antisense pharmaceutical products such as Genasense®, based upon oligonucleotide technology. While we have demonstrated the activity of antisense oligonucleotide technology in model systems in vitro and in animals, Genasense® is our only antisense product to have been tested in humans. Several of our other technologies that serve as a possible basis for pharmaceutical products are only in preclinical testing. Results obtained in preclinical studies or early clinical investigations are not necessarily indicative of results that will be obtained in extended human clinical trials. Our products may prove to have undesirable and unintended side effects or other characteristics that may prevent our obtaining FDA or foreign regulatory approval for any indication. In addition, it is possible that research and discoveries by others will render our oligonucleotide technology obsolete or noncompetitive.

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

Clinical trials are very costly and time-consuming. The length of time required to complete a clinical study depends upon many factors, including, but not limited to, the size of the patient population, the ability of patients to get to the site of the clinical study, the criteria for determining which patients are eligible to join the study and other issues.

Delays in patient enrollment and other unforeseen developments could delay completion of a clinical study and increase its costs, which could also delay any eventual commercial sale of the drug that is the subject of the clinical trial.

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

- inability to obtain sufficient quantities of materials for use in clinical trials;
- inability to adequately monitor patient progress after treatment;
- unforeseen safety issues;
- the failure of the products to perform well during clinical trials; and
- government or regulatory delays.

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

The FDA imposes substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve lengthy and detailed preclinical and clinical testing and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more depending upon the type, complexity and novelty of the product. We cannot apply for FDA approval to market any of our products under development until preclinical and clinical trials on the product are successfully completed. Several factors could

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



prevent successful completion or cause significant delays of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that the product is safe and effective for use in humans. If safety concerns develop, the FDA could stop our trials before completion. We may not market or sell any product for which we have not obtained regulatory approval.

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

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

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

In addition to product approval, any facility in which our products are manufactured or tested for its ability to meet required specifications must be approved by the FDA and/or the EMEA. Failure of the facility to be approved could delay approval.

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

Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of our products or product candidates, entail higher costs and result in our being unable to effectively commercialize our products. Furthermore, if our third-party manufacturers fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenues.

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

Ganite®, Genasense® and tesetaxel (if they obtain regulatory approval), and any other product we may develop will be subject to ongoing regulatory oversight, primarily by the FDA. Failure to comply with post-marketing

If the third party manufacturers upon which we rely fail to produce our products in the volumes that we require on a

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

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application of such restrictions could limit our ability to market our product candidates and may have a material adverse effect on our business, results of operations and financial condition. Such failures or restrictions may also prompt regulatory recalls of one or more of our products, which could have material and adverse effects on our business.

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

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

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

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

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

The administration of drugs to humans, whether in clinical trials or commercially, exposes us to potential product and professional liability risks, which are inherent in the testing, production, marketing and sale of human therapeutic products. Product liability claims can be expensive to defend and may result in large judgments or settlements against us, which could have a negative effect on our financial performance and materially and adversely affect our business.

We maintain product liability insurance (subject to various deductibles), but our insurance coverage may not be sufficient to cover claims. Furthermore, we cannot be certain that we will always be able to maintain or increase our insurance coverage at an affordable price. Even if a product liability claim is not successful, the adverse publicity and time and expense of defending such a claim may interfere with or adversely affect our business and financial performance.

The raw materials for our products are produced by a limited number of suppliers, and our business could suffer if v

**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;

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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 the pending shareholder class action and shareholder derivative actions are uncertain.**

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

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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 will proceed 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. We intend to continue our vigorous defense of this matter.

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

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

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

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

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

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

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



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

The market price of our common stock 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;

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fluctuations in our operating results; and  
market conditions for biopharmaceutical stocks in general.

At December 31, 2009, we had 192.8 million shares of common stock outstanding, 260.6 million shares reserved for the conversion of our outstanding convertible preferred stock, convertible notes, warrants and the exercise of outstanding restricted stock units, and 189.4 million shares of common stock reserved for the issuance of shares under our 2009 Stock Incentive Plan 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.



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**Item 1B. Unresolved Staff Comments**

None

**Item 2. Properties**

We lease approximately 25,000 square feet of office space in Berkeley Heights, New Jersey. Our annual rental costs for this space are approximately \$0.7 million. Our lease on this space terminates in August 2010.

**Item 3. Legal Proceedings**

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

In September 2008, several 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 will proceed 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. We intend to continue our vigorous defense of this matter.

**Item 4. Reserved**

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## PART II

### Item 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

#### Market Information

Our common stock was traded on the NASDAQ Global Market under the symbol GNTA until May 7, 2008. The following table sets forth the high and low prices per share of our common stock, as reported on the NASDAQ Global Market, for the periods indicated.

2008	High	Low
First Quarter	\$ 43.50	\$ 18.50
Second Quarter (through May 7, 2008)	\$ 22.50	\$ 7.50

On May 7, 2008, our common stock began trading on the OTC Bulletin Board under the symbol GNTA.OB and on July 13, 2009, our OTC Bulletin Board symbol changed to GETA.OB. The following table sets forth the high and low prices per share of our common stock, as reported on the OTC Bulletin Board, for the periods indicated.

2008	High*	Low*
Second Quarter (from May 7, 2008)	\$ 20.50	\$ 5.00
Third Quarter	\$ 37.50	\$ 12.50
Fourth Quarter	\$ 20.00	\$ 0.135

2009		
First Quarter	\$ 15.50	\$ 0.145
Second Quarter	\$ 1.06	\$ 0.27
Third Quarter	\$ 1.26	\$ 0.34
Fourth Quarter	\$ 1.15	\$ 0.07

\* all figures prior to June 26, 2009 have been retroactively adjusted to reflect a 1-for-50 reverse stock split effected in June 2009

#### Holder

There were 120 holders of record of our common stock as of March 29, 2010. We estimate that there are approximately 19,250 beneficial owners of our common stock.

#### Dividends

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.

## Equity Compensation Plan Information

The following table summarizes the number of outstanding options granted to employees and directors, as well as the number of securities remaining available for future issuance, under our equity compensation plans as of December 31, 2009.

Plan category	Number of securities to be issued upon exercise of outstanding RSUs	Weighted-average exercise price of outstanding RSUs	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first column)
Equity compensation plans approved by security holders	44,402,970	\$ 0*	29,721,227
Equity compensation plans not approved by security holders	0		0
Total	44,402,970	\$ 0	29,721,227

\* As of December 31, 2009, we had 44,402,970 restricted stock units (RSUs) outstanding, with vesting of those RSUs taking place through 2012.

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## Performance Graph

*The following Performance Graph and related information shall not be deemed soliciting material or to be filed with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.*

The following table compares total Stockholder returns for Genta over the last five years to the NASDAQ Composite Index and the NASDAQ Biotechnology Index assuming a \$100 investment made on December 31, 2004. The stock performance shown on the graph below is not necessarily indicative of future price performance.

### COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*

Among Genta Incorporated, the NASDAQ Composite Index  
and the NASDAQ Biotechnology Index

\* \$100 invested on 12/31/04 in stock or index, including reinvestment of dividends.  
Fiscal year ending December 31.

	12/04	12/05	12/06	12/07	12/08	12/09
Genta Incorporated	100.00	82.95	25.11	4.73	0.02	0.02
NASDAQ Composite	100.00	101.33	114.01	123.71	73.11	105.61
NASDAQ Biotechnology	100.00	117.54	117.37	121.37	113.41	124.58

## Use of proceeds

On April 2, 2009, we placed approximately \$6 million of the April 2009 Notes, and corresponding warrants to purchase common stock. On July 7, 2009, we placed approximately \$3 million of July 2009 Notes, common stock and July 2009 Warrants. On September 4, 2009, we closed on \$7 million of additional July 2009 Notes, common stock and July 2009 Warrants and we closed on \$3 million of September 2009 Notes, common stock and September 2009 Warrants.

The net proceeds from these sales were used for the continuation of the AGENDA Phase 3 trial, development of tesetaxel and for general corporate purposes.

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**Purchases of equity securities by the issuer and affiliated purchasers**

None

**Item 6. Selected Financial Data**

Not applicable.

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## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

### **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 December 31, 2009, we have incurred a cumulative net deficit of \$1,030.4 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.

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

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

The design of AGENDA was based on data obtained from a similarly designed Phase 3 trial that was published in 2006. Results from this antecedent study showed that treatment with Genasense® plus dacarbazine compared with dacarbazine alone was associated with a statistically significant increase in overall response, complete response, durable response, and PFS. However, the primary endpoint of overall survival approached but did not quite reach statistical significance ( $P=0.077$ ) in the entire intent-to-treat population. Our further analysis of this trial showed that there was a significant treatment interaction effect related to levels of a blood enzyme known as LDH. When this effect was analyzed by treatment arm, survival was shown to be significantly superior for patients with a non-elevated LDH who received Genasense® ( $P=0.018$ ;  $n=508$ ). Moreover, this benefit was particularly noteworthy for patients whose baseline LDH did not exceed 80% of the upper limit of normal for this lab value. LDH had also been previously described by others as the single most important prognostic factor in advanced melanoma. Thus, the AGENDA trial sought to confirm the observations that were previously observed in the antecedent trial in a biomarker-defined patient population.

A total of 315 patients were enrolled into AGENDA. In October 2009, we announced that AGENDA did not show a statistically significant benefit for its co-primary endpoint of PFS. Secondary endpoints of overall response rate and disease control rate (which includes complete and partial responses, plus stable disease greater than 3 months

duration) also did not show a statistically significant benefit. According to the prespecified analysis plan, the statistical significance of durable response, (a secondary endpoint that measures the proportion of patients who achieved a complete or partial response that lasts greater than 6 months), is too early to evaluate. However, the observed differences in PFS, overall response, disease control and durable response all numerically favored the group that received Genasense®.

Overall survival, the other co-primary endpoint in AGENDA, is too early to evaluate, as prospectively specified. An analysis for futility, which was defined as greater than 50% conditional power to observe a statistically significant benefit of Genasense® under the prospectively assumed hazard ratio of 0.69, was

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conducted for the co-primary endpoint of overall survival. AGENDA passed this futility analysis, and an Independent Data Monitoring Committee has recommended that the trial continue to completion for the determination of the overall survival endpoint. The safety profile of Genasense® in AGENDA was consistent with prior studies. We have indicated our intention to continue patient follow-up in the AGENDA trial to determine whether Genasense® will yield a statistically significant improvement in its co-primary endpoint of overall survival. We currently project that this information may be available in the first quarter of 2011. If the final analysis for overall survival is statistically significant, we plan to resubmit our NDA to the FDA and seek approval for treatment of patients with advanced melanoma with Genasense®. We anticipate that such a filing would take place in 2011.

We have been conducting other trials of Genasense® in melanoma, including a Phase 2 trial of Genasense® plus chemotherapy consisting of Abraxane® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus temozolomide (Temodar®). We also expect to examine whether different dosing regimens would improve efficacy and dosing convenience of Genasense®.

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 (Flu/Cy) with or without Genasense®. The trial achieved its primary endpoint: a statistically significant increase (17% vs. 7%;  $P=0.025$ ) in the proportion of patients who achieved a complete response (CR), defined as a complete or nodular partial response. Patients who achieved this level of response also experienced disappearance of predefined disease symptoms. A key secondary endpoint, duration of CR, was also significantly longer for patients treated with Genasense® (median exceeding 36+ months in the Genasense® group, versus 22 months in the chemotherapy-only group).

