GENTA INC DE/
Form 10-K
February 13, 2009

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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, 2008

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

Commission File Number 000-19635
GENTA INCORPORATED
(Exact name of registrant as specified in its charter)

Delaware	**33-0326866**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
200 Connell Drive	
Berkeley Heights, New Jersey	**07922**
(Address of principal executive offices)	**(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	**Over-the-Counter Bulletin Board**
Series G Participating Cumulative 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 o No x

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 o No x

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

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. o

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

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 $13,969,012 as of June 30, 2008 (the last business day of the registrant s most recently completed second fiscal quarter).

As of February 4, 2009, the registrant had 946,497,242 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. We intend that all forward-looking statements be subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect our views as of the date they are made with respect to future events and financial performance, but are subject to many risks and uncertainties, which could cause actual results to differ materially from any future results expressed or implied by such forward-looking statements. Forward-looking statements include, without limitation, statements about:

- the adequacy of our capital resources and cash flow projections, our ability to obtain sufficient financing to maintain our planned operations, or our risk of bankruptcy;
- our current and future license agreements, collaboration agreements, and other strategic alliances, if any;
- our ability to obtain necessary regulatory approval for Genasense® from the U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMEA);
- the safety and efficacy of our products;
- the commencement and completion of clinical trials;
- our assessment of our clinical trials;
- our ability to develop, manufacture and sell our products or product candidates;
- the adequacy of our patents and proprietary rights;
- the impact of litigation that has been brought against us and our 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 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 the investigational compounds tesetaxel and G4544).

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.

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).

Genasense® has been submitted for regulatory approval in the U.S. on two occasions and to the European Union (EU) once. These applications proposed the use of Genasense® plus chemotherapy for patients with advanced melanoma (U.S. and EU) and relapsed or refractory chronic lymphocytic leukemia (CLL) (U.S.-only). None of these applications was approved. At present, an appeal of a denial of a New Drug Application (NDA) for CLL is pending before the FDA. Nonetheless, we believe that Genasense® can ultimately be approved and commercialized for both of these indications, as well as for other diseases, and we have undertaken a number of initiatives in this regard that are described below. We are finalizing accrual of patients to a second randomized Phase 3 study in patients with advanced melanoma, known as AGENDA, which should complete in 2009.

The initial NDA for Genasense® in melanoma was withdrawn in 2004 after an advisory committee to FDA failed to recommend approval. A negative decision was also received for a similar application in melanoma from the European Medicines Agency (EMEA) in 2007. Data from the Phase 3 trial that comprised the primary basis for these applications were published in a peer-reviewed journal in 2006. These results showed that treatment with Genasense® plus dacarbazine compared with dacarbazine alone in patients with advanced melanoma was associated with a statistically significant increase in overall response, complete response, durable response, and progression-free survival (PFS). However, the primary endpoint of overall survival approached but did not quite reach statistical significance (P=0.077). Subsequently, our analysis of this trial showed that there was a significant treatment interaction effect related to levels of a blood enzyme known as LDH. When this effect was analyzed by treatment arm, survival was shown to be significantly superior for patients with a non-elevated LDH who received Genasense®

(P=0.018; n=508). Moreover, this benefit was particularly noteworthy for patients whose baseline LDH did not exceed 80% of the upper limit of normal for this lab value. LDH had also been previously described by others as the single most important prognostic factor in advanced melanoma.

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

AGENDA is designed to expand evidence for the safety and efficacy of Genasense® when combined with dacarbazine for patients who have not previously been treated with chemotherapy. The study prospectively targets patients who have low-normal levels of LDH. We expect to enroll approximately 300 subjects at approximately 80 sites worldwide in this trial. Genasense® in melanoma has been designated an Orphan Drug in Australia and the United States, and the drug has Fast Track designation in the United States. Data on the final assessment of PFS and an interim assessment of overall survival are expected in 2009. If these data are positive, we expect to discuss these results with the FDA and EMEA and to secure agreement from these agencies that Genta may commence submission of new regulatory applications for the approval of Genasense® plus chemotherapy in patients with advanced melanoma. Approval by FDA and EMEA will allow Genasense® to be commercialized by us in the U.S. and in the European Union.

Given our belief in the activity of Genasense® in melanoma, we have initiated additional clinical studies in this disease. One such study is a Phase 2 trial of Genasense® plus a chemotherapy regimen consisting of Abraxane® (paclitaxel albumen) plus temozolomide (Temodar®). We also expect to examine different dosing regimens that will improve the dosing convenience and commercial acceptance of Genasense®, including its administration by brief IV infusions over 1 to 2 hours.

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

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

We submitted our NDA to the FDA in December 2005 in which we sought accelerated approval for the use of Genasense® in combination with Flu/Cy for the treatment of patients with relapsed or refractory CLL who had previously received fludarabine. In December 2006, we received a non-approvable notice for that application from FDA. However, we believed that our application met the regulatory requirements for approval, in April 2007, we filed an appeal of the non-approvable notice using FDA s Formal Dispute Resolution process. In March 2008, we received a formal notice from FDA s Center for Drug Evaluation and Research (CDER) that indicated additional confirmatory evidence would be required to support approval of Genasense® in CLL. In that communication, FDA recommended two alternatives for exploring that confirmatory evidence. One option was to conduct an additional clinical trial. The other option was to collect additional information regarding the clinical course and progression of disease in patients from the completed trial. We have elected to pursue both of these options.

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For the first option, we submitted a new protocol in the second quarter of 2008 that sought Special Protocol Assessment (SPA) from the FDA and Scientific Advice from the EMEA. This protocol is similar in design to the completed trial and uses the same chemotherapy and randomization scheme. The major difference is that the trial focuses on the patient population who derived maximal benefit in the completed trial. This group is characterized by patients who had received less extensive chemotherapy prior to entering the trial and who were defined as being non-refractory to fludarabine. We have deferred initiation of this trial until we receive a response to the second option, described below.

For the second option, we sought information regarding long-term survival on patients who had been accrued to our already completed Phase 3 trial. At a scientific meeting in June 2008, we announced the results of long-term follow-up from the completed Phase 3 trial that comprised the original NDA. With 5 years of follow-up, we showed that patients treated with Genasense® plus chemotherapy who achieved either a complete response (CR) or a partial response (PR) had also achieved a statistically significant increase in survival.

Previous analyses had shown a significant survival benefit accrued to patients in the Genasense® group who attained CR. Extended follow-up showed that all major responses (CR+PR) achieved with Genasense® were associated with significantly increased survival compared with all major responses achieved 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.

We believe that the significant survival benefit associated with major responses to Genasense® may provide the confirmatory evidence of clinical benefit that was requested by FDA. We submitted these new data to FDA in the second quarter of 2008, and the submission was accepted by the FDA as a complete response to the non-approvable decision letter. In December 2008, we received a complete response letter from the Office of Oncology Drug Products (OODP) at the FDA, indicating that the Division cannot approve the NDA in its present form and suggested the need for an additional clinical study. We have appealed this decision to CDER and expect a decision on this appeal in the first half of 2009.

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

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

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On March 7, 2008, we obtained an exclusive worldwide license for tesetaxel, 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 and other regulatory agencies 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 on June 23, 2008. We received notice from FDA that tesetaxel has been granted designation as an Orphan Drug for treatment of patients with advanced melanoma in December 2008, and for treatment of patients with advanced gastric cancer in January 2009. Orphan drug status provides for a period of marketing exclusivity, certain tax benefits, and an exemption from certain fees upon submission of a NDA. In January 2009, we announced that we had initiated a new clinical trial with tesetaxel that will examine the clinical pharmacology of the drug over a narrow dosing range around the established Phase 2 dose.

The tesetaxel program seeks to secure a first-to-market advantage for tesetaxel relative to other oral taxanes. We believe success in this competitive endeavor will maximize return to stockholders. Accordingly, we have identified three oncology indications in which we believe tesetaxel may have sufficient efficacy and safety to warrant regulatory approval. We believe it may be possible to secure regulatory approval in these indications on the basis of endpoints that can be achieved in clinical trials that may be relatively limited in scope. We submitted a proposed trial design to FDA for Special Protocol Assessment in gastric cancer in February 2009.