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

We received a non-approvable notice from the FDA in December 2006 for our NDA that proposed the use of Genasense® in combination with Flu/Cy for the treatment of patients with relapsed or refractory CLL who had previously received fludarabine. We appealed this decision with FDA's Center for Drug Evaluation and Research (CDER) using the agency's Formal Dispute Resolution process. In June 2008, we announced results from 5 years of follow-up on patients who had been accrued to our completed Phase 3 trial. These data showed that patients treated with Genasense® plus chemotherapy who achieved either a complete response (CR) or a partial response (PR) also achieved a statistically significant increase in survival compared with patients treated with chemotherapy alone (median = 56 months vs. 38 months, respectively). After 5 years of follow-up, 22 of 49 (45%) responders in the Genasense® group were alive compared with 13 of 54 (24%) responders in the chemotherapy-only group (hazard ratio = 0.6;  $P = 0.038$ ). Moreover, with 5 years of follow-up, 12 of 20 patients (60%) in the Genasense® group who achieved CR were alive, 5 of these patients remained in continuous CR without relapse, and 2 additional patients had relapsed but had not required additional therapy. By contrast, only 3 of 8 CR patients in the chemotherapy-only group were alive, all 3 had relapsed, and all 3 had required additional anti-leukemic treatment. However, in March 2009, CDER decided that available data were still insufficient to support approval of Genasense® in CLL, and the Agency recommended conducting another clinical trial. In the absence of a co-development partner to share expenses, we have determined that we will not conduct the recommended study in the CLL indication until the survival results of the AGENDA trial are known. We have made no decision whether to pursue the current application for regulatory approval in other territories.

As with melanoma, we have believed the clinical activity in CLL, as well as in NHL and other types of cancer, should be explored with additional clinical research. We are currently assessing whether to proceed with such studies in advance of the final survival results in AGENDA.

In March 2008, we obtained an exclusive worldwide license for tesetaxel from Daiichi Sankyo Company Ltd. Maintenance of the license from Daiichi Sankyo requires certain milestone payments. If such payments are not made, Daiichi Sankyo may elect to terminate the license. Tesetaxel is a novel taxane compound that is

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taken by mouth. Tesetaxel has completed Phase 2 trials in a number of cancer types, and the drug has shown definite evidence of antitumor activity in gastric cancer and breast cancer. Tesetaxel also appears to be associated with a lower incidence of peripheral nerve damage, a common side effect of taxanes that limits the maximum amount of these drugs that can be given to patients. At the time we obtained the license, tesetaxel was on clinical hold by FDA due to the occurrence of several fatalities in the setting of severe neutropenia. In the second quarter of 2008, we filed a response to the FDA requesting a lift of the clinical hold, which was granted in June 2008. In January 2009, we initiated a new clinical trial with tesetaxel to examine the clinical pharmacology of the drug over a narrow dosing range around the established Phase 2 dose. That trial has now been completed and its results have been submitted for presentation at the June 2010 annual meeting of the American Society of Clinical Oncology (ASCO). We plan to initiate several new clinical trials with tesetaxel during 2010.

We have also submitted applications to FDA for designation of tesetaxel as an Orphan Drug for treatment of patients with advanced gastric cancer and for patients with advanced melanoma. Both of these designations were granted. Our current priorities for clinical testing of tesetaxel include the evaluation of safety and efficacy in patients with advanced gastric cancer, advanced melanoma and prostate cancer. Other disease priorities for clinical research include cancers of the bladder and breast, among other disorders.

Our third pipeline project consists of several formulations of an oral gallium-containing compound. One of these formulations is known as G4544, which was developed in collaboration with Emisphere Technologies, Inc. We completed a single-dose Phase 1 study of an initial formulation of this new drug known as G4544(a), the results of which were presented in the second quarter of 2008. We are currently contemplating whether a modified formulation, known as G4544(b), will prove more clinically acceptable.

If we are able to identify a clinically and commercially acceptable formulation of an oral gallium-containing compound, we currently intend to evaluate whether an expedited regulatory approval may be possible. We believe a drug of this class may also be broadly useful for treatment of other diseases associated with accelerated bone loss, such as bone metastases, Paget's disease and osteoporosis. In addition, new uses of gallium-containing compounds have been identified for treatment of certain infectious diseases. While we have no current plans to begin clinical development in the area of infectious disease, we intend to support research conducted by certain academic institutions by providing clinical supplies of our gallium-containing drugs for patients with cystic fibrosis.

We are currently marketing Ganite® in the U.S., which is an intravenous formulation of gallium, for treatment of cancer-related hypercalcemia that is resistant to hydration. Sales of Ganite® have been low relative to original expectations in part due to our under-investment in its marketing for a small indication. Since Ganite® has now lost patent protection, we do not plan to substantially increase our investment in the drug, but we believe the product has strategic importance for our franchise of gallium-containing compounds and we currently intend for Ganite® to remain on the market.

TABLE OF CONTENTS**Results of Operations**

(\$ thousands)	Summary Operating Results For the year ended December 31,		
	2009	2008	2009 vs. 2008
Product sales net	\$ 218	\$ 363	\$ (145 )
Cost of goods sold	40	102	(62 )
Gross margin	178	261	(83 )
Operating expenses:			
Research and development	15,144	19,991	(4,847 )
Selling, general and administrative	17,233	10,452	6,781
Settlement of office lease obligation		3,307	(3,307 )
Provision for settlement of litigation		(340 )	340
Total operating expenses	32,377	33,410	(1,033 )
Other (expense)/ income, net	(1,188 )	(1,435 )	247
Amortization of deferred financing costs and debt discount	(29,092 )	(11,229 )	(17,863 )
Fair value conversion feature liability	(19,040 )	(460,000 )	440,960
Fair value warrant liability	(7,655 )	(2,000 )	(5,655 )
Loss before income taxes	(89,174 )	(507,813 )	418,639
Income tax benefit	2,873	1,975	898
Net loss	\$ (86,301 )	\$ (505,838 )	\$ 419,537

**Product sales net**

Product sales net were \$0.2 million in 2009 compared with \$0.4 million in 2008. Unit sales of Ganite® declined 34% in 2009 due to the continued absence of promotional support, and reported product sales net in 2009 include the negative impact of returns of Ganite® due to expired dating of product.

**Cost of goods sold**

During 2009, 37% of the units sold of Ganite® were from product that had been previously accounted for as excess inventory, resulting in a higher gross margin percentage in 2009 compared to 2008.

**Research and development expenses**

Research and development expenses declined to \$15.1 million in 2009, compared with \$20.0 million in 2008, primarily due to lower expenses resulting from the completion of the AGENDA clinical trial and to a lesser extent, lower payroll expense resulting from lower headcount. Partially offsetting these lower expenses was an increase in share-based compensation expense of \$3.7 million. During 2009, with the establishment of the 2009 Stock Incentive Plan, or the 2009 Plan, and implementation of two Equity Award Exchange programs, outstanding stock option awards granted under the 1998 Non-Employee Directors Plan, as amended, and 1998 Stock Incentive Plan, as amended, were exchanged for grants of new restricted stock units (RSUs). Incremental compensation cost for the new RSUs was measured as the excess of the fair value of the RSUs over the fair value of the stock option awards on the date of exchange. The incremental compensation cost of the RSUs is being recognized over the remaining amortization period of the exchanged stock option awards. Share-based compensation expense recognized for the year

ended December 31, 2009 and 2008 was \$3.9 million and \$0.2 million, respectively, for those employees categorized as research and development.

Research and development expenses incurred on the Genasense® project in 2009 were approximately \$12.9 million, representing 85% of research and development expenses and in 2008 were approximately \$15.0 million, representing 75% 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

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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 \$17.2 million in 2009, compared with \$10.5 million in 2008. Share-based compensation expense recognized for the years ended December 31, 2009 and 2008 was \$9.4 million and \$0.4 million, respectively, for employees categorized as selling, general and administrative. Partially offsetting the increase in share-based compensation was lower office rent of \$0.7 million, lower payroll expense resulting from lower headcount of \$0.8 million and other reductions in expenses of \$0.8 million.

### **Settlement of office lease obligation**

In May 2008, we entered into an amendment of our lease for office space with The Connell Company (Connell), whereby the lease for one floor of our office space in Berkeley Heights, New Jersey was terminated. Connell received a termination payment of \$1.3 million, comprised solely of our security deposits and we agreed to pay Connell \$2.0 million on July 1, 2009. We accrued for the \$2.0 million and it is included on our Consolidated Balance Sheets. In January 2009, we entered into another amendment of our agreement with Connell whereby our future payment of \$2.0 million is now payable on January 1, 2011, with 6.0% interest paid in arrears.

### **Provision for settlement of litigation**

In 2008, a settlement in principle of a class action litigation was finalized, resulting in a reduction in a liability for the settlement of litigation that had originally been established in 2006. See Note 5 to our Consolidated Financial Statements for a further discussion of this provision.

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

The total of the above referenced accounts resulted in net expense of \$1.2 million in 2009 and \$1.4 million in 2008. This decline was primarily due to lower interest expense on our 2008 Notes, (due to conversions), mostly offset by interest on our April 2009 Notes, July 2009 Notes and September 2009 Notes.

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

For the year ended December 31, 2009, amortization of deferred financing costs and debt discount of \$29.1 million was comprised of amortization related to the 2008 Notes of \$21.3 million, for the April 2009 Notes of \$4.2 million, for the July 2009 Notes of \$2.1 million and for the September 2009 Notes and July 2009 Notes issued in September of \$1.5 million. In the prior-year, the \$11.2 million amortization of deferred financing costs and debt discount resulted from the 2008 Notes.

### **Fair value    conversion feature liability**

On the dates that we issued the 2008 Notes and April 2009 Notes, there were an insufficient number of authorized shares of common stock in order to permit conversion of all of the notes. When there are insufficient authorized shares



to allow for settlement of convertible financial instruments, the conversion obligation for the notes is classified as a liability and measured at fair value on the balance sheet.

On June 9, 2008, using a Black-Scholes valuation model, we calculated a fair value of the conversion feature of the 2008 Notes of \$380.0 million and expensed \$360.0 million, the amount that exceeded the proceeds of the \$20.0 million from the closing. On October 6, 2008, our stockholders approved an amendment to Genta's Restated Certificate of Incorporation, as amended, to increase the total number of authorized shares of capital stock available for issuance. We re-measured the conversion feature liability and credited it to Stockholders' equity, resulting in an expense for the year ended December 31, 2008 of \$460.0 million.

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On April 2, 2009, using a Black-Scholes valuation model, we calculated a fair value of the conversion feature of the April 2009 Notes of \$67.8 million and expensed \$61.8 million, the amount that exceeded the proceeds of the \$6.0 million from the closing. On June 26, 2009, our stockholders authorized our Board of Directors to effect a reverse stock split and our Board of Directors effected a 1-for-50 reverse stock split, resulting in us having enough shares of common stock in order to permit conversion of all the April 2009 Notes. We re-measured the conversion feature liability and credited it to Stockholders' equity, resulting in an expense for the year ended December 31, 2009 of \$19.0 million.

### **Fair value warrant liability**

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

The warrants issued with the 2008 Notes were initially recorded at a fair value of \$7.6 million based upon a Black-Scholes valuation model. On October 6, 2008, we re-measured the warrant liability and credited it to Stockholders' equity, resulting in an expense for the year ended December 31, 2008 of \$2.0 million.

On April 2, 2009, using a Black-Scholes valuation model, we calculated a fair value for the warrants issued with the April 2009 Notes of \$20.8 million. On June 26, 2009, the date of the reverse stock split, we re-measured the warrants at a fair value and credited it to Stockholders' equity, resulting in an expense for the year ended December 31, 2009 of \$7.7 million.

### **Income tax benefit**

New Jersey has legislation permitting certain corporations located in the state to sell state tax loss carryforwards and state research and development credits. We sold portions of our New Jersey net operating losses and research and development credits for \$2.9 million and \$2.0 million in 2009 and 2008, respectively, that are recognized as income tax benefit.

If still available under New Jersey law, we will attempt to sell our remaining tax losses in 2010. We cannot be assured that the New Jersey program will continue next year, nor can we estimate what percentage of our saleable tax benefits New Jersey will permit us to sell, how much money will be received in connection with the sale, if we will be able to find a buyer for our tax benefits or if such funds will be available in a timely manner.

### **Net loss**

Genta recorded a net loss of \$86.3 million, or net loss per basic and diluted share of \$0.84, for 2009 and a net loss of \$505.8 million, or net loss per basic and diluted share of \$455.09 for 2008.

The lower net loss for 2009 was primarily due to lower expenses from marking to market the conversion feature liabilities of our notes. The results for 2009 also include increased amortization of financing costs and debt discount, higher share-based compensation, and higher expense from marking to market our warrant liabilities, partially offset by lower payroll expense resulting from lower headcount and the recognition in last year's results of a provision for the settlement of our office lease obligation,

## Critical Accounting Policies and Estimates

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

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

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

*Valuation of restricted stock units ( 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.

## Liquidity and Capital Resources

At December 31, 2009, we had cash and cash equivalents totaling \$1.2 million, compared with \$4.9 million at December 31, 2008, reflecting our April 2009 financing, July 2009 financing and September 2009 financing offset by funds used in operating our company.

During the year ended December 31, 2009, cash used in operating activities was \$21.5 million compared with \$25.7 million for the same period in 2008, reflecting lower expenses resulting from the completion of the AGENDA clinical trial and lower payroll expense resulting from the reduced size of our company.

On March 5, 2010, we entered into a securities purchase agreement with certain accredited investors pursuant to which we agreed to issue \$25 million of units consisting of various senior unsecured convertible notes. In connection with the sale of the 2010 Units, we also agreed to issue warrants in an amount equal to 40% of the purchase price paid for each such 2010 Unit. On March 9, 2010, the financing closed. We have direct access to \$20 million of the proceeds, and the remaining \$5 million of the proceeds were placed in a blocked account as collateral security for \$5 million in principal amount one of the series of notes. On March 17, 2010 and March 22, 2010, three of our investors who had participated in our April 2009 financing, exercised their rights to acquire convertible notes of \$879 thousand. Net cash used in operating activities through December 31, 2009 was \$21.5 million, which represents an average monthly outflow of \$1.8 million. We expect that our average monthly outflow will be \$1.2 million during 2010.

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.

## Contractual Obligations

Future contractual obligations at December 31, 2009 are as follows (\$ thousands):

	Total	Less than 1 year	1 3 years	3 5 years	More than 5 years
Uncertain tax positions*	\$ 895	\$ 895	\$	\$	\$
Operating lease obligations	510	482	28		
Office settlement lease obligation	1,979		1,979		
Maturity of convertible notes	13,990	1,787	12,203		
Milestone payment to Daiichi Sankyo	1,000	1,000			

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Total	\$ 18,374	\$ 4,164	\$ 14,210	\$	\$
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\* see Note 9 to the Consolidated Financial Statements

Virtually all of the operating lease obligations result from our lease of approximately 25,000 square feet of office space in Berkeley Heights, New Jersey. Our lease on this space terminates in August 2010. In May 2008, we entered into an amendment of our lease for office space with The Connell Company (Connell), whereby the lease for one floor of our office space in Berkeley Heights, New Jersey was terminated. Connell received a termination payment of \$1.3 million, comprised solely of our security deposits and we agreed to pay Connell \$2.0 million on July 1, 2009. We accrued for the \$2.0 million and it is included on our

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Consolidated Balance Sheets. In January 2009, we entered into another amendment of our agreement with Connell whereby our future payment of \$2.0 million is now payable on January 1, 2011, with 6.0% interest paid in arrears.

Our 2008 Notes, April 2009 Notes, July 2009 Notes, and September 2009 Notes and July 2009 Notes issued in September, mature on June 9, 2011, April 2, 2012, July 7, 2011 and September 4, 2011 respectively, (see Note 8 to the Consolidated Financial Statements). Holders of the notes have the right, but not the obligation, to convert their notes, or a portion of their notes, in to shares of Genta common stock at a conversion rate of 100,000 shares of common stock for every \$1,000 of principal. The amount in the table above, \$14.0 million, is the face value of convertible notes outstanding at December 31, 2009. This amount would be due on their respective maturity dates assuming no voluntary conversions by noteholders prior to the maturity date. As of March 29, 2010, our total outstanding face value of all of the notes listed above is \$12.3 million.

On March 7, 2008, we entered into a license agreement with Daiichi Sankyo Company, Limited, a Japanese corporation based in Tokyo, Japan, whereby we obtained the exclusive license for tesetaxel. Pursuant to the agreement, as of December 31, 2009, we owed Daiichi Sankyo an earned milestone payment of \$1.0 million. The agreement also provides for additional payments by us upon achievement of certain clinical and regulatory milestones and royalties on net product sales. The milestone payment was paid to Daiichi Sankyo in March 2010.

Not included in the above table are any Genasense® bulk drug purchase obligations to Avecia per the terms of the Manufacturing and Supply Agreement entered into between Avecia and Genta in May 2008. The agreement calls for Genta to purchase a percentage of its global Genasense® bulk drug requirements from Avecia during the term of the agreement. Due to the uncertainties regarding the timing of any Genasense® approval and sales/volume projections, specific obligation amounts cannot be estimated at this time. Due to past purchases of Genasense® bulk drug substance, the Company has access to sufficient drug for its current needs. In addition, not included in the above table are potential milestone payments to be made to Emisphere and other suppliers of services, since such payments are contingent on the occurrence of certain events.

## **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

## **Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

Our carrying values of cash, accounts payable, accrued expenses and debt are a reasonable approximation of their fair value. The estimated fair values of financial instruments have been determined by us using available market information and appropriate valuation methodologies (see Note 1 to our consolidated financial statements). We have not entered into and do not expect to enter into, financial instruments for trading or hedging purposes. We do not currently anticipate entering into interest rate swaps and/or similar instruments.

Our primary market risk exposure with regard to financial instruments is to changes in interest rates, which would impact interest income earned on such instruments. We have no material currency exchange or interest rate risk exposure as of December 31, 2009. Therefore, there will be no ongoing exposure to a potential material adverse effect on our business, financial condition or results of operation for sensitivity to changes in interest rates or to changes in currency exchange rates.



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**Item 8. Financial Statements and Supplementary Data**

**Genta Incorporated**

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# **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
Genta Incorporated:

We have audited the accompanying balance sheets of Genta Incorporated and Subsidiaries (the Company) as of December 2009 and 2008, and the related statements of operations, stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2009 and 2008, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

/s/ Amper, Politziner & Mattia, LLP

Edison, New Jersey  
March 29, 2010

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# GENTA INCORPORATED

## CONSOLIDATED BALANCE SHEETS

	December 31, 2009	December 31, 2008
	(In thousands, except par value data)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,216	\$ 4,908
Accounts receivable net of allowances of \$23 at December 31, 2009 and \$12 at December 31, 2008	2	2
Receivable on sale of New Jersey tax losses	2,873	
Inventory (Note 3)	81	121
Prepaid expenses and other current assets	971	973
Total current assets	5,143	6,004
Property and equipment, net (Note 6)	205	300
Deferred financing costs on sale of convertible notes, warrants and common stock (Note 9)	6,881	6,389
Total assets	\$ 12,229	\$ 12,693
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable and accrued expenses (Note 7)	\$ 8,829	\$ 11,224
Convertible notes due June 9, 2010, \$1,787 outstanding, net of debt discount of (\$115) at December 31, 2009 (Note 8)	1,672	
Total current liabilities	10,501	11,224
Long-term liabilities:		
Office lease settlement obligation (Note 4)	1,979	1,979
Convertible notes due June 9, 2010, \$15,540 outstanding, net of debt discount of (\$11,186) at December 31, 2008 (Note 8)		4,354
Convertible notes due April 2, 2012, \$4,452 outstanding, net of Debt discount of (\$3,150) (Note 8)	1,302	
Convertible notes due July 7, 2011, \$751 outstanding, net of debt discount of (\$570) (Note 8)	181	
Convertible notes due September 4, 2011, \$7,000 outstanding, net of debt discount of (\$5,872) (Note 8).	1,128	
Total long-term liabilities	4,590	6,333
Commitments and contingencies (Note 13)		
Stockholders' deficit (Note 10):		
Preferred stock, 5,000 shares authorized:		
Series A convertible preferred stock, \$.001 par value; 8 shares issued and outstanding, liquidation value of \$385 at December 31, 2009 and December		

31, 2008, respectively

Series G participating cumulative preferred stock, \$.001 par value; 0 shares issued and outstanding at December 31, 2009 and December 31, 2008, respectively

Common stock, \$.001 par value; 6,000,000 shares authorized 192,832 and 9,734 shares issued and outstanding at December 31, 2009 and December 31, 2008, respectively

Additional paid-in capital	1,027,372	939,252
Accumulated deficit	(1,030,427)	(944,126)
Total stockholders' deficit	(2,862 )	(4,864 )
Total liabilities and stockholders' deficit	\$ 12,229	\$ 12,693

*See accompanying notes to consolidated financial statements.*

TABLE OF CONTENTS**GENTA INCORPORATED****CONSOLIDATED STATEMENTS OF OPERATIONS**

	Years Ended December 31,	
	2009	2008
	(In thousands, except per share data)	
Product sales net	\$ 218	\$ 363
Cost of goods sold	40	102
Gross margin	178	261
Operating expenses:		
Research and development	15,144	19,991
Selling, general and administrative	17,233	10,452
Settlement of office lease obligation (Note 4)		3,307
Provision for settlement of litigation (Note 5)		(340 )
Total operating expenses	32,377	33,410
Other income/(expense), net:		
Gain on maturity of marketable securities		31
Interest income and other income, net	3	252
Interest expense	(1,191 )	(1,718 )
Amortization of deferred financing costs and debt discount (Note 8)	(29,092 )	(11,229 )
Fair value conversion feature liability (Note 8)	(19,040 )	(460,000 )
Fair value warrant liability (Note 8)	(7,655 )	(2,000 )
Total other income, net	(56,975 )	(474,664 )
Loss before income tax benefit	(89,174 )	(507,813 )
Income tax benefit (Note 9)	2,873	1,975
Net loss	\$ (86,301 )	\$ (505,838 )
Net loss per basic and diluted share	\$ (0.84 )	\$ (455.09 )
Shares used in computing net loss per basic and diluted share	102,715	1,112

*See accompanying notes to consolidated financial statements.*

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**GENTA INCORPORATED**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS'**  
**EQUITY/(DEFICIT)**  
**For the Years Ended December 31, 2009 and 2008**

*See accompanying notes to consolidated financial statements.*

TABLE OF CONTENTS**GENTA INCORPORATED****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Years Ended December 31,	
	2009	2008
	(In thousands)	
Operating activities:		
Net loss	\$(86,301 )	\$(505,838 )
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation and amortization	147	154
Loss on disposition of equipment	3	10
Amortization of deferred financing costs and debt discount	29,092	11,229
Share-based compensation (Note 11)	13,299	489
Provision for sales returns	143	79
Sale of New Jersey tax losses proceeds not received until 2010	(2,873 )	
Gain on maturity of marketable securities		(31 )
Interest payment settled in shares of common stock		647
Provision for settlement of litigation, net (Note 5)		(340 )
Change in fair value conversion feature liability (Note 8)	19,040	460,000
Change in fair value warrant liability (Note 8)	7,655	2,000
Changes in operating assets and liabilities:		
Accounts receivable		29
Inventory	40	104
Prepaid expenses and other current assets	2	198
Accounts payable and accrued expenses	(1,699 )	5,615
Net cash and cash equivalents used in operating activities	(21,452 )	(25,655 )
Investing activities:		
Maturities of marketable securities		2,000
Release of restricted cash deposits (Note 4)		1,731
Purchase of property and equipment	(55 )	(141 )
Net cash and cash equivalents (used in) provided by investing activities	(55 )	3,590
Financing activities:		
Net proceeds from sales of convertible notes, common stock and warrants (Note 8)	17,640	
Net proceeds from exercise of warrants (Note 8)	175	
Net proceeds from sale of common stock, net (Note 10)		2,876
Repayments of note payable		(512 )
Issuance of convertible notes net of financing cost of \$1,205 (Note 8)		18,795
Net cash and cash equivalents provided by financing activities	17,815	21,159
Decrease in cash and cash equivalents	(3,692 )	(906 )
Cash and cash equivalents at beginning of year	4,908	5,814

Cash and cash equivalents at end of year	\$1,216	\$4,908
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*See accompanying notes to consolidated financial statements.*

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## **GENTA INCORPORATED**

# **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## **For the years ended December 31, 2009 and 2008**

### **1. Organization and Liquidity**

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

The Company has had recurring annual operating losses 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 December 31, 2009, the Company had an accumulated deficit of \$1,030.4 million. Cash and cash equivalents as of December 31, 2009 were \$1.2 million. The Company has historically financed its activities from the sale of convertible notes, shares of common stock and warrants.