In addition to these three smaller indications, we are interested in examining the activity of tesetaxel in patients with hormone-refractory prostate cancer (HRPC) and in breast cancer. Docetaxel (Taxotere®) is the only taxane approved for first-line use in patients with HRPC. Although docetaxel has been shown to extend survival in men with HRPC, its use is associated with a high incidence of moderate-to severe toxicity. If tesetaxel is shown to be active in HRPC, we believe its safety profile may be substantially superior to docetaxel and may supplant that drug for first-line use in this indication. However, the development of drugs in this indication is very costly. Additional funding will be required to support the extended clinical testing that will be required to secure regulatory approval in HRPC. As previously noted, the Phase 2a study previously conducted in patients with advanced breast cancer was positive and yielded an overall response rate of 38%.

Our third pipeline product is G4544, which is a novel oral formulation of a gallium-containing compound that we developed in collaboration with Emisphere Technologies, Inc. We completed a single-dose Phase 1 study of an initial formulation of this new drug known as G4544(a) and the results were presented at a scientific meeting in the second quarter of 2008. We are planning another study using a modified formulation, known as G4544(b) . The FDA has indicated that a limited, animal toxicology study in a single species will be required prior to initiation of multi-dose studies of G4544(b). Progress in the clinical development of G4544 program was delayed in 2008 due to financial constraints, but we currently expect to continue our program when our financial condition improves.

We currently intend to pursue a 505(b)(2) strategy to establish bioequivalence to our marketed product, Ganite®, for the initial regulatory approval of G4544. However, we believe this drug may also be 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.

Lastly, we have announced our intention to seek a buyer for Ganite®, our sole marketed product. Our financial constraints have prevented us from investing in adequate commercial support for Ganite®, and the intellectual property that provided us with an exclusive position in the United States has now expired.

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We maintain an active Business Development program. We are seeking development and commercialization partners for our existing products and are seeking to acquire additional drugs that will enhance the value of our pipeline to our shareholders.

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 a variety of human cancer types; 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 (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.

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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.

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.

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Clinical Studies

Genasense® has been in clinical trials since 1995. We currently have efficacy and safety data on over 2,000 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, non-Hodgkin s lymphoma (NHL), multiple myeloma and cancers of the prostate, colon, lung, breast and other tumor types. Since 2001, Genta and its collaborators have jointly initiated approximately twenty clinical trials. 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. The results of most of these trials have been publicly presented at scientific meetings and/or published in peer-reviewed scientific journals.

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

In August 2007, we announced that the first patients had been enrolled in a confirmatory Phase 3 trial of Genasense® plus chemotherapy in advanced melanoma. The trial, known as AGENDA, is a randomized, double-blind, placebo-controlled study in which patients are randomly assigned to receive Genasense® plus dacarbazine (DTIC) or DTIC alone. The study targets patients using LDH as a biomarker to identify patients who may be most likely to respond, based on data obtained from our preceding trial in melanoma. We expect that AGENDA will accrue approximately 300 patients, a target that should be achieved in the first quarter of 2009. In the fourth quarter of 2007, we reported initial results from a non-randomized trial using Genasense® combined with temozolomide (Temodar®) plus Abraxane® (albumen bound paclitaxel).

While our appeal in CLL has been pending with FDA, we have deferred making a decision on the conduct of future trials in this indication. Finally, although several non-randomized trials have shown activity of Genasense® in patients with advanced non-Hodgkin s lymphoma, we have not initiated any registration-quality trials in this indication due to funding constraints.

In the first quarter of 2007, we completed a trial using a concentrated solution of Genasense® administered by bolus subcutaneous (SC) injection. This trial showed that a total dose of 225 mg could be administered as a single SC injection, which is approximately equivalent to the daily dose used in the Phase 3 trial of Genasense® in CLL. The limiting reaction in this study was a localized and reversible skin rash. In 2007, we began a new Phase 1 trial of Genasense® administered as an IV infusion over 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.

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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 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.)

In May 2004, we eliminated our sales force and significantly reduced our marketing support for Ganite®. Since then, we have continued only minimal marketing support of the product. On March 2, 2006, we announced publication of a randomized, double blind, Phase 2 trial that showed Ganite® was highly effective when compared with Aredia® (pamidronate disodium; Novartis, Inc.) in hospitalized patients with cancer-related hypercalcemia.

Ganite® as a Treatment for Non-Hodgkin s Lymphoma and Other Cancer Types

Based on previously published data, Ganite® showed clear anticancer activity in patients with certain types of cancer, particularly NHL. Due to patent expirations previously described, we do not plan further clinical trials for Ganite® as an anticancer drug.

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 (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 the Company s 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. Progress in the clinical development of G4544 program was delayed in 2008 due to financial constraints, but we currently expect to continue our program when our financial condition improves.

Antisense and RNAi Research and Discovery

We have had several other oligonucleotide-based discovery programs and collaborations devoted to the identification of both antisense- and RNAi-based inhibitors of oncology gene targets. However, spending on these research

programs was sharply reduced due to financial constraints. We have no current agents that we consider lead compounds that would justify advancement into late-stage preclinical testing.

We intend to continue to evaluate novel nucleic acid chemistries, through sponsored research and collaborative agreements, depending upon the availability of resources.

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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 ten U.S. patents relating to the composition of Genasense® and its backbone chemistry that expire between 2008 and 2015. The U.S. composition patents for Genasense may be eligible for extension under Waxman-Hatch provisions. Corresponding patent applications have been filed in three foreign countries. We also own five U.S. patent applications relating to methods of using Genasense® expected to expire in 2020 and 2026, with approximately 50 corresponding foreign patent applications and granted patents.

Included among Genta s intellectual property rights are certain rights licensed from the NIH covering phosphorothioate oligonucleotides. We also acquired from the University of Pennsylvania exclusive rights 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 employing them. Other related U.S. and corresponding foreign patent applications are still pending.

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 product. 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 above, 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 to 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.

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 $20.0 million, $13.5 million and $28.1 million during the years ended December 31, 2008, 2007 and 2006, respectively.

Sales and Marketing

Currently we do not have a sales force. Personnel who had been hired into our sales teams were terminated following workforce reductions that took place in 2004 and 2006, owing to adverse regulatory decisions. W. Lloyd Sanders, who is presently Senior Vice President and Chief Operating Officer, was hired in January 2006 to run our sales and marketing programs.

At the present time, we do not contemplate rebuilding a sales and marketing infrastructure in the United States absent favorable regulatory actions on Genasense®. For international product sales, we may distribute our products through collaborations with third parties.

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®.

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.

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, 2008, we had 25 employees, 8 of whom hold doctoral degrees. As of that date, there were 15 employees engaged in research, development and other technical activities and 10 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.

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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.

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.

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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 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.

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Risks Related to Our Business

Our business will suffer if we fail to obtain timely funding.

Our operations to date have required significant cash expenditures. Our future capital requirements will depend on the results of our research and development activities, preclinical studies and clinical trials, competitive and technological advances, and regulatory activities of the FDA and other regulatory authorities. In order to commercialize our products, seek new product candidates and continue our research and development programs, we will need to raise additional funds.

On June 5, 2008, we entered into definitive agreements with institutional and accredited investors to place senior secured convertible notes due 2010 totaling in aggregate up to $40 million in gross proceeds before fees and expenses. The closing of the first $20 million of notes took place on June 9, 2008.

The notes bear interest at an annual rate of 15% payable at quarterly intervals in stock or cash at our option, and are convertible into shares of Genta common stock at a conversion rate of 100,000 shares of common stock for every $1,000 of principal. Holders of the notes have the right, but not the obligation, for the following 12 months following the initial closing date to purchase in whole or in part up to an additional $20 million of the notes. We have the right to force conversion of the notes in whole or in part if the closing bid price of our common stock exceeds $0.50 for a period of 20 consecutive trading days. Certain members of our senior management participated in this offering. The notes are secured by a first lien on all assets of Genta.

We will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing. We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. Future collaborations or similar arrangements may require us to license valuable intellectual property to, or to share substantial economic benefits with, our collaborators. If we raise additional capital by issuing additional equity or securities convertible into equity, our stockholders may experience dilution and our share price may decline. Any debt financing may result in restrictions on our spending.

If we are unable to raise additional funds, we will need to do one or more of the following:

- delay, scale back or eliminate some or all of our research and product development programs;
- license third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;
- attempt to sell our company;
- cease operations; or
- declare bankruptcy.