On March 9, 2010, the Company issued \$25 million of units consisting of various senior unsecured convertible notes. In connection with the sale of the units, the Company also agreed to issue warrants in an amount equal to 40% of the purchase price paid for each such unit. The Company has direct access to \$20 million of the proceeds, and the remaining \$5 million of the proceeds were placed in a blocked account as collateral security for \$5 million in principal amount one of the series of notes. On March 17, 2010 and March 22, 2010, three investors who had participated in the Company's April 2009 financing exercised their rights to acquire convertible notes of \$0.9 million. Net cash used in operating activities through December 31, 2009 was \$21.5 million, which represents an average monthly outflow of \$1.8 million. The Company expects that its average monthly outflow will be \$1.2 million during 2010.

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.

### **2. Summary of Significant Accounting Policies**

#### **Accounting Standards Updates**

In June 2009, the Financial Accounting Standards Board ( FASB ) issued its final Statement of Financial Accounting Standards ( SFAS ) No. 168 *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162*. SFAS No. 168 made the FASB Accounting Standards Codification ( the Codification ) the single source of U.S. GAAP used by nongovernmental entities in the preparation of financial statements, except for rules and interpretive releases of the Securities & Exchange Commission ( SEC ) under authority of federal securities laws, which are sources of authoritative accounting guidance for SEC registrants. The Codification is meant to simplify user access to all authoritative accounting guidance by reorganizing U.S. GAAP pronouncements into roughly 90 accounting topics within a consistent structure; its purpose



is not to create new accounting and reporting guidance. The Codification supersedes all existing non-SEC accounting and reporting standards and was effective for the Company beginning July 1, 2009. Following SFAS No. 168, the FASB will not issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts; instead, it will issue Accounting Standards Updates. The FASB will not consider Accounting Standards Updates as authoritative in their own right; these updates will serve only to update the Codification, provide background information about the guidance and provide the bases for conclusions on the change(s) in the Codification. In the description of Accounting Standards Updates that follows, references in *italics* relate to Codification Topics and Subtopics and their descriptive titles, as appropriate. Adoption of the Codification does not have an impact on the Company's financial position or results of operations.

In June 2008, the FASB published *Determining Whether an Instrument is Indexed to an Entity's Own Stock* (FASB ASC 815-40) to address concerns regarding the meaning of *indexed to an entity's own stock* contained in FASB ASC 815-10 *Accounting for Derivative Instruments and Hedging Activities*. This related

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**GENTA INCORPORATED**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**For the years ended December 31, 2009 and 2008**

**2. Summary of Significant Accounting Policies (continued)**

to the determination of whether a freestanding equity-linked instrument should be classified as equity or debt. If an instrument is classified as debt, it is valued at fair value, and this value is remeasured on an ongoing basis, with changes recorded in earnings in each reporting period. FASB ASC 815-40 was effective for years beginning after December 15, 2008. Adoption of FASB ASC 815-40 did not have an impact on the Company's financial statements.

**Accounting Standards Updates Not Yet Effective**

In October 2009, an update was made to *Revenue Recognition - Multiple Deliverable Revenue Arrangements*. This update removes the objective-and-reliable-evidence-of-fair-value criterion from the separation criteria used to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting, replaces references to fair value with selling price to distinguish from the fair value measurements required under the *Fair Value Measurements and Disclosures* guidance, provides a hierarchy that entities must use to estimate the selling price, eliminates the use of the residual method for allocation, and expands the ongoing disclosure requirements. This update is effective for the Company beginning January 1, 2011 and can be applied prospectively or retrospectively. Management is currently evaluating the effect that adoption of this update will have, if any, on the Company's consolidated financial position and results of operations when it becomes effective in 2011.

Other Accounting Standards Updates not effective until after December 31, 2009, are not expected to have a significant effect on the Company's consolidated financial position or results of operations.

**Basis of Presentation**

The consolidated financial statements are presented on the basis of accounting principles generally accepted in the United States of America. Such financial statements include the accounts of the Company and all majority-owned subsidiaries.

**Use of Estimates**

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make certain estimates and assumptions that affect reported earnings, financial position and various disclosures. Actual results could differ from those estimates.

**Cash and Cash Equivalents**

Cash and cash equivalents consist of highly liquid instruments with maturities of three months or less from the date acquired and are stated at cost that approximates their fair market value. At December 31, 2009, the amounts on

deposit that exceeded the \$250,000 federally insured limit was \$0.5 million.

## **Revenue Recognition**

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

## **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

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**GENTA INCORPORATED**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**For the years ended December 31, 2009 and 2008**

**2. Summary of Significant Accounting Policies (continued)**

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 ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and when temporary differences become deductible. The Company considers, among other available information, uncertainties surrounding the recoverability of deferred tax assets, scheduled reversals of deferred tax liabilities, projected future taxable income and other matters in making this assessment. The Company reviewed its deferred tax assets and at both December 31, 2009 and December 31, 2008, recorded a valuation allowance to reduce these assets to zero to reflect that, more likely than not, they will not be realized. Utilization of the Company's net operating loss (NOL) and research and development (R&D) credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the Code), as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups.

The Company's policy for recording interest and penalties associated with audits is that penalties and interest expense are recorded in interest expense in the Company's Consolidated Statements of Operations.

**Restricted Stock Units and Stock Options**

Restricted stock units (RSUs) and stock options are recognized in the Consolidated Statements of Operations based on their fair values. The amount of compensation cost is measured based on the grant-date fair value of the equity instrument issued. During 2009, with the implementation of two Equity Award Exchange programs, outstanding stock option awards granted under the 1998 Non-Employee Directors Plan, as amended, and 1998 Stock Incentive Plan, as amended, were exchanged for grants of new RSUs under the Company's 2009 Stock Incentive Plan. Incremental compensation cost for the new RSUs was measured as the excess of the fair value of the RSUs over the fair value of the exchanged stock option awards on the date of exchange. The incremental compensation cost of the RSUs is being recognized over the remaining amortization period of the exchanged stock option awards. The Company utilizes a Black-Scholes option-pricing model to measure the fair value of RSUs and stock options granted to employees. See Note 11 to the Consolidated Financial Statements for a further discussion on share-based compensation.

**Deferred Financing Costs**

In conjunction with the issuance of the 2008 Notes, the April 2009 Notes, the July 2009 Notes, the September 2009

Notes and corresponding warrants, the Company incurred certain costs, including the issuance to its placement agent of warrants to purchase the Company's common stock. These costs are being amortized over the term of the notes through the earliest maturity date using the effective interest method. Under this method, interest expense recognized each period will increase significantly as the instrument approaches its maturity date. If the maturity of the 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 Loss Per Common Share**

Net loss per common share for the years ended December 31, 2009 and 2008, respectively, are based on the weighted average number of shares of common stock outstanding during the periods. Basic and diluted loss per share are identical for both periods presented as potentially dilutive securities have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would

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**GENTA INCORPORATED**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**For the years ended December 31, 2009 and 2008**

**2. Summary of Significant Accounting Policies (continued)**

be antidilutive. At December 31, 2009 and 2008, respectively, the potentially dilutive securities include 231 million and 32 million shares, respectively, reserved for the conversion of convertible notes, convertible preferred stock, vesting of RSUs and the exercise of outstanding options and warrants.

**3. Inventory**

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

	December 31,	
	2009	2008
Raw materials	\$ 24	\$ 24
Work in process		
Finished goods	57	97
	\$ 81	\$ 121

During the twelve months ended December 31, 2009, 37% of the units sold of Ganite® were from product that had been previously accounted as excess inventory.

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

**4. Settlement of Office Lease Obligation and Operating Leases**

In May 2008, we entered into an amendment of our lease for office space with The Connell Company (Connell), whereby the lease for one floor of our office space in Berkeley Heights, New Jersey was terminated. Connell received a termination payment of \$1.3 million, comprised solely of our security deposits and we agreed to pay Connell \$2.0 million on July 1, 2009. We accrued for the \$2.0 million and it is included on our Consolidated Balance Sheets. In January 2009, we entered into another amendment of our agreement with Connell whereby our future payment of \$2.0 million is now payable on January 1, 2011, with 6.0% interest paid in arrears.

Future minimum obligations under operating leases at December 31, 2009, (including the \$2.0 million payable to Connell in 2011) are as follows (\$ thousands):

2010

\$ 482

2011

2,007

\$ 2,489

Annual rent expense incurred by the Company during 2009 and 2008 was \$0.7 million and \$4.8 million, respectively. The annual rent expense in 2008 of \$4.8 million includes the termination payment of \$1.3 million to Connell and the liability of \$2.0 million to Connell.

## 5. Provision for Settlement of Litigation, net

In 2008 the Company reached an agreement to settle a class action litigation in consideration for issuance of 40,000 shares of common stock of the Company and \$18.0 million in cash for the benefit of plaintiffs and the stockholder class. The Company also entered into release and settlement agreements with its insurance carriers, pursuant to which insurance covered the settlement fee and various costs incurred in connection with the action. In 2006, the Company had recorded an expense of \$5.3 million related to the issuance of shares of common stock and had marked this liability to market until the agreement had been finalized. The liability for the settlement of litigation was measured at \$0.7 million at December 31, 2009 and 2008, respectively and is

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**For the years ended December 31, 2009 and 2008****5. Provision for Settlement of Litigation, net (continued)**

included in accounts payable and accrued expenses in the Company's Consolidated Balance Sheets. In February 2010, the shares of common stock were distributed to class action members.

**6. Property and Equipment, Net**

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

	Estimated Useful Lives	December 31,	
		2009	2008
Computer equipment	3	\$ 2,145	\$ 2,298
Software	3	3,214	3,206
Furniture and fixtures	5	898	899
Leasehold improvements	Life of lease	470	463
Equipment	5	51	182
		6,778	7,048
Less accumulated depreciation and amortization		(6,573 )	(6,748 )
		\$ 205	\$ 300

**7. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses is comprised of the following (\$ thousands):

	December 31,	
	2009	2008
Accounts payable	\$ 3,152	\$ 4,654
Accrued compensation	1,212	751
Reserve for settlement of litigation obligation	700	700
License obligations/Milestone payments to Daiichi Sankyo	1,000	2,125
State of New Jersey (AMA) tax liability	895	841
Other accrued expenses	1,870	2,153
	\$ 8,829	\$ 11,224

The carrying amount of accounts payable approximates fair value due to the short-term nature of these instruments.



## 8. Convertible Notes and Warrants

On June 9, 2008, the Company placed \$20 million of the 2008 Notes, due June 9, 2010 with certain institutional and accredited investors. The two-year notes bear interest at an annual rate of 15% payable at quarterly intervals in other 2008 Notes to the holder, and originally were convertible into shares of Genta common stock at a conversion rate of 2,000 shares of common stock for every \$1,000.00 of principal, (adjusted for the reverse stock split). As a result of issuing convertible notes on April 2, 2009, (see below), these notes are presently convertible into shares of Genta common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal. The 2008 Notes were secured by a first lien on all assets of Genta until December 1, 2009, at which time the security interest on the notes was removed.

At the time the 2008 Notes were issued, the Company recorded a debt discount (beneficial conversion) relating to the conversion feature in the amount of \$20 million. The aggregate intrinsic value of the difference between the market price of the Company's share of stock on June 9, 2008 and the conversion price of the 2008 Notes was in excess of the face value of the \$20 million 2008 Notes, and thus, a full debt discount was

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**GENTA INCORPORATED**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**For the years ended December 31, 2009 and 2008**

**8. Convertible Notes and Warrants (continued)**

recorded in an amount equal to the face value of the debt. The Company is amortizing the resultant debt discount over the term of the 2008 Notes through their maturity date.

From January 1, 2009 through December 31, 2009, holders of the 2008 Notes voluntarily converted approximately \$14.4 million of outstanding notes into common stock, resulting in an issuance of 102 million shares of common stock. These conversions resulted in additional amortization of \$12.2 million during 2009. At December 31, 2009, approximately \$1.8 million of the 2008 Notes were outstanding.

Upon the occurrence of an event of default, holders of the 2008 notes have the right to require the Company to prepay all or a portion of their 2008 notes as calculated as the greater of (a) 150% of the aggregate principal amount of the note plus accrued interest or (b) the aggregate principal amount of the note plus accrued interest divided by the conversion price; multiplied by a weighted average price of the Company's common stock.

In addition, in connection with the placement of the 2008 Notes, the Company issued a warrant to its private placement agent to purchase 800,000 shares of common stock at an exercise price of \$1.00 per share and incurred a financing fee of \$1.2 million. The financing fees and the initial value of the warrant are being amortized over the term of the convertible notes. At December 31, 2009 and 2008, respectively, the unamortized balances of the financing fee were \$0.1 million and \$0.9 million, respectively, and the warrants were \$0.7 million and \$5.4 million, respectively.

On April 2, 2009, the Company placed approximately \$6 million of April 2009 Notes, due April 2, 2012, and corresponding warrants to purchase common stock. The April 2009 Notes bear interest at an annual rate of 8% payable semi-annually in other April 2009 Notes to the holder, and are convertible into shares of the Company's common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal amount outstanding. The April 2009 Notes were also secured by a first lien on all assets of Genta, which security interest was pari passu with the security interest held by the holders of the 2008 Notes, but as of December 1, 2009, the April 2009 Notes are unsecured. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase up to approximately \$6 million of additional notes with similar terms.

From April 2, 2009 through December 31, 2009, holders of the April 2009 Notes voluntarily converted approximately \$1.7 million of outstanding notes into common stock, resulting in an issuance of 17 million shares of common stock.

These conversions resulted in additional amortization of \$1.5 million during 2009. At December 31, 2009, approximately \$4.5 million of the April 2009 Notes were outstanding.

In connection with the placement of the April 2009 Notes, the Company issued a warrant to its private placement agent to purchase 3.6 million shares of common stock at an exercise price of \$0.50 per share and incurred financing fees of \$0.6 million. The financing fees and the initial value of the warrant are being amortized over the term of the convertible notes. At December 31, 2009, the unamortized balances of the financing fee and the warrant were \$0.5

million and \$3.0 million, respectively.

The Company concluded that it should initially account for conversion options embedded in the 2008 Notes and April 2009 Notes by bifurcating the conversion options embedded in convertible notes from their host instruments and to account for them as free standing derivative financial instruments. If the conversion option requires net cash settlement in the event of circumstances that are not solely within the Company's control, then the embedded conversion feature should be classified as a liability measured at fair value on the balance sheet. In this case, if the Company was not successful in obtaining approval of its stockholders to increase the number of authorized shares to accommodate the potential number of shares that the notes convert into, the Company would have been required to cash settle the conversion option.

At the time the April 2009 Notes were issued, the aggregate intrinsic value of the difference between the market price of the Company's share of stock on April 2, 2009 and the conversion price of the April 2009 Notes was in excess of the face value of the \$6 million April 2009 Notes, and thus, a full debt discount was

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For the years ended December 31, 2009 and 2008****8. Convertible Notes and Warrants (continued)**

recorded in an amount equal to the face value of the debt. The Company is amortizing the resultant debt discount over the term of the April 2009 Notes through their maturity date. At April 2, 2009, there were an insufficient number of authorized shares of common stock in order to permit exercise of all of the issued convertible notes. When there are insufficient authorized shares, the conversion obligation for the notes should be classified as a liability measured at fair value on the balance sheet. At April 2, 2009, in connection with the \$6 million closing, the fair value of the conversion feature, \$67.8 million, exceeded the proceeds of \$6 million. The difference of \$61.8 million was charged to expense as the change in the fair market value of conversion liability.

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

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

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

As there were an insufficient number of authorized shares of common stock in order to fulfill all existing obligations at the time of issuance, the Company classified the April 2009 warrant obligations as liabilities to be measured at fair value on the balance sheet. Accordingly, at April 2, 2009, the Company recorded the warrant liabilities at a fair value of \$20.8 million, based upon the Black-Scholes valuation model. The warrant liability was re-measured at June 26, 2009 at a fair value of \$7.7 million, and credited to permanent equity, resulting in an expense of \$7.7 million. The

warrant liability was valued at April 2, 2009 and June 26, 2009 using the Black-Scholes valuation model using the following assumptions:

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

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**GENTA INCORPORATED**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**For the years ended December 31, 2009 and 2008**

**8. Convertible Notes and Warrants (continued)**

On July 7, 2009, the Company entered into a securities purchase agreement with certain accredited institutional investors to place up to \$10 million in aggregate principal amount of units consisting of (i) 70% July 2009 Notes and (ii) 30% common stock. In connection with the sale of the units, the Company also issued to the investors July 2009 Warrants. The Company closed on \$3 million of such July 2009 Notes, due July 7, 2011, common stock and July 2009 warrants on July 7, 2009. The July 2009 Notes bear interest at an annual rate of 8% payable semi-annually in other July 2009 Notes to the holder, and are convertible into shares of the Company's common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal amount outstanding.

From July 7, 2009 through December 31, 2009, holders of the July 2009 Notes voluntarily converted approximately \$1.3 million of outstanding notes into common stock, resulting in an issuance of 13 million shares of common stock.

These conversions resulted in additional amortization of \$1.3 million during 2009. At December 31, 2009, approximately \$0.8 million of the July 2009 Notes were outstanding.

In connection with the placement of the July 2009 Notes, the Company issued a warrant to its private placement agent to purchase 1.8 million shares of common stock at an exercise price of \$1.00 per share and incurred financing fees of \$0.1 million. The Company measured the initial value of the placement agent warrant at \$0.7 million using a Black Scholes model incorporating the following assumptions: a stock price of \$0.3906, an expected life of 2.5 years, annualized volatility of 269% and a risk-free interest rate of 1.25%. The financing fees and the initial value of the warrant are being amortized over the term of the convertible notes. At December 31, 2009, the financing fee was fully amortized and the unamortized balance of the warrant was \$0.2 million, respectively.

At the time the July 2009 Notes were issued, the aggregate intrinsic value, representing the difference between the market price of the Company's share of stock on July 7, 2009 and the conversion price of the July 2009 Notes was in excess of the face value of the \$2.1 million of July 2009 Notes, and thus, a full debt discount was recorded in an amount equal to the face value of the debt. The Company is amortizing the resultant debt discount over the term of the July 2009 Notes through their maturity date.

On September 4, 2009, the Company closed on \$7 million of additional July 2009 Notes, due September 4, 2011, common stock and July 2009 Warrants. Also on September 4, 2009, the Company entered into a securities purchase agreement with certain accredited institutional investors, pursuant to which the Company issued \$3 million of units consisting of (i) 70% September 2009 Notes, and (ii) 30% common stock. In connection with the sale of the units, the Company also issued to the investors September 2009 Warrants. The September 2009 Notes, due September 4, 2011, bear interest at an annual rate of 8% payable semi-annually in other September 2009 Notes to the holder, and are convertible into shares of the Company's common stock at a conversion rate of 10,000 shares of common stock for every \$1,000.00 of principal amount outstanding.

There has been no conversion of September 2009 Notes and July 2009 Notes issued on September 4, 2009.

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 6.0 million shares of common stock at an exercise price of \$1.00 per share and incurred financing fees of \$0.6 million. The Company measured the initial value of the placement agent warrant at \$2.2 million using a Black Scholes model incorporating the following assumptions: a stock price of \$0.395, an expected life of 2.5 years, annualized volatility of 269% and a risk-free interest rate of 1.2%. The financing fees and the initial value of the warrants are being amortized over the term of the convertible notes. At December 31, 2009, the unamortized balances of the financing fee and the warrant were \$0.5 million and \$1.9 million, respectively.

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For the years ended December 31, 2009 and 2008****8. Convertible Notes and Warrants (continued)**

At the time the September 2009 Notes and July 2009 Notes were issued on September 4, 2009, the aggregate intrinsic value, representing the difference between the market price of the Company's share of stock on September 4, 2009 and the effective conversion price of the notes was in excess of the face value of the \$7.0 million of notes issued on September 4, 2009, and thus, a full debt discount was recorded in an amount equal to the face value of the debt. The Company is amortizing the resultant debt discount over the term of the notes through their maturity date.

The Company is in compliance with all debt-related covenants at December 31, 2009.

At December 31, 2009, the maturities of the Company's convertible notes are as follows:

(\$000 face value)	2010	2011	2012
2008 Notes	\$ 1,787	\$	\$
April 2009 Notes			4,452
July 2009 Notes		751	
September 2009 Notes and July 2009 Notes issued in September 2009		7,000	
Total	\$ 1,787	\$ 7,751	\$ 4,452

**9. Income Taxes**

Significant components of the Company's deferred tax assets as of December 31, 2009 and 2008 and related valuation reserves are presented below (\$ thousands):

	December 31, 2009	2008
Deferred tax assets:		
Net operating loss carryforwards	136,769	135,990
Research and development credit and Orphan Drug credit carryforwards	48,817	51,288
Depreciation and amortization, net	206	193
Share-based compensation expense	6,205	1,683
Provision for settlement of litigation, net	308	308
Write-off of prepaid royalties	558	558
New Jersey Alternative Minimum Assessment (AMA) Tax	730	730
New Jersey research and development credits	4,016	4,979



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Provision for excess inventory	526	714
License agreement	1,447	248
Accrued liabilities	1,335	1,328
Other, net	369	197
Total deferred tax assets	201,286	198,216
Valuation allowance for deferred tax assets	(194,491)	(190,884)
Net deferred tax assets	\$6,795	\$7,332
Deferred tax liabilities:		
Deferred financing costs	\$(2,524 )	\$(4,922 )
Debt discount	(4,271 )	(2,410 )
Total deferred tax liabilities	\$(6,795 )	\$(7,332 )
Net deferred tax assets (liabilities)	\$	\$

A full valuation allowance has been provided at December 31, 2009 and 2008, respectively, to reserve for deferred tax assets, as it appears more likely than not that net deferred tax assets will not be realized.

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For the years ended December 31, 2009 and 2008****9. Income Taxes (continued)**

As of December 31, 2009 and 2008, the Company recorded a liability for \$895 thousand and \$841 thousand, respectively, of unrecognized tax benefits (UTB's), of which \$895 thousand and \$841 thousand is included in accounts payable and accrued expenses on the Company's Consolidated Balance Sheets, respectively. The amount of UTB's that would have an impact on the effective tax rate, if recognized, is \$533 thousand.

A reconciliation of the total amount of unrecognized tax benefits (UTB's) is as follows:

(\$ in thousands)	2009	2008
Unrecognized tax benefits at January 1	\$ 1,845	\$ 1,567
Gross increases: Tax positions taken in prior periods		
Gross decreases: Tax positions taken in prior periods		
Gross Increases Current period tax positions	77	278
Lapse of Statute of Limitations		
Unrecognized tax benefits: December 31	\$ 1,922	\$ 1,845

The Company files corporate tax returns at the federal level and in the State of New Jersey. The open tax years that are subject to examination for these jurisdictions are 2006 through 2009 for federal returns and 2002 through 2009 for tax returns for the State of New Jersey.