Presently, with no further financing, we will run out of funds in the first quarter of 2009. We currently do not have any additional financing in place. If we are unable to raise additional financing, we could be required to reduce our spending plans, reduce our workforce, license to others products or technologies we would otherwise seek to commercialize ourselves and sell certain assets. There can be no assurance that we can obtain financing, if at all, on terms acceptable to us.

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

The commercialization of our pharmaceutical products involves a number of significant challenges. In particular, our ability to commercialize products, such as Ganite® and Genasense®, depends, in large part, on the success of our clinical development programs, our efforts to obtain regulatory approvals and our sales and marketing efforts directed at physicians, patients and third-party payors. A number of factors could affect these efforts, including:

our ability to demonstrate clinically that our products are useful and safe in particular indications;

delays or refusals by regulatory authorities in granting marketing approvals;

our limited financial resources and sales and marketing experience relative to our competitors;

actual and perceived differences between our products and those of our competitors;

the availability and level of reimbursement for our products by third-party payors;

incidents of adverse reactions to our products;

side effects or misuse of our products and the unfavorable publicity that could result; and

the occurrence of manufacturing, supply or distribution disruptions.

We cannot assure you that Genasense® will receive FDA or EMEA approval. For example, the NDA for Genasense® in melanoma was withdrawn in 2004 after an advisory committee to the FDA failed to recommend approval. A negative decision was also received for a similar application in melanoma from the EMEA in 2007. Our initial NDA for the use of Genasense® plus chemotherapy in patients with relapsed or refractory CLL was also unsuccessful. At present, an appeal of our NDA for CLL is pending before FDA and we expect to receive a response in the first half of 2009. We are also currently accruing patients to our randomized AGENDA Phase 3 study in patients with advanced melanoma that should complete in 2009.

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.

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

Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and as a result, our independent registered public accounting firm included an

explanatory paragraph in its report on our consolidated financial statement for the year ended December 31, 2008 with respect to this uncertainty. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of the common shares of our stock and we may have a more difficult time obtaining financing.

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

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

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

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

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

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

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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, 2008, we have incurred a cumulative net deficit of $944.1 million. We may never achieve revenue sufficient for us to attain profitability. Achieving profitability is unlikely unless Genasense® receives approval from the FDA or EMEA for commercial sale in one or more indications.

Our business depends heavily on a small number of products.

We currently market and sell one product, Ganite® and the principal patent covering its use for the approved indication expired in April 2005. If Genasense® is not approved, if approval is significantly delayed, or if in the event of approval the product is commercially unsuccessful, we do not expect significant sales of other products to offset this loss of potential revenue.

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

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

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

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

preserve trade secrets; and

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

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

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

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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 have licensed ten U.S. patents relating to Genasense® and its backbone chemistry that expire between 2008 and 2015. The U.S. composition patents for Genasense® may be eligible for extension under Waxman-Hatch provisions. Corresponding patent applications have been filed in three foreign countries. We also own five U.S. patent applications relating to methods of using Genasense® expected to expire in 2020 and 2026, with approximately 50 corresponding foreign patent applications and granted patents.

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

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

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We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results or if our clinical trials do not demonstrate safety and efficacy in humans.

Our success will depend on the success of our currently ongoing clinical trials and subsequent clinical trials that have not yet begun. It may take several years to complete the clinical trials of a product, and a failure of one or more of our clinical trials can occur at any stage of testing. We believe that the development of each of our product candidates involves significant risks at each stage of testing. If clinical trial difficulties and failures arise, our product candidates may never be approved for sale or become commercially viable. We do not believe that any of our product candidates have alternative uses if our current development activities are unsuccessful.

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

- we may discover that a product candidate does not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude regulatory approval or limit commercial use if approved;
- the results from early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;
- institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;
- subjects may drop out of our clinical trials;
- our preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials; and
- the cost of our clinical trials may be greater than we currently anticipate.

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

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

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

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

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

inability to adequately monitor patient progress after treatment;

unforeseen safety issues;

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

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government or regulatory delays.

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

The FDA imposes substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve lengthy and detailed preclinical and clinical testing and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more depending upon the type, complexity and novelty of the product. We cannot apply for FDA approval to market any of our products under development until preclinical and clinical trials on the product are successfully completed. Several factors could prevent successful completion or cause significant delays of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that the product is safe and effective for use in humans. If safety concerns develop, the FDA could stop our trials before completion. We may not market or sell any product for which we have not obtained regulatory approval. We cannot assure you that the FDA will ever approve the use of our products that are under development. If the patient populations for which our products are approved are not sufficiently broad, or if approval is accompanied by unanticipated labeling restrictions, the commercial success of our products could be limited and our business, results of operations and financial condition could consequently be materially adversely affected.

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

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

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

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

Any of these factors could cause us to delay or suspend clinical trials, regulatory submissions, required approvals or commercialization of our products or product candidates, entail higher costs and result in our being unable to effectively commercialize our products. Furthermore, if our third-party manufacturers fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable

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

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

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

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

The raw materials that we require to manufacture our drugs, particularly oligonucleotides, 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.

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

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

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

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

difficulties in assimilating the operations and personnel of acquired companies;

diversion of our management s attention from ongoing business concerns;

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

additional expense associated with amortization of acquired assets;

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

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

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

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

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

compete directly with any products that may be offered by us.

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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 September 2008, several shareholders of our Company, on behalf of themselves and all others similarly situated, filed a class action complaint against our Company, our Board of Directors, and certain of our executive officers in Superior Court of New Jersey, captioned Collins v. Warrell, Docket No. L-3046-08. The complaint alleges that in issuing convertible notes, our Board of Directors, and certain officers breached their fiduciary duties, and the Company aided and abetted the breach of fiduciary duty. Defendants filed a motion to dismiss on December 29, 2008. Plaintiffs opposition is due on or before February 13, 2009, and Defendants reply is due March 16, 2009. It is possible that oral argument on the motion will be held on March 20, 2009. Discovery has begun. Our Company, Board of Directors and Officers deny these allegations and intend to vigorously defend this lawsuit.

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 and of the complaint intend to vigorously defend this lawsuit.

Risks Related to Our Common Stock

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

Provisions in our restated certificate of incorporation and bylaws may discourage third parties from seeking to obtain control of us and, therefore, could prevent our stockholders from receiving a premium for their shares. Our restated

certificate of incorporation gives our Board of Directors the power to issue shares of preferred stock without approval of the holders of common stock. Any preferred stock that is issued in the future could have voting rights, including voting rights that could be superior to that of our common stock. The affirmative vote of 662/3% 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.

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

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

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

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

Our stock price is volatile.

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

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

At December 31, 2008, we had 486.7 million shares of common stock outstanding, 43.4 million shares reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants, 1.7 billion shares reserved for interest payments and conversion of outstanding convertible notes and 2.5 billion shares reserved for interest payments and conversion of our yet-to-be issued second tranche of convertible notes. 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.

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

On June 5, 2008, we entered into a securities purchase agreement with certain institutional and accredited investors, to place up to $40 million of senior secured convertible notes, referred to herein as the notes, with such investors. On June 9, 2008, we placed $20 million of such notes in the initial closing. The notes bear interest at an annual rate of 15% per annum payable at quarterly intervals in stock or cash at the Company s option, and will be convertible into shares of the Company s common stock at a conversion rate of 100,000 shares of common stock for every $1,000 of principal; provided, however, at no time may the holder of a note convert such note if such conversion would cause the holder to beneficially own more than 4.999% of the then outstanding shares of common stock of the Company. Until June 9, 2009, the holders of the notes have the right, but not the obligation, to purchase in whole or in part up to an additional $20 million of notes. We have the right to force conversion of the notes in whole or in part if the closing bid price of our common stock exceeds $0.50 for a period of 20 consecutive trading days. Certain members of our senior management participated in the initial closing. Pursuant to the general security agreement, the notes are secured by a first lien on all of our assets, subject to certain exceptions set forth in such security agreement.

Through February 4, 2009, we have issued 905.6 million shares of our common stock upon the voluntary conversion of convertible notes and have issued 4.0 million shares of our common stock in lieu of cash for interest payments on the convertible notes.

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

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

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

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

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

Item 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 2010.