New Jersey has enacted legislation permitting certain corporations located in the state to sell state tax loss carryforwards and state research and development credits. In 2009, the Company sold portions of its New Jersey net operating losses and research and development credit carryforwards and received \$2.9 million in February 2010; the \$2.9 million is included in the Company's Consolidated Balance Sheets at December 31, 2009. In 2008, the Company sold portions of its New Jersey net operating losses and research and development credit carryforwards for \$2.0 million. These sales are accounted for as income tax benefits in the Company's Consolidated Statement of Operations.

If still available under New Jersey law, the Company will attempt to sell its tax loss carryforwards in 2010. The

Company cannot be assured that the New Jersey program will continue in 2010, nor can they estimate what percentage of Genta's saleable tax benefits New Jersey will permit it to sell, how much money will be received in connection with the sale, or if the Company will be able to find a buyer for its tax benefits.

The Company's Federal tax returns have never been audited. In January 2006, the State of New Jersey concluded its fieldwork with respect to a tax audit for the years 2000 through 2004. The State of New Jersey took the position that amounts reimbursed to Genta by Aventis Pharmaceutical Inc. for co-development expenditures during the audit period were subject to Alternative Minimum Assessment (AMA), resulting in a liability at that time of approximately \$533 thousand. Although the Company and its outside tax advisors believe the State's position on the AMA liability is unjustified, there is little case law on the matter and it is probable that the Company will be required to ultimately pay

the liability. As of December 31, 2009, the Company had accrued a tax liability of \$533 thousand, penalties of \$27 thousand and interest of \$335 thousand related to this assessment. The Company appealed this decision to the New Jersey Division of Taxation, and in February 2008, the Division of Taxation notified the Company that its appeal had not been granted. On April 25, 2008, the Company filed a complaint with the Tax Court of the State of New Jersey to appeal the assessment. A bench trial took place on September 18, 2009. After considering the evidence and reviewing the parties' legal briefs, the judge is expected to render a decision in the case in late 2010.

The Company recorded \$54 thousand and \$65 thousand, in interest expense related to the State of New Jersey assessment during 2009 and 2008, respectively.

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**9. Income Taxes (continued)**

At December 31, 2009, the Company has federal and state net operating loss carryforwards of approximately \$328.8 million and \$234.7 million, respectively. The federal tax loss carryforward balance at December 31, 2009 begins to expire in 2010 and completely expires in 2029. The Company also has Research and Development credit and Orphan Drug credit carryforwards totaling \$50.4 million; the balance at December 31, 2009 begins to expire in 2010 and completely expires in 2029.

**10. Stockholders Deficit**

**Common Stock**

As part of its September 4, 2009 financings, the Company closed on \$4.9 million of July 2009 Notes, due September 4, 2011, and issued 21.0 million shares of common stock and July 2009 Warrants for 16.5 million shares of common stock. Also on September 4, 2009, the Company issued \$2.1 million of September 2009 Notes, due September 4, 2011, 9.0 million shares of common stock and September 2009 Warrants for 7.0 million shares.

On July 7, 2009, the Company closed on \$2.1 million of July 2009 Notes, due July 7, 2011, and issued 9.0 million shares of common stock and July 2009 Warrants for 7.1 million shares of common stock.

At a Special Meeting of Stockholders held on June 26, 2009, the Company's stockholders authorized its Board of Directors to effect a reverse stock split of all outstanding shares of common stock, and the Board of Directors subsequently approved the implementation of a reverse stock split on June 26, 2009 at a ratio of one for fifty shares. All 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 June 26, 2009.

On October 6, 2008, at the Annual Meeting of Stockholders, the Company's stockholders approved an amendment to Genta's Restated Certificate of Incorporation, as amended, to increase the total number of authorized shares of capital stock available for issuance from 255,000,000, consisting of 250,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock, to 6,005,000,000, consisting of 6,000,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock.

In February 2008, the Company sold 123 thousand shares of the Company's common stock at a price of \$25.00 per share, raising approximately \$3.1 million, before estimated fees and expenses.

## **Preferred Stock Purchase Right**

In 2005 the Board of Directors adopted a Stockholder Rights Plan and declared a dividend of one preferred stock purchase right (a Right) for each outstanding share of common stock of the Company, payable to holders of record as of the close of business on September 27, 2005. Generally, the rights become exercisable upon the earlier of the close of business on the tenth business day following the first public announcement that any person or group has become a beneficial owner of 15% or more of the Company's common stock and the close of business on the tenth business day after the date of the commencement of a tender or exchange offer by any person which would, if consummated, result in such person becoming a beneficial owner of 15% or more of the Company's common stock. Each Right shall be exercisable to purchase, for \$25.00, subject to adjustment, one one-hundredth of a newly registered share of Series G Participating Cumulative Preferred Stock, par value \$0.001 per share of the Company.

## **Series A Preferred Stock**

Each share of Series A Preferred Stock is immediately convertible into shares of the Company's common stock, at a rate determined by dividing the aggregate liquidation preference of the Series A Preferred Stock by the conversion price. The conversion price is subject to adjustment for antidilution. As of December 31, 2009 and December 31, 2008, each share of Series A Preferred Stock was convertible into 33.1181 and 3.0687

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shares of common stock, respectively. At December 31, 2009 and December 31, 2008, the Company had 7,700 shares of Series A Convertible Preferred Stock issued and outstanding.

In the event of a liquidation of the Company, the holders of the Series A Preferred Stock are entitled to a liquidation preference equal to \$50 per share, or \$0.4 million at December 31, 2009.

**Series G Preferred Stock**

The Company has 5.0 million shares of preferred stock authorized, of which 2.0 million shares has been designated Series G Participating Cumulative Preferred.

**Warrants**

Warrant transactions consisted of the following during the year ended December 31, 2009.

	Number of Shares (in thousands)	Exercise Price
2008 Warrants outstanding at December 31, 2008	800	\$ 1.00
April 2009 Warrants issued in April 2009	18,595	\$ 0.50
July 2009 Warrants issued in July 2009	7,053	\$ 1.00
September 2009 Warrants and July 2009 Warrants issued in September 2009	23,500	\$ 1.00
Exercise of April 2009 Warrants	(3,662 )	\$ 0.50
Outstanding at December 31, 2009	46,286	

Warrants outstanding at December 31, 2009 expire as follows:

Year	Warrants Expiring (in thousands)	Exercise Price
2010		\$
2011		\$
2012 April 2009 Warrants	14,933	\$ 0.50

	July 2009 Warrants	7,053	\$ 1.00
	September 2009 Warrants and July 2009 Warrants issued in September 2009	23,500	\$ 1.00
2013	2008 Warrants	800	\$ 1.00
	Outstanding at December 31, 2009	46,286	

### Common Stock Reserved

At December 31, 2009, the Company had 192.8 million shares of common stock outstanding, 44.7 million shares reserved for the conversion of convertible preferred stock and the exercise of outstanding RSUs, 46.1 million shares reserved for the conversion of outstanding warrants, 188.2 million shares reserved for the conversion of convertible notes and interest on those notes and 29.7 million additional shares of common stock authorized for issuance and remaining to be granted under the Company's 2009 Stock Incentive Plan.

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During 2009, the Company had the following share-based compensation plans, which are described below:

**2009 Stock Incentive Plan**

On July 9, 2009 the Company's Board of Directors approved the establishment of the 2009 Stock Incentive Plan, ( 2009 Plan ), subject to approval by the Company's stockholders. In addition, the Board of Directors approved an Equity Award Exchange Offer Program for non-employee Directors, whereby each non-employee Director was given an opportunity to exchange his outstanding stock options to purchase shares of Genta common stock for new RSUs to be granted pursuant to the Director grant program under the 2009 Plan. All of our eligible non-employee Directors submitted their eligible stock options for cancellation, and accordingly, each non-employee Director was granted a RSU award on July 16, 2009, subject to approval of the 2009 Plan by the Company's stockholders. At the Annual Meeting of Stockholders of Genta Incorporated held on August 26, 2009, the Company's stockholders approved the establishment of the 2009 Plan. Upon approval of the 2009 Plan by the Company's stockholders, the stock options submitted pursuant to the Equity Award Exchange Offer were cancelled and the RSUs became fully vested.

On August 26, 2009 the Compensation Committee of the Board of Directors approved an Equity Award Exchange Offer Program for all U.S. employees, whereby each employee was given an opportunity to exchange his outstanding stock options that had been granted under the Company's 1998 Stock Incentive Plan, as amended ( 1998 Plan ), to purchase shares of Genta common stock for new replacement RSUs. All eligible employees submitted their eligible stock options for cancellation, and accordingly, each employee was granted a RSU award on August 31, 2009. The surrender of the options was accounted for as a modification of an award. The Company determined the compensation cost of the modification as the difference in the fair value of the options immediately before the modification and the fair value of the RSUs immediately after the modification. A charge of \$8.2 million was recorded in the Consolidated Statement of Operations related to the modification of awards that were vested as of the modification date. The incremental cost for awards that were not vested as of the modification date will be expensed over the remaining vesting period.

The following table summarizes the RSU activity under the 2009 Plan during 2009:

Restricted Stock Units	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value per Share
Outstanding nonvested RSUs at July 9, 2009		
Granted	56,378	\$ 0.395



Vested	(9,355 )	\$ 0.395
Forfeited or expired	(2,620 )	\$ 0.395
Outstanding nonvested RSUs at December 31, 2009	44,403	\$ 0.395

Based on the closing price of Genta common stock of \$0.087 per share on December 31, 2009, the intrinsic value of the nonvested RSUs at December 31, 2009 is \$3.9 million. As of December 31, 2009, there was approximately \$4.3 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.

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**(continued)**

Stock options were also awarded to employees during 2009 and subsequently cancelled. The following table summarizes the stock option activity under the 2009 Plan during 2009:

Stock Options	Number of Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at July 9, 2009				
Granted	300	\$ 0.77		
Exercised				
Forfeited or expired	(300 )	\$ 0.77		
Outstanding at December 31, 2009				

**1998 Stock Incentive Plan**

Pursuant to the 1998 Plan, 68 thousand shares had been provided for the grant of stock options to employees, directors, consultants and advisors of the Company. As of May 27, 2008, the authorization to provide grants under the 1998 Plan expired. With the completion of the Equity Award Exchange Offer Program, virtually all options under the 1998 Plan have been cancelled.

The following table summarizes the option activity under the 1998 Plan as of December 31, 2009 and changes during the two years then ended:

Stock Options	Number of Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2008	43	\$ 1,152.50		
Granted				
Exercised				

Forfeited or expired	(6 )	888.00
Outstanding at December 31, 2008	37	\$ 1,191.50
Granted		
Exercised		
Forfeited or expired	(37 )	1,191.50
Outstanding at December 31, 2009		

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The following table summarizes the RSU activity under the 1998 Plan as of December 31, 2009 and changes during the two years then ended:

Restricted Stock Units	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value per Share
Outstanding nonvested RSUs at January 1, 2008		
Granted	10	\$ 20.50
Vested		
Forfeited or expired	(5 )	\$ 20.50
Outstanding nonvested RSUs at December 31, 2008	5	\$ 20.50
Granted		
Vested	(5 )	\$ 20.50
Forfeited or expired		
Outstanding nonvested RSUs at December 31, 2009		

**1998 Non-Employee Directors Plan**

Pursuant to the Company's 1998 Non-Employee Directors Plan, as amended (the Directors Plan), 12 thousand shares had been provided for the grant of non-qualified stock options to the Company's non-employee members of the Board of Directors. Upon stockholder approval of the 2009 Plan, the Directors Plan was terminated.