Item 3. ***Legal Proceedings***

In 2004, numerous complaints were filed in the United States District Court for the District of New Jersey, or the Court, against Genta and certain of our principal officers on behalf of purported classes of our shareholders who purchased our securities during several class periods. We reached an agreement with plaintiffs to settle the class action litigation in consideration for the issuance of 2.0 million shares of our common stock (adjusted for any subsequent event that results in a change in the number of shares outstanding as of January 31, 2007) and $18.0 million in cash for the benefit of plaintiffs and the shareholder class. The cash portion of the proposed settlement will be covered by our insurance carriers. A Court order approving the settlement was issued on May 27, 2008 and the settlement became final on June 27, 2008. The settlement has not been distributed to the plaintiffs and the shareholder class as of December 31, 2008. The settlement did not constitute an admission of guilt or liability.

In February 2007, a complaint against us was filed in the Superior Court of New Jersey by Howard H. Fingert, M.D., a former employee of Genta. The complaint alleges, among other things, breach of contract as to our stock option plan and as to a consulting agreement allegedly entered into by us and Dr. Fingert subsequent to termination of Dr. Fingert s employment with us, breach of implied covenant of good faith and fair dealing with respect to our stock option plan and the alleged consulting agreement, promissory estoppel with respect to the exercise of stock options and provision of consulting services after termination of employment, and fraud and negligent misrepresentation with respect to exercise of stock options and provision of consulting services after termination of employment. The complaint sought monetary damages, including punitive and consequential damages. We and Dr. Fingert settled this complaint in January 2009. The settlement did not constitute an admission of guilt or liability.

In November 2007, a complaint against us was filed in the United States District Court for the District of New Jersey by Ridge Clearing & Outsourcing Solutions, Inc. The complaint alleges, among other things, that we caused or contributed to losses suffered by one of our stockholders, which have been incurred by Ridge. We and Ridge settled

this complaint in September 2008. The settlement did not constitute an admission of guilt or liability.

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In September 2008, several shareholders of our Company, on behalf of themselves and all others similarly situated, filed a class action complaint against our Company, our Board of Directors, and certain of our executive officers in Superior Court of New Jersey, captioned Collins v. Warrell, Docket No. L-3046-08. The complaint alleges that in issuing convertible notes, our Board of Directors, and certain officers breached their fiduciary duties, and the Company aided and abetted the breach of fiduciary duty. Defendants filed a motion to dismiss on December 29, 2008. Plaintiffs opposition is due on or before February 13, 2009, and Defendants reply is due March 16, 2009. It is possible that oral argument on the motion will be held on March 20, 2009. Discovery has begun. Our Company, Board of Directors and Officers deny these allegations and intend to vigorously defend this lawsuit.

In November 2008, a complaint against our Company 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 our Company and our transfer agent caused or contributed to losses suffered by the stockholder. Our Company denies the allegations of the complaint and we intend to vigorously defend this lawsuit.

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

(a) We held our Annual Meeting of Stockholders, herein referred to as the Annual Meeting, on October 6, 2008. There were present at the Annual Meeting in person or by proxy, stockholders holding an aggregate of 25,446,310 out of a total number of 36,760,558 shares of common stock issued and outstanding and entitled to vote at the meeting.

(b) Proxies for the meeting were solicited pursuant to Regulation 14A of the Exchange Act. There was no solicitation in opposition to the Board of Directors nominees for directors listed in our definitive proxy statement dated as of August 28, 2008. All of the nominees for the Board of Directors were elected.

(c) At the Annual Meeting, stockholders voted to approve all resolutions that were proposed in the proxy statement. Briefly described below is each resolution voted upon at the Annual Meeting and the corresponding results.

(i) Election of five directors. The result of the voting was as follows:

Directors	Votes For	Withheld
Raymond P. Warrell, Jr., M.D.	23,768,345	1,677,965
Martin J. Driscoll	23,814,486	1,631,824
Christopher P. Parios	23,819,431	1,626,879
Daniel D. Von Hoff, M.D.	23,800,102	1,646,208
Douglas G. Watson	23,826,234	1,620,076

(ii) Approval of an amendment to our 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. The result of the voting was as follows:

For: 20,900,129 votes

Against:	4,341,140 votes
Abstain:	205,041 votes

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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.

	High*	Low*
2007		
First Quarter	$ 3.36	$ 1.86
Second Quarter	$ 2.46	$ 1.68
Third Quarter	$ 1.80	$ 0.80
Fourth Quarter	$ 1.31	$ 0.52
2008		
First Quarter	$ 0.87	$ 0.37
Second Quarter (through May 7, 2008)	$ 0.45	$ 0.15

* *all figures prior to July 2007 have been retroactively adjusted for 1-for-6 reverse stock split in July 2007.*

Our common stock began trading on the OTC Bulletin Board under the symbol GNTA.OB on May 7, 2008. 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.

	High	Low
2008		
Second Quarter (from May 7, 2008)	$ 0.41	$ 0.10
Third Quarter	$ 0.75	$ 0.25
Fourth Quarter	$ 0.40	$ 0.0027

Holders

There were 564 holders of record of our common stock as of February 5, 2009. We estimate that there are approximately 31,000 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.

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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, 2008.

Plan category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	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	1,979,730	$ 23.77	153,541
Equity compensation plans not approved by security holders	0		0
Total	1,979,730	$ 23.77	153,541

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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 Shareholder 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, 2003. 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 12/31/03 in stock & index-including reinvestment of dividends.
Fiscal year ending December 31.

	12/03	12/04	12/05	12/06	12/07	12/08
Genta Incorporated	100.00	16.87	14.00	4.24	0.83	.0027
NASDAQ Composite	100.00	110.08	112.88	126.51	138.13	80.47
NASDAQ Biotechnology	100.00	112.17	130.53	130.05	132.24	122.10

Use of proceeds

In February 2008, we sold 6.1 million shares of our common stock at a price of $0.50 per share, raising net proceeds of $2.9 million. In June 2008, we issued $20 million of senior convertible notes, raising net proceeds of $18.7 million. The net proceeds from these sales were used for research and development, the establishment of the AGENDA Phase 3 trial and for general corporate purposes.

Purchases of equity securities by the issuer and affiliated purchasers

None

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Item 6. ***Selected Consolidated Financial Data***

(In thousands, except per share data)	Years Ended December 31, 2008	2007	2006	2005	2004
Consolidated Statements of Operations Data:					
Revenues:					
License fees and royalties	$	$	$	$ 5,241	$ 3,022
Development funding				20,988	12,105
Product sales net	363	580	708	356	(512)
Total revenues	363	580	708	26,585	14,615
Cost of goods sold	102	90	108	52	170
Provision for excess inventory					1,350
Total cost of goods sold	102	90	108	52	1,520
Operating expenses:					
Research and development	19,991	13,491	28,064	20,902	71,494
Selling, general and administrative	10,452	16,865	25,152	16,100	28,576
Settlement of office lease obligation	3,307				
Provision for settlement of litigation	(340)	(4,240)	5,280		
Write-off of prepaid royalty			1,268		
Total operating expenses gross	33,410	26,116	59,764	37,002	100,070
sanofi-aventis reimbursement				(6,090)	(43,292)
Total operating expenses net	33,410	26,116	59,764	30,912	56,778
Gain on forgiveness of debt				1,297	11,495
Amortization of deferred financing costs and debt discount	(11,229)				
Fair value conversion feature liability	(460,000)				
Fair value warrant liability	(2,000)				
Other (expense)/income net	(1,435)	836	1,454	502	(147)
Loss before income taxes	(507,813)	(24,790)	(57,710)	(2,580)	(32,335)
Income tax benefit	1,975	1,470	929	381	904
Net loss	$ (505,838)	$ (23,320)	$ (56,781)	$ (2,199)	$ (31,431)
Net loss per basic and diluted common share	$ (9.10)	$ (0.79)	$ (2.52)	$ (0.13)	$ (2.36)
Shares used in computing net loss per basic and diluted common share	55,576	29,621	22,553	17,147	13,300

	As of December 31,

	2008	2007	2006	2005	2004
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 4,908	$ 7,813	$ 29,496	$ 21,282	$ 42,247
Working capital (deficit)	(5,220)	877	12,682	11,703	(4,269)
Total assets	12,693	29,293	51,778	27,386	50,532
Total stockholders (deficit)/equity	(4,864)	2,931	14,642	15,697	1,752

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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, 2008, we have incurred a cumulative net deficit of $944.1 million. Our recurring losses from operations and our negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. We expect that such losses will continue at least until our lead product, Genasense®, receives approval from the FDA or EMEA for commercial sale in one or more indications. Achievement of profitability is currently dependent on the timing of Genasense® regulatory approvals.

On June 5, 2008, we entered into a securities purchase agreement with certain institutional and accredited investors to place up to $40 million of our senior secured convertible notes with such investors. On June 9, 2008, we placed $20 million of such notes in the initial closing. We had $4.9 million of cash and cash equivalents at December 31, 2008, and presently, with no further financing, we will run out of funds in the first quarter of 2009. We currently do not have any additional financing in place. If we are unable to raise additional financing, we could be required to delay, scale back or eliminate some or all of our research and product development programs; license third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves; attempt to sell our company; cease operations; or declare bankruptcy. There can be no assurance that we can obtain financing, if at all, on terms acceptable to us.

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).

Genasense® has been submitted for regulatory approval in the U.S. on two occasions and to the European Union (EU) once. These applications proposed the use of Genasense® plus chemotherapy for patients with advanced melanoma (U.S. and EU) and relapsed or refractory chronic lymphocytic leukemia (CLL) (U.S.-only). None of these applications was approved. At present, an appeal of a denial of a New Drug Application (NDA) for CLL is pending before the FDA. Nonetheless, we believe that Genasense® can ultimately be approved and commercialized for both of these indications, as well as for other diseases, and we have undertaken a number of initiatives in this regard that are described below. We are finalizing accrual of patients to a second randomized Phase 3 study in patients with advanced melanoma that should complete in 2009.

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The initial NDA for Genasense® in melanoma was withdrawn in 2004 after an advisory committee to the Food and Drug Administration (FDA) failed to recommend approval. A negative decision was also received for a similar application in melanoma from the European Medicines Agency (EMEA) in 2007. Data from the Phase 3 trial that comprised the primary basis for these applications were published in a peer-reviewed journal in 2006. These results showed that treatment with Genasense® plus dacarbazine compared with dacarbazine alone in patients with advanced melanoma was associated with a statistically significant increase in overall response, complete response, durable response, and progression-free survival (PFS). However, the primary endpoint of overall survival approached but did not quite reach statistical significance (P=0.077). Subsequently, our analysis of this trial showed that there was a significant treatment interaction effect related to levels of a blood enzyme known as LDH. When this effect was analyzed by treatment arm, survival was shown to be significantly superior for patients with a non-elevated LDH who received Genasense® (P=0.018; n=508). Moreover, this benefit was particularly noteworthy for patients whose baseline LDH did not exceed 80% of the upper limit of normal for this lab value. LDH had also been previously described by others as the single most important prognostic factor in advanced melanoma.

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

AGENDA is designed to expand evidence for the safety and efficacy of Genasense® when combined with dacarbazine for patients who have not previously been treated with chemotherapy. The study prospectively targets patients who have low-normal levels of LDH. We expect to enroll approximately 300 subjects at approximately 80 sites worldwide in this trial. Genasense® in melanoma has been designated an Orphan Drug in Australia and the United States, and the drug has Fast Track designation in the United States. Data on the final assessment of PFS and an interim assessment of overall survival are expected in 2009. If these data are positive, we expect to discuss these results with the FDA and EMEA and to secure agreement from these agencies that Genta may commence submission of new regulatory applications for the approval of Genasense® plus chemotherapy in patients with advanced melanoma. Approval by FDA and EMEA will allow Genasense® to be commercialized by us in the U.S. and in the European Union.

Given our belief in the activity of Genasense® in melanoma, we have initiated additional clinical studies in this disease. One such study is a Phase 2 trial of Genasense® plus a chemotherapy regimen consisting of Abraxane® (paclitaxel albumen) plus temozolomide (Temodar®). We also expect to examine different dosing regimens that will improve the dosing convenience and commercial acceptance of Genasense®, including its administration by brief IV infusions over 1 to 2 hours.

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

Other 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®.

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We submitted our NDA to the FDA in December 2005 in which we sought accelerated approval for the use of Genasense® in combination with Flu/Cy for the treatment of patients with relapsed or refractory CLL who had previously received fludarabine. In December 2006, we received a non-approvable notice for that application from FDA. However, we believed that our application met the regulatory requirements for approval, in April 2007, we filed an appeal of the non-approvable notice using FDA s Formal Dispute Resolution process. In March 2008, we received a formal notice from FDA s Center for Drug evaluation and Research (CDER) that indicated additional confirmatory evidence would be required to support approval of Genasense® in CLL. In that communication, FDA recommended two alternatives for exploring that confirmatory evidence. One option was to conduct an additional clinical trial. The other option was to collect additional information regarding the clinical course and progression of disease in patients from the completed trial. We have elected to pursue both of these options.

For the first option, we submitted a new protocol in the second quarter of 2008 that sought Special Protocol Assessment (SPA) from the FDA and Scientific Advice from the EMEA. This protocol is similar in design to the completed trial and uses the same chemotherapy and randomization scheme. The major difference is that the trial focuses on the patient population who derived maximal benefit in the completed trial. This group is characterized by patients who had received less extensive chemotherapy prior to entering the trial and who were defined as being non-refractory to fludarabine. We have deferred initiation of this trial until we receive a response to the second option, described below.

For the second option, we sought information regarding long-term survival on patients who had been accrued to our already completed Phase 3 trial. At a scientific meeting in June 2008, we announced the results of long-term follow-up from the completed Phase 3 trial that comprised the original NDA. With 5 years of follow-up, we showed that patients treated with Genasense® plus chemotherapy who achieved either a complete response (CR) or a partial response (PR) had also achieved a statistically significant increase in survival.

Previous analyses had shown a significant survival benefit accrued to patients in the Genasense® group who attained CR. Extended follow-up showed that all major responses (CR+PR) achieved with Genasense® were associated with significantly increased survival compared with all major responses achieved 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.

We believe that the significant survival benefit associated with major responses to Genasense® may provide the confirmatory evidence of clinical benefit that was requested by FDA. We submitted these new data to FDA in the second quarter of 2008, and the submission was accepted by the FDA as a complete response to the non-approvable decision letter. In December 2008, we received a complete response letter from the Office of Oncology Drug Products (OODP) at the FDA, indicating that the Division cannot approve the NDA in its present form and suggested the need for an additional clinical study. We have appealed this decision to CDER and expect a decision on this appeal in the first half of 2009.

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

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

In March 2008, we obtained an exclusive worldwide license for tesetaxel, 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 and other regulatory agencies 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. We received notice from FDA that tesetaxel has been granted designation as an Orphan Drug for treatment of patients with advanced melanoma in December 2008, and for treatment of patients with advanced gastric cancer in January 2009. Orphan drug status provides for a period of marketing exclusivity, certain tax benefits, and an exemption from certain fees upon submission of a New Drug Application. In January 2009, we announced that we had initiated a new clinical trial with tesetaxel that will examine the clinical pharmacology of the drug over a narrow dosing range around the established Phase 2 dose.

The tesetaxel program seeks to secure a first-to-market advantage for tesetaxel relative to other oral taxanes. We believe success in this competitive endeavor will maximize return to stockholders. Accordingly, we have identified three oncology indications in which we believe tesetaxel may have sufficient efficacy and safety to warrant regulatory approval. We believe it may be possible to secure regulatory approval in these indications on the basis of endpoints that can be achieved in clinical trials that may be relatively limited in scope. We submitted a proposed trial design to FDA for Special Protocol Assessment in gastric cancer in February 2009.

In addition to these three smaller indications, we are interested in examining the activity of tesetaxel in patients with hormone-refractory prostate cancer (HRPC) and in breast cancer. Docetaxel (Taxotere®) is the only taxane approved for first-line use in patients with HRPC. Although docetaxel has been shown to extend survival in men with HRPC, its use is associated with a high incidence of moderate-to severe toxicity. If tesetaxel is shown to be active in HRPC, we believe its safety profile may be substantially superior to docetaxel and may supplant that drug for first-line use in this indication. However, the development of drugs in this indication is very costly. Additional funding will be required to support the extended clinical testing that will be required to secure regulatory approval in HRPC. As previously noted, the Phase 2a study previously conducted in patients with advanced breast cancer was positive and yielded an overall response rate of 38%.