The following table summarizes the option activity under the Directors Plan as of December 31, 2009 and changes during the two years then ended:

Stock Options	Number of Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2008	2	\$ 1,130.47		

Granted		
Exercised		
Forfeited or expired		
Outstanding at January 1, 2009	2	\$ 1,130.47
Granted		
Exercised		
Forfeited or expired	(2 )	\$ 1,130.47
Outstanding at December 31, 2009		

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The Company estimates the fair value of each stock option award on the date of the grant using the Black-Scholes option valuation model. Expected volatilities are based on the historical volatility of the Company's common stock over a period commensurate with the options' expected term. The expected term represents the period of time that options granted are expected to be outstanding and is calculated in accordance with the SEC guidance provided in the SEC's Staff Accounting Bulletin 107, (SAB 107) and Staff Accounting Bulletin 110 (SAB 110), using a simplified method. The Company will continue to use the simplified method as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate an expected term. The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of the Company's stock options. The following table summarizes the weighted-average assumptions used in the Black-Scholes model for options granted during the twelve months ended December 31, 2009:

Expected volatility	193	%
Expected dividends		
Expected term (in years)	6.25	
Risk-free rate	2.6	%

With the implementation of the Equity Award Exchange programs, outstanding stock option awards granted under the Directors' Plan and 1998 Plan were exchanged for grants of new RSUs. Incremental compensation cost for the new RSUs was measured as the excess of the fair value of the RSUs over the fair value of the stock option awards on the date of exchange. The incremental compensation cost of the RSUs is being recognized over the remaining amortization period of the stock option awards.

Share-based compensation expense recognized for the years ended December 31, 2009 and December 31, 2008 follows:

(\$ thousands, except per share data)	2009	2008
Research and development expenses	\$ 3,901	\$ 151
Selling, general and administrative	9,398	338
Total share-based compensation expense	\$ 13,299	\$ 489
Share-based compensation expense, per basic and diluted common share	\$ 0.13	\$ 0.44

## **12. Employee Savings Plan**

In 2001, the Company initiated sponsorship of the Genta Incorporated Savings and Retirement Plan, a defined contribution plan under Section 401(k) of the Internal Revenue Code. The Company's matching contribution to the Plan was \$0.1 million and \$0.2 million for 2009 and 2008, respectively.

## **13. Commitments and Contingencies**

### **Litigation and Potential Claims**

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

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

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**13. Commitments and Contingencies (continued)**

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 will proceed 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 Company, Board of Directors and Officers deny these allegations and intend to vigorously defend this lawsuit.

**14. Supplemental Disclosure of Cash Flows Information and Non-Cash Investing and Financing Activities**

No interest or income taxes were paid with cash during the twelve months ended December 31, 2009. During 2009, the Company issued approximately \$664 thousand of 2008 Notes in lieu of interest due on its 2008 Notes and \$175 thousand of April 2009 Notes in lieu of interest due on its April 2009 Notes.

From January 1, 2009 through December 31, 2009, holders of the Company's convertible notes voluntarily converted approximately \$17.5 million, resulting in an issuance of 132.8 million shares of common stock.

During 2009 and 2008, the Company retired approximately \$0.3 million and \$0.7 million of equipment, computer equipment and furniture and fixtures, respectively.

During 2008, the Company paid \$850,000 in cash in interest payments and issued 80,000 shares of common stock in lieu of interest on the 2008 Notes. No income taxes were paid during 2008.

For the twelve months ended December 31, 2008, holders of convertible notes voluntarily converted approximately \$4.5 million of their notes, resulting in an issuance of 8.9 million shares of common stock.

**15. Related Party Transactions**

On June 9, 2008, the Company placed \$20 million of the 2008 Notes. Dr. Raymond Warrell, Chief Executive Officer and Chairman, and Dr. Loretta Itri, President, Pharmaceutical Development and Chief Medical Officer, participated in



the initial closing by purchasing \$2.0 million and \$0.3 million, respectively, of such notes. The remaining members of the Board of Directors independently discussed Dr. Warrell and Dr. Itri's participation in the transaction and resolved that such participation would not interfere with Dr. Warrell or Dr. Itri's exercise of independent judgment in carrying out their responsibilities in their respective positions. In connection with the June 2008 convertible note financing and in accordance with the Audit Committee Charter, the Audit Committee reviewed and approved the June 2008 convertible note financing with Dr. Warrell and Dr. Itri.

## 16. Subsequent Events

From January 1, 2010 through March 29, 2010, holders of convertible notes have voluntarily converted approximately \$2.1 million of their notes, resulting in an issuance of 140.4 million shares of common stock.

On March 5, 2010, the Company entered into a securities purchase agreement with certain accredited investors, pursuant to which it agreed to issue \$25 million of units (the "2010 Units"), each 2010 Unit consisting of (i) 40% of a senior unsecured convertible note (the "B Notes"), (ii) 40% of a senior unsecured convertible note (the "C Notes") and (iii) 20% of a senior secured convertible note (the "D Notes"). In

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**16. Subsequent Events (continued)**

connection with the sale of the 2010 Units, the Company also agreed to issue warrants (the Debt Warrants ) to purchase senior unsecured convertible notes (the E Notes ) in an amount equal to 40% of the purchase price paid for each such 2010 Unit. The notes in this transaction, or the March 2010 Notes, bear interest at an annual rate of 12% payable semiannually in cash or in other convertible notes to the holder, and are convertible into shares of Genta common stock at a conversion rate of 100,000 shares of common stock for every \$1,000.00 of principal. The March 2010 Financing closed on March 9, 2010. The Company has direct access to \$20 million of the proceeds, and the remaining \$5 million of the proceeds were placed in a blocked account as collateral security for the \$5 million in principal amount of the D Notes. On March 17, 2010 and March 22, 2010, three investors who had participated in the Company's April 2009 financing, exercised their rights to acquire convertible notes of \$0.9 million.

Since the conversion price of the March 2010 Notes was less than the current conversion price for the 2008 Notes, April 2009 Notes, July 2009 Notes and September 2009 Notes the conversion price for those notes reset upon the closing of the March 2010 Financing to \$0.01 per share of Common Stock, pursuant to the terms of those Notes.

The Company has also extended the maturity date of the outstanding 2008 Notes in exchange for three-year warrants to purchase the same number of shares of the Company's Common Stock issuable upon conversion of such 2008 Notes.

There are currently 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 will initially account for conversion options embedded in convertible notes in accordance with *Accounting for Derivative Instruments and Hedging Activities* , FASB ASC 815-10, and *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* (FASB ASC 815-40). FASB ASC 815-10 generally requires companies to bifurcate conversion options embedded in convertible notes from their host instruments and to account for them as free standing derivative financial instruments in accordance with FASB ASC 815-40. FASB ASC 815-40 states that if the conversion option requires net cash settlement in the event of circumstances that are not solely within the Company's control, that the notes should be classified as a liability measured at fair value on the balance sheet. In this case, the holder of each March 2010 Note has the right to require the Company to repay 100% of the outstanding principal and accrued interest on each note in cash on the second anniversary of the closing date of the March 2010 financing.

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

At the time the notes were issued, the Company recorded a debt discount (beneficial conversion) relating to the conversion feature in the amount of \$25.0 million. The aggregate intrinsic value of the difference between the market price of a share of the Company's stock on March 9, 2010 and the conversion price of the notes was in excess of the face value of the \$25.0 million notes, and thus, a full debt discount was recorded in an amount equal to the face value of the notes. The Company will amortize the resultant debt discount over the term of the notes through their maturity date.

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## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

## **Item 9A(T). 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 Finance Officer conducted an evaluation as of the end of the period covered by this report of the effectiveness of Genta's disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)). Based on that evaluation, our Chief Executive Officer and Principal Accounting and Finance Officer concluded that as of December 31, 2009, our disclosure controls and procedures were (1) effective in that they were designed to ensure that material information relating to us is made known to our Chief Executive Officer and Principal Accounting and Finance Officer by others within this entity, as appropriate to allow timely decisions regarding required disclosures, and (2) effective in that they provide that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

### **Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control – Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2009.

This Annual Report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this Annual 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 last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## Item 9B. Other Information

On December 23, 2009, the Securities and Exchange Commission, ( SEC ), granted effectiveness to the Company's filed S-1/A. The S-1/A relates to offers and resales or other dispositions by certain of the Company's security holders or their transferees of up to 54,713,329 shares of the Company's common stock, including 37,391,688 shares issued as part of the July 7, 2009 and September 4, 2009 financings, 1,215,000 shares issuable upon the exercise of the July 2009 Warrants, 14,574,141 shares issuable upon the conversion of the July 2009 Notes, and 1,532,500 shares issuable upon the conversion of the September 2009 Notes. The Company will not receive any of the proceeds from the disposition of these shares by the selling stockholders, other than as a result of the exercise of July 2009 Warrants for cash held by the selling stockholders.

On January 10, 2010, the SEC granted effectiveness to the Company's filed S-3/A. The Form S-3/A allows the Company to issue, in one or more offerings, any combination of senior or subordinated debt securities, warrants, preferred stock, common stock or units up to a total dollar amount of \$50,000,000.00. The Form S-3/A provides flexibility for the Company in the event it needs to raise additional funds to support ongoing activities or future initiatives. As set forth in the Form S-3/A, these potential expenditures would relate to general corporate funding, initiation of new studies, and acceleration of clinical research in our pipelines programs and the expansion of our business through internal growth or acquisitions.

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## **PART III**

### **Item 10. Directors and Executive Officers of the Registrant and Corporate Governance**

The information required in this item is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 2010 pursuant to Regulation 14A of the General Rules and Regulations under the Securities Exchange Act of 1934, as amended ( Regulation 14A ).

### **Item 11. Executive Compensation**

The information required in this item is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 2010 pursuant to Regulation 14A.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required in this item is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 2010 pursuant to Regulation 14A.

### **Item 13. Certain Relationships and Related Transactions and Director Independence**

The information required in this item is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 2010 pursuant to Regulation 14A.

### **Item 14. Principal Accounting Fees and Services**

The information required in this item is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 2010 pursuant to Regulation 14A.

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**PART IV**

**Item 15. Exhibits and Financial Statement Schedules.**

Exhibit Number	Description of Document
3.1.a	Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1995, Commission File No. 0-19635)
3.1.b	Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i) to the Company's Current Report on Form 8-K filed on February 28, 1997, Commission File No. 0-19635)
3.1.c	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.d	Amended Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.e	Certificate of Increase of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).5 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.f	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)
3.1.g	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)
3.1.h	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).8 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.i	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.i to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)
3.1.j	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.j to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)
3.1.k	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.k to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, Commission File No. 0-19635)
3.1.l	Certificate of Designation of Series G Participating Cumulative Preferred Stock of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on September 21, 2005, Commission File No. 0-19635)
3.1.m	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, Commission File No. 0-19635)

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- 3.1.n Certificate of Amendment of Restated Certificate of Incorporation of the Company  
(incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on July 13, 2007, Commission File No. 0-19635)
- 3.1.o Certificate of Amendment of Restated Certificate of Incorporation of the Company  
(incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on June 29, 2009, Commission File No. 0-19635)

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Exhibit Number	Description of Document
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, Commission File No. 0-19635)
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)
4.2	Rights Agreement, dated September 20, 2005, between the Company and Mellon Investor Services LLC, as Rights Agent (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on September 21, 2005, Commission File No. 0-19635)
4.3	Form of Senior Unsecured Convertible Note ( "B Note" ) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).
4.4	Form of Senior Unsecured Convertible Note ( "C Note" ) (incorporated by reference to Exhibit 4.2 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).
4.5	Form of Senior Secured Convertible Note ( "D Note" ) (incorporated by reference to Exhibit 4.3 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).
4.6	Form of Senior Unsecured Convertible Note ( "E Note" ) (incorporated by reference to Exhibit 4.4 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).
4.7	Form of Senior Unsecured Convertible Note ( "F Note" ) (incorporated by reference to Exhibit 4.5 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).
4.8	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.6 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).
4.9	Form of Senior Unsecured Convertible Promissory Note Purchase Warrant (incorporated by reference to Exhibit 4.7 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).
10.1	Form of Indemnification Agreement entered into between the Company and its directors and officers (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1, Commission File No. 0-19635)
10.2	Agreement of Lease dated June 28, 2000 by and between The Connell Company and the Company (incorporated by reference to Exhibit 10.76 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)
10.2A	Amendment of Lease, dated June 19, 2002 by and between The Connell Company and the Company (incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.2B	Amendment of Lease, dated September 23, 2009 by and between The Connell Company and the Company (filed herewith)
10.3*	Manufacture and Supply Agreement, dated December 20, 2002, between Genta Incorporated and Avecia Biotechnology Inc. (incorporated by reference to Exhibit 10.88 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, Commission File No. 0-19635)
10.3A*	