Our third pipeline product is G4544, which is a novel oral formulation of a gallium-containing compound that we developed in collaboration with Emisphere Technologies, Inc. We completed a single-dose Phase 1 study of an initial formulation of this new drug known as G4544(a) and the results were presented at a scientific meeting in the second quarter of 2008. We are planning another study using a modified formulation, known as G4544(b) . The FDA has indicated that a limited, animal toxicology study in a single species will be required prior to initiation of multi-dose studies of G4544(b). Progress in the clinical development of G4544 program was delayed in 2008 due to financial constraints, but we currently expect to continue our program when our financial condition improves.

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We currently intend to pursue a 505(b)(2) strategy to establish bioequivalence to our marketed product, Ganite®, for the initial regulatory approval of G4544. However, we believe this drug may also be 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.

Lastly, we have announced our intention to seek a buyer for Ganite®, our sole marketed product. Our financial constraints have prevented us from investing in adequate commercial support for Ganite®, and the intellectual property that provided us with an exclusive position in the United States has now expired.

Results of Operations

Summary Operating Results
For the years ended December 31,

($ thousands)	2008	2007	2006	$ Change 08 vs. 07	$ Change 07 vs. 06
Product sales net	$ 363	$ 580	$ 708	$ (217)	$ (128)
Cost of goods sold	102	90	108	12	(18)
Gross margin	261	490	600	(229)	(110)
Operating expenses:					
Research and development	19,991	13,491	28,064	6,500	(14,573)
Selling, general and administrative	10,452	16,865	25,152	(6,423)	(8,287)
Settlement of office lease obligation	3,307			3,307	
Provision for settlement of litigation	(340)	(4,240)	5,280	3,900	(9,520)
Write-off of prepaid royalty			1,268		(1,268)
Total operating expenses	33,410	26,116	59,764	7,294	(33,648)
Other (expense)/income, net	(1,435)	836	1,454	(2,271)	(618)
Amortization of deferred financing costs and debt discount	(11,229)			(11,229)	
Fair value conversion feature liability	(460,000)			(460,000)	
Fair value warrant liability	(2,000)			(2,000)	
Loss before income taxes	(507,813)	(24,790)	(57,710)	(483,023)	32,920
Income tax benefit	1,975	1,470	929	505	541
Net loss	$ (505,838)	$ (23,320)	$ (56,781)	$ (482,518)	$ 33,461

Product sales net

Product sales net were $0.4 million in 2008 compared with $0.6 million in 2007. Product sales-net in 2008 included $25 thousand of sales of Ganite® and in 2007 included $60 thousand in sales of Genasense® through the named-patient program managed for us by IDIS Limited (a privately owned company based in the United Kingdom), whereby IDIS distributes Ganite® and Genasense® on a named patient basis. Named patient distribution refers to the distribution or sale of a product to a specific healthcare professional for the treatment of an individual patient. Unit sales of Ganite® increased 2.7% in 2008, but reported product sales net in 2008 include the negative impact of returns of Ganite® due to expired dating of product. Product sales-net in 2007 and 2006 included favorable adjustments to a reserve for returns of Ganite® of $0.1 million and $0.3 million, respectively.

Cost of goods sold

Cost of goods sold increased in 2008 compared to the prior year due to higher unit sales of Ganite® and higher unit costs. Lower cost of goods sold in 2007 than in 2006 is primarily the result of lower unit sales of Ganite®.

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Research and development expenses

Research and development expenses were $20.0 million in 2008, compared with $13.5 million in 2007. This increase was primarily due to the recognition of $2.5 million in March 2008 for license payments on tesetaxel, $1.0 million in accrued milestone payments related to tesetaxel, and higher expenses from the AGENDA clinical trial. In addition, during the fourth quarter of 2007, we revised our estimate of certain accrued expenses in the amount of $4.7 million, since such amount was no longer deemed probable. These factors were partially offset by lower compensation expense resulting from our workforce reductions in April 2008 and May 2008.

Research and development expenses incurred on the Genasense® project in 2008 were approximately $15.0 million, representing 75% of research and development expenses, (including the $2.5 million for license payments and $1.0 million in milestone payments related to tesetaxel).

Research and development expenses were $13.5 million in 2007 compared with $28.1 million in 2006. The prior year included higher manufacturing and other expenses incurred in preparation for the possible commercial launch of Genasense® and expenses related to regulatory review. The decline in expenses in 2007 reflects the comparison to this higher level of expenses in 2006, as well as the impact of a staff reduction in December 2006. Also, in 2007, we revised our estimate of certain accrued expenses in the amount of $4.7 million, since such amount was no longer deemed probable. Research and development expenses incurred on the Genasense® project in 2007 were approximately $10.3 million, representing 76% of research and development expenses.

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are subject to wide variability. Results from clinical trials may not be favorable. Data from clinical trials are subject to varying interpretation and may be deemed insufficient by the regulatory bodies that review applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

Selling, general and administrative expenses

Selling, general and administrative expenses were $10.5 million in 2008, compared with $16.9 million in 2007. The decrease is primarily due to our efforts at lowering administrative expenses, lower office rent of $1.1 million and lower compensation expense resulting from our workforce reductions in April 2008 and May 2008.

Selling, general and administrative expenses were $16.9 million in 2007, compared with $25.2 million in 2006. The prior year included a buildup of sales and marketing expenses incurred in preparation for a possible commercial launch of Genasense®. The decline in expenses in 2007 reflects the comparison to this higher level of expenses in 2006, as well as the impact of our December 2006 staff reduction. In addition, depreciation expense declined by $0.8 million and share-based compensation declined by $1.1 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 upon the earlier of July 1, 2009 or our receipt of at least $5.0 million in upfront cash from a business development deal. In January 2009, we entered into another amendment of our agreement with Connell whereby our future payment of $2.0 million is now payable on January 1, 2011. We accrued for the $2.0 million and it is included on our Consolidated Balance Sheets. We will pay 6.0% interest in arrears to Connell from July 1, 2009 through the

new payment date. The initial interest payment of approximately $30 thousand will be payable as of October 1, 2009.

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Provision for settlement of litigation

In 2006, we recorded an expense of $5.3 million that provided for the issuance of 2.0 million shares of our common stock, for a settlement in principle of class action litigation. At December 31, 2007, the revised estimated value of the common shares portion of the litigation settlement was $1.0 million, resulting in a reduction in the liability for the settlement of litigation of $4.2 million. On June 27, 2008, the date that the settlement was finalized, the revised value of the 2.0 million shares was $0.7 million, resulting in a reduction in the liability for the settlement of litigation of $0.3 million. See Note 6 to our Consolidated Financial Statements for a further discussion of this provision.

Write-off of prepaid royalty

In December 2000, we recorded $1.3 million as the fair value for our commitment to issue 27,056 shares of common stock to a major university as consideration for an amendment to a license agreement initially executed on August 1991 related to antisense technology licensed from the university. The amendment provided for a reduction in the royalty percentage rate to be paid to the university based on the volume of sales of our products containing the antisense technology licensed from such university. These shares were issued in 2001. In December 2006, we received a non-approvable notice from the FDA for our NDA for the use of Genasense® plus chemotherapy in patients with CLL. As a result, we accounted for the impairment of these prepaid royalties and recorded a write-off of this asset, (see Note 8 to our Financial Statements).

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

The total of the above referenced accounts resulted in expense, net of $(1.4) million in 2008 and income, net of $0.8 million in 2007. This decline was primarily due to interest incurred on the convertible notes, as well as lower interest income, resulting from lower investment balances. Other income, net of $0.8 million in 2007 declined from $1.5 million in 2006, primarily due to lower interest income, resulting from lower investment balances, along with higher interest expense.

Amortization of deferred financing costs and debt discount

On June 9, 2008, we issued $20 million of our senior secured convertible notes, issued our private placement agent a warrant to purchase 40,000,000 shares of our common stock at an exercise price of $0.02 per share and incurred a financing fee of $1.2 million. The deferred financing costs, including the financing fee and the value of the warrant, are being amortized over the two-year term of the convertible notes, resulting in amortization of $11.2 million in 2008.

Fair value conversion feature liability

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

On June 9, 2008, based upon a Black-Scholes valuation model that included a closing price of our common stock of $0.20 per share, we calculated a fair value of the conversion feature of $380.0 million and expensed $360.0 million, the amount that exceeded the proceeds of the $20.0 million from the initial closing. On October 6, 2008, the date on

which 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 total expense for the year ended December 31, 2008 of $460.0 million.

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Fair value warrant liability

The warrant was also treated as a liability and was initially recorded at a fair value of $7.6 million based upon a Black-Scholes valuation model that included a closing price of our common stock of $0.20 per share. On October 6, 2008, we re-measured the warrant liability and credited it to Stockholders equity, resulting in total expense for the year ended December 31, 2008 of $2.0 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 research and development credits and received approximate payments of $2.0 million in 2008, $1.5 million in 2007 and $0.9 million in 2006 that are recognized as income tax benefit.

If still available under New Jersey law, we will attempt to sell our remaining tax losses in 2009. We can not 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 incurred a net loss of $505.8 million, or $9.10 per share, for 2008, $23.3 million, or $0.79 per share, for 2007 and $56.8 million, or $2.52 per share, for 2006.

The larger net loss in 2008 compared to 2007 is primarily due to the fair value charge of the conversion feature liability of $460.0 million, the amortization of deferred financing costs and debt discount of $11.2 million, the expenses resulting from the reduction in our office space of $3.3 million, the fair value charge of the warrant liability of $2.0 million, the recognition of $2.5 million in March 2008 for license payments on tesetaxel, $1.0 million in accrued milestone payments related to tesetaxel and higher expenses resulting from the AGENDA clinical trial, slightly offset by lower compensation expense resulting from the two reductions in workforce, as well as lower administrative expenses.

The lower net loss in 2007 compared to 2006 is primarily due to a comparison with a prior year that reflected a buildup of sales, marketing and manufacturing expenses incurred in anticipation of a possible commercial launch of Genasense®. In addition, the lower loss in 2007 reflects our staff reduction in December 2006, lower share-based compensation expense, lower depreciation expense and includes a benefit of $4.2 million due to a reduction in the provision for settlement of litigation.

Recent Accounting Pronouncements

In June 2008 the FASB issued EITF 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock* . EITF 07-5 provides guidance in assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity s own stock for purposes of determining whether the appropriate accounting treatment falls under the scope of SFAS 133, *Accounting For Derivative Instruments and Hedging Activities* and/or EITF 00-19, *Accounting For Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock* . EITF 07-05 is effective as of the beginning of our 2009 fiscal year. We do not expect the adoption of EITF 07-05 to have a material impact on our consolidated financial position or results of operations.

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In May 2008, the FASB issued FASB Staff Position (FSP) APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*. FSP APB14-1 will require us to account separately for the liability and equity components of our convertible debt. The debt would be recognized at the present value of its cash flows discounted using our nonconvertible debt borrowing rate at the time of issuance. The equity component would be recognized as the difference between the proceeds from the issuance of the note and the fair value of the liability. The FSP also requires accretion of the resultant debt discount over the expected life of the debt. The FSP is effective for fiscal years beginning after December 15, 2008, and interim periods within those years. Entities are required to apply the FSP retrospectively for all periods presented. We are currently evaluating FSP APB 14-1 and have not yet determined the impact its adoption will have on our consolidated financial statements. However, the impact of this new accounting treatment may be significant and may result in a significant increase to non-cash interest expense beginning in fiscal year 2009 for financial statements covering past and future periods.

In May 2008, the Financial Accounting Standards Board (FASB) issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* . The statement is intended to improve financial reporting by identifying a consistent hierarchy for selecting accounting principles to be used in preparing financial statements that are prepared in conformance with generally accepted accounting principles. The statement is effective 60 days following the Securities and Exchange Commission s (SEC) approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with GAAP* , and is not expected to have any impact on our financial statements.

In March 2008, the FASB issued SFAS 161, *Disclosures about Derivative Instruments and Hedging Activities*, *an amendment of FASB SFAS 133* (SFAS 161), which requires enhanced disclosures for derivative and hedging activities. SFAS 161 will become effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The adoption of this standard did not have a material impact on our financial statements.

In December 2007, the FASB issued SFAS 141(R), *Business Combinations* (SFAS 141(R)), which replaces SFAS 141. SFAS 141(R) establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any controlling interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141(R) is to be applied prospectively to business combinations for which the acquisition date is on or after an entity s fiscal year that begins after December 15, 2008. This standard will have an impact on our financial statements when an acquisition occurs.

In December 2007, the FASB issued SFAS 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51* (SFAS 160). SFAS 160 establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Specifically, this statement requires the recognition of a noncontrolling interest (minority interest) as equity in the consolidated financial statements and separate from the parent s equity. The amount of net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement. SFAS 160 clarifies that changes in a parent s ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, this statement requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. SFAS 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The adoption of this standard did not have a material impact on our financial statements.

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In December 2007, the SEC issued Staff Accounting Bulletin 110 (SAB 110), which permits entities, under certain circumstances, to continue to use the simplified method of estimating the expected term of plain options as discussed in SAB No. 107 and in accordance with SFAS 123R. The guidance in this release was effective January 1, 2008. The implementation of this standard did not have a material effect on our consolidated financial statements.

In December 2007, the FASB issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, which is effective for calendar year companies on January 1, 2009. The Task Force clarified the manner in which costs, revenues and sharing payments made to, or received by, a partner in a collaborative arrangement should be presented in the income statement and set forth certain disclosures that should be required in the partners financial statements. The adoption of this standard did not have a material impact on our financial statements.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, which was effective for calendar year companies on January 1, 2008. The Task Force concluded that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. The implementation of this standard did not have a material effect on our consolidated financial statements.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 permits all entities to choose to elect, at specified election dates, to measure eligible financial instruments at fair value. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date and recognize upfront costs and fees related to those items in earnings as incurred and not deferred. SFAS 159 applies to fiscal years beginning after November 15, 2007, with early adoption permitted for an entity that has also elected to apply the provisions of SFAS 157, *Fair Value Measurements* . The implementation of this standard did not have a material effect on our consolidated financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements* . SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States of America and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements. We were required to adopt SFAS 157 beginning January 1, 2008. In February 2008, the FASB released FASB Staff Position (FSP FAS 157-2 Effective Date of FASB Statement No. 157), which delayed the effective date of SFAS No. 157 for all non-financial assets and liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The adoption of SFAS No. 157 for our financial assets and liabilities did not have a material impact on our consolidated financial statements. We do not expect that adoption of SFAS No. 157 for our non-financial assets and liabilities, effective January 1, 2009, will have a material impact on our financial statements.

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Critical Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements. In preparing our financial statements in accordance with accounting principles generally accepted in the United States of America, management is required to make estimates and assumptions that, among other things, affect the reported amounts of assets and liabilities and reported amounts of revenues and expenses. These estimates are most significant in connection with our critical accounting policies, namely those of our accounting policies that are most important to the portrayal of our financial condition and results and require management s most difficult, subjective or complex judgments. These judgments often result from the need to make estimates about the effects of matters that are inherently uncertain. Actual results may differ from those estimates under different assumptions or conditions. We believe that the following represents our critical accounting policies:

Going concern. Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and as a result, our independent registered public accounting firms included an explanatory paragraph in their reports on our consolidated financial statements for the years ended December 31, 2008 and December 31, 2007 with respect to this uncertainty. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

Revenue recognition. We recognize revenue from product sales when title to product and associated risk of loss has passed to the customer and we are reasonably assured of collecting payment for the sale. All revenue from product sales are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances. We allow return of our product for up to twelve months after product expiration.

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

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

Liquidity and Capital Resources

At December 31, 2008, we had cash, cash equivalents and marketable securities totaling $4.9 million, compared with $7.8 million at December 31, 2007, reflecting the net proceeds from the placement of $20 million of notes on June 9, 2008 offset by funds used in operating our company. During 2008, cash used in operating activities was $25.7 million compared with $31.7 million in 2007, reflecting our efforts to lower our spending.