Manufacture and Supply Agreement, dated May 1, 2008, between Genta Incorporated and Avecia Biotechnology Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, Commission File No. 0-19635)

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Exhibit Number	Description of Document
10.4*	License Agreement dated August 1, 1991, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)
10.4A*	Amendment to License Agreement, dated December 19, 2000, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)
10.4AA*	Second Amendment to License Agreement, dated October 22, 2003, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)
10.5	Settlement Agreement and Release, dated October 22, 2003, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.4 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)
10.6*	Development and License Agreement, dated March 22, 2006 by and between the Company and Emisphere Technologies, Inc.* (incorporated by reference to Exhibit 10.5 to the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, Commission File No. 0-19635)
10.7	Employment Agreement, dated as of March 28, 2006, between the Company and Loretta M. Itri, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, Commission File No. 0-19635)
10.8*	Supply and Distribution Agreement between the Company and IDIS Limited, dated March 6, 2007 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed on May 8, 2007, Commission File No. 0-19635)
10.9*	Project Contract with ICON Clinical Research, L.P., dated November 19, 2007 (incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K for the year ended December 31, 2007, Commission File No. 0-19635)
10.10	Amended and Restated Employment Agreement, dated as of November 30, 2007, between the Company and Raymond P. Warrell, Jr. M.D. (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K for the year ended December 31, 2007, Commission File No. 0-19635)
10.11*	License Agreement, dated March 7, 2008, between the Company and Daiichi Sankyo (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, Commission File No. 0-19635)
10.12	Securities Purchase Agreement, dated June 5, 2008, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on June 10, 2008, Commission File No. 0-19635)
10.13	General Security Agreement, dated June 9, 2008, by and among the Company, certain additional grantors as set forth therein and Tang Capital Partners, L.P. as agent (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on June 10, 2008, Commission File No. 0-19635)
10.14	2009 Stock Incentive Plan, effective (incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009,

Commission File No. 0-19635)

- 10.15 Form of Restricted Stock Unit Issuance Agreement (incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q, filed on November 16, 2009, Commission File No. 0-19635)

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Exhibit Number	Description of Document
10.16*	Form of Securities Purchase Agreement, dated April 2, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on April 6, 2009, Commission File No. 0-19635)
10.17	Form of Amended and Restated General Security Agreement, dated April 2, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on April 6, 2009, Commission File No. 0-19635)
10.18*	Form of Consent Agreement, dated April 2, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed on April 6, 2009, Commission File No. 0-19635)
10.19	Form of Securities Purchase Agreement, dated July 7, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on July 8, 2009, Commission File No. 0-19635)
10.20	Form of Registration Rights Agreement, dated July 7, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on July 8, 2009, Commission File No. 0-19635)
10.21	Form of Consent Agreement, dated July 7, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed on July 8, 2009, Commission File No. 0-19635)
10.22	Form of Amendment Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on August 12, 2009, Commission File No. 0-19365)
10.23	Form of Amendment Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on September 9, 2009, Commission File No. 0-19365)
10.24	Form of Consent and Amendment Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on September 9, 2009, Commission File No. 0-19365)
10.25	Form of Securities Purchase Agreement, dated September 4, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed on September 9, 2009, Commission File No. 0-19635)
10.26	Form of Registration Rights Agreement, dated September 4, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed on September 9, 2009, Commission File No. 0-19635)
10.27	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).
10.28	Form of Note Conversion and Amendment Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).
10.29	Form of Security Agreement (incorporated by reference to Exhibit 10.3 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).
16.1	Letter from Deloitte & Touche LLP, dated July 16, 2008, regarding change in certifying accountant (incorporated by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K, filed on July 22, 2008, Commission File No. 0-19365)

21	Subsidiaries of the Registrant
23.1	Consent of Amper Politziner & Mattia, LLP

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Exhibit 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)
*	The Company has been granted confidential treatment of certain portions of this exhibit.

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# SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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, on this 29th day of March 2010.

**Genta Incorporated**

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

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

Chairman and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Capacity	Date
/s/ RAYMOND P. WARRELL, JR., M.D. Raymond P. Warrell, Jr., M.D.	Chairman and Chief Executive Officer and Director (principal executive officer)	March 29, 2010
/s/ GARY SIEGEL Gary Siegel	Vice President, Finance (principal financial and accounting officer)	March 29, 2010
/s/ CHRISTOPHER P. PARIOS Christopher P. Parios	Director	March 29, 2010
/s/ DANIEL D. VON HOFF, M.D. Daniel D. Von Hoff, M.D.	Director	March 29, 2010
/s/ DOUGLAS G. WATSON Douglas G. Watson	Director	March 29, 2010



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Exhibit Number	Description of Document	Sequentially Numbered Pages
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3.1.b	Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i) to the Company's Current Report on Form 8-K filed on February 28, 1997, Commission File No. 0-19635)	
3.1.c	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
3.1.d	Amended Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
3.1.e	Certificate of Increase of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).5 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
3.1.f	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)	
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3.1.h	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).8 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
3.1.i	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.i to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)	
3.1.j	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.j to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)	
3.1.k	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.k to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, Commission File No. 0-19635)	
3.1.l	Certificate of Designation of Series G Participating Cumulative Preferred Stock of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on September 21, 2005,	



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Exhibit Number	Description of Document	Sequentially Numbered Pages
3.1.m	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, Commission File No. 0-19635)	
3.1.n	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on July 13, 2007, Commission File No. 0-19635)	
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, Commission File No. 0-19635)	
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)	
4.2	Rights Agreement, dated September 20, 2005, between the Company and Mellon Investor Services LLC, as Rights Agent (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on September 21, 2005, Commission File No. 0-19635)	
4.3	Form of Senior Unsecured Convertible Note ( B Note ) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).	
4.4	Form of Senior Unsecured Convertible Note ( C Note ) (incorporated by reference to Exhibit 4.2 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).	
4.5	Form of Senior Secured Convertible Note ( D Note ) (incorporated by reference to Exhibit 4.3 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).	
4.6	Form of Senior Unsecured Convertible Note ( E Note ) (incorporated by reference to Exhibit 4.4 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).	
4.7	Form of Senior Unsecured Convertible Note ( F Note ) (incorporated by reference to Exhibit 4.5 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).	
4.8	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.6 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).	
4.9	Form of Senior Unsecured Convertible Promissory Note Purchase Warrant (incorporated by reference to Exhibit 4.7 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).	
10.1	Form of Indemnification Agreement entered into between the Company and its directors and officers (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1, Commission File No. 0-19635)	
10.2	Agreement of Lease dated June 28, 2000 by and between The Connell Company and the Company (incorporated by reference to Exhibit 10.76 to the	

Company's Annual Report on Form 10-K for the year ended December 31,  
2001, Commission File No. 0-19635)

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Exhibit Number	Description of Document	Sequentially Numbered Pages
10.2A	Amendment of Lease, dated June 19, 2002 by and between The Connell Company and the Company (incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.2B	Amendment of Lease, dated September 23, 2009 by and between The Connell Company and the Company (filed herewith)	
10.3*	Manufacture and Supply Agreement, dated December 20, 2002, between Genta Incorporated and Avecia Biotechnology Inc. (incorporated by reference to Exhibit 10.88 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, Commission File No. 0-19635)	
10.3A*	Manufacture and Supply Agreement, dated May 1, 2008, between Genta Incorporated and Avecia Biotechnology Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, Commission File No. 0-19635)	
10.4*	License Agreement dated August 1, 1991, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)	
10.4A*	Amendment to License Agreement, dated December 19, 2000, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)	
10.4AA*	Second Amendment to License Agreement, dated October 22, 2003, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)	
10.5	Settlement Agreement and Release, dated October 22, 2003, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.4 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)	
10.6*	Development and License Agreement, dated March 22, 2006 by and between the Company and Emisphere Technologies, Inc. (incorporated by reference to Exhibit 10.5 to the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, Commission File No. 0-19635)	
10.7	Employment Agreement, dated as of March 28, 2006, between the Company and Loretta M. Itri, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, Commission File No. 0-19635)	
10.8*	Supply and Distribution Agreement between the Company and IDIS Limited, dated March 6, 2007 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed on May 8, 2007, Commission File No. 0-19635)	
10.9*	Project Contract with ICON Clinical Research, L.P., dated November 19, 2007 (incorporated by reference to Exhibit 10.37 to the Company's Annual Report	

on Form 10-K for the year ended December 31, 2007, Commission File No.  
0-19635)

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Exhibit Number	Description of Document	Sequentially Numbered Pages
10.10	Amended and Restated Employment Agreement, dated as of November 30, 2007, between the Company and Raymond P. Warrell, Jr. M.D. (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K for the year ended December 31, 2007, Commission File No. 0-19635)	
10.11*	License Agreement, dated March 7, 2008, between the Company and Daiichi Sankyo (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, Commission File No. 0-19635)	
10.12	Securities Purchase Agreement, dated June 5, 2008, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on June 10, 2008, Commission File No. 0-19635)	
10.13	General Security Agreement, dated June 9, 2008, by and among the Company, certain additional grantors as set forth therein and Tang Capital Partners, L.P. as agent (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on June 10, 2008, Commission File No. 0-19635)	
10.14	2009 Stock Incentive Plan, effective (incorporated by reference to Exhibit 10.11 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, Commission File No. 0-19635)	
10.15	Form of Restricted Stock Unit Issuance Agreement (incorporated by reference to Exhibit 10.12 to the Company's Quarterly Report on Form 10-Q, filed on November 16, 2009, Commission File No. 0-19635)	
10.16*	Form of Securities Purchase Agreement, dated April 2, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on April 6, 2009, Commission File No. 0-19635)	
10.17	Form of Amended and Restated General Security Agreement, dated April 2, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on April 6, 2009, Commission File No. 0-19635)	
10.18*	Form of Consent Agreement, dated April 2, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed on April 6, 2009, Commission File No. 0-19635)	
10.19	Form of Securities Purchase Agreement, dated July 7, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on July 8, 2009, Commission File No. 0-19635)	
10.20	Form of Registration Rights Agreement, dated July 7, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on July 8, 2009, Commission File No. 0-19635)	
10.21	Form of Consent Agreement, dated July 7, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to	

Exhibit 10.3 to the Company's Current Report on Form 8-K, filed on July 8, 2009, Commission File No. 0-19635)



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Exhibit Number	Description of Document	Sequentially Numbered Pages
10.22	Form of Amendment Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on August 12, 2009, Commission File No. 0-19365)	
10.23	Form of Amendment Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on September 9, 2009, Commission File No. 0-19365)	
10.24	Form of Consent and Amendment Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on September 9, 2009, Commission File No. 0-19365)	
10.25	Form of Securities Purchase Agreement, dated September 4, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed on September 9, 2009, Commission File No. 0-19635)	
10.26	Form of Registration Rights Agreement, dated September 4, 2009, by and among the Company and certain accredited investors set forth therein (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed on September 9, 2009, Commission File No. 0-19635)	
10.27	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).	
10.28	Form of Note Conversion and Amendment Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).	
10.29	Form of Security Agreement (incorporated by reference to Exhibit 10.3 to the Company's Current Report on form 8-K filed on March 9, 2010, Commission File No. 0-19635).	
16.1	Letter from Deloitte & Touche LLP, dated July 16, 2008, regarding change in certifying accountant (incorporated by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K, filed on July 22, 2008, Commission File No. 0-19365)	
21	Subsidiaries of the Registrant	
23.1	Consent of Amper Politziner & Mattia, LLP	
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)	

\* The Company has been granted confidential treatment of certain portions of this exhibit.