On June 9, 2008, we issued 2-year senior convertible promissory notes bearing interest at an annual rate of 15%, payable at quarterly intervals in stock or cash at our option and the notes 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. Holders of the notes have the right, but not the obligation, for the following 12 months following the initial closing date to purchase in whole, or in part, up to an additional $20 million of the notes. We have the right to force conversion of the notes in whole, or in part, if the closing bid price of our common stock exceeds $0.50 for a period of 20 consecutive trading days. Certain members of our senior management participated in this offering. The notes are secured by a first lien on all of our assets. In addition, the notes prohibit any additional financing without the approval of holders of more than two-thirds of the principal amount of the notes.

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The notes included certain events of default, including a requirement that we obtain stockholder approval within a specified period of time to amend our certificate of incorporation to authorize additional shares of common stock. On October 6, 2008, at the Annual Meeting of Stockholders, 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 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 accordance with the terms of the notes, we elected to pay interest due on the notes on December 9, 2008 in shares of our common stock to all noteholders where the issuance of the shares would not cause the noteholder to beneficially own more than 4.999% of our outstanding common stock. Accordingly, on December 9, 2008, we issued 4.0 million shares and $0.1 million to satisfy our interest payment.

Through December 31, 2008, our noteholders have voluntarily converted approximately $4.5 million of our convertible notes, resulting in us issuing 446.0 million shares of common stock. From January 1, 2009 through February 4, 2009, holders of convertible notes have voluntarily converted approximately $4.6 million of their notes, resulting in an issuance of 459.6 million shares of common stock.

Upon the occurrence of an event of default, holders of the notes have the right to require us to prepay all, or a portion, of their 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 our common stock. Pursuant to a general security agreement, entered into concurrently with the notes, the notes are secured by a first lien on all of our assets.

In February 2008, the Company sold 6.1 million shares of the Company s common stock at a price of $0.50 per share, raising approximately $3.1 million, before estimated fees and expenses.

Effective May 7, 2008, we moved the trading of our common stock from The NASDAQ Capital Markets to the Over-the-Counter Bulletin Board (OTCBB) maintained by FINRA (formerly, the NASD). This action was taken pursuant to receipt of notification from the NASDAQ Listing Qualifications Panel that we had failed to demonstrate our ability to sustain compliance with the $2.5 million minimum stockholders equity requirement for continued listing on The NASDAQ Capital Markets. On July 10, 2008, we received notification from The NASDAQ Capital Market that The NASDAQ Capital Market had determined to remove our common stock from listing on such exchange. The delisting was effective at the opening of the trading session on July 21, 2008.

In March 2007, we sold 5.0 million shares of our common stock at a price of $2.16 per share, raising net proceeds of $10.2 million.

During 2007, the Company issued notes payable to finance premiums for its corporate insurance policies of $1.1 million at interest rates running from 5.2% to 5.9%. Payments were scheduled for seven or ten equal monthly installments for the notes initiated in 2007. The remaining balance on the notes payable was $0.5 million at December 31, 2007, which was then fully paid off during 2008.

Presently, with no further financing, we will run out of funds in the first quarter of 2009. We currently do not have any additional financing in place. If we are unable to raise additional financing, we could be required to reduce our spending plans, reduce our workforce, license to others products or technologies we would otherwise seek to commercialize ourselves and sell certain assets. There can be no assurance that we can obtain financing, if at all, on terms acceptable to us.

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

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

Contractual Obligations

Future contractual obligations at December 31, 2008 are as follows ($ thousands):

	Total	Less than 1 year	1 3 years	3 5 years	More than 5 years
Uncertain tax positions*	$ 841	$ 841	$ 0	$ 0	$ 0
Operating lease obligations	2,859	706	2,153	0	0
Maturity of convertible notes	15,540	0	15,540	0	0
License obligations to Daiichi Sankyo	2,125	2,125	0	0	0
Total	$ 21,365	$ 3,672	$ 17,693	$ 0	$ 0

* see Note 13 to the Consolidated Financial Statements

Virtually all of the operating lease obligations result from our lease of approximately 25 thousand square feet of office space in Berkeley Heights, New Jersey. Our lease on this space terminates in 2010. In May 2008, we entered into an amendment of our lease agreement with The Connell Company, (Connell) whereby the lease for one floor of our office space was terminated. We agreed to pay Connell a payment of $2.0 million upon the earlier of July 1, 2009 or our receipt of at least $5.0 million in upfront cash from a business development deal. In February 2009, we entered into another amendment of our agreement with Connell whereby our future payment of $2.0 million is now payable on January 1, 2011. We will pay 6.0% interest in arrears to Connell from July 1, 2009 through the new payment date. The initial interest payment of approximately $30 thousand will be payable as of October 1, 2009.

On June 9, 2008, we issued senior convertible promissory notes maturing on June 9, 2010, (see Note 12 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, $15.5 million, is the face value of convertible notes outstanding at December 31, 2008. This amount would be due on June 9, 2010 assuming no voluntary conversions by noteholders prior to the maturity date. As of February 4, 2009, the amount is $10.9 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, 2008, we owe Daiichi Sankyo two installments of $562,000 and 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 agreement provides provisions whereby failure to make timely payments to Daiichi Sankyo may provide grounds for termination of the agreement.

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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, marketable securities, accounts payable, accrued expenses and debt are a reasonable approximation of their fair value. The estimated fair values of financial instruments have been determined by us using available market information and appropriate valuation methodologies (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, 2008. Therefore there will be no ongoing exposure to a potential material adverse effect on our business, financial condition or results of operation for sensitivity to changes in interest rates or to changes in currency exchange rates.

Item 8. Financial Statements and Supplementary Data

Genta Incorporated
Index to Financial Statements

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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 consolidated balance sheet of Genta Incorporated and Subsidiaries (the Company) as of December 31 2008, and the related consolidated statement of operations, stockholders (deficit) equity, and cash flows for the year 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit 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 audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Genta Incorporated and Subsidiaries as of December 31, 2008, and the results of their operations and their cash flows for the year then ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company s recurring losses from operations and negative cash flows from operations raise substantial doubt about its ability to continue as a going concern. Management s plans considering these matters are also described in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ AMPER, POLITZINER & MATTIA, LLP

Edison, New Jersey
February 12, 2009

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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 consolidated balance sheet of Genta Incorporated and subsidiaries (the Company) as of December 31, 2007, and the related consolidated statements of operations, stockholders (deficit) equity, and cash flows for each of the two years in the period ended December 31, 2007. 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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, such consolidated financial statements present fairly, in all material respects, the financial position of Genta Incorporated and subsidiaries as of December 31, 2007, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company s recurring losses from operations and negative cash flows from operations raise substantial doubt about its ability to continue as a going concern. Management s plans concerning these matters are also described in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 2 to the consolidated financial statements, the Company adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109*, effective January 1, 2007.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey
March 17, 2008

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GENTA INCORPORATED
CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,908	$ 5,814
Marketable securities (Note 3)		1,999
Accounts receivable net of allowances of $12 at December 31, 2008 and $38 at December 31, 2007	2	31
Inventory (Note 4)	121	225
Prepaid expenses and other current assets (Note 6)	973	19,170
Total current assets	6,004	27,239
Property and equipment, net (Note 7)	300	323
Deferred financing costs on convertible note financing (Note 11)	911	
Deferred financing costs warrant (Note 11)	5,478	
Other assets (Note 5)		1,731
Total assets	$ 12,693	$ 29,293
LIABILITIES AND STOCKHOLDERS (DEFICIT)/EQUITY		
Current liabilities:		
Accounts payable and accrued expenses (Note 6 and Note 9)	$ 11,224	$ 25,850
Notes payable (Note 10)		512
Total current liabilities	11,224	26,362
Long-term liabilities:		
Office lease settlement obligation (Note 5)	1,979	
Convertible notes due June 9, 2010, $15,540 outstanding, net of debt discount of ($11,186) (Note 11)	4,354	
Total long-term liabilities	6,333	
Commitments and contingencies (Note 18)		
Stockholders (deficit)/equity (Note 13):		
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, 2008 and December 31, 2007, respectively		
Series G participating cumulative preferred stock, $.001 par value; 0 shares issued and outstanding at December 31, 2008 and December 31, 2007,		

respectively		
Common stock, $.001 par value; 6,000,000 and 250,000 shares authorized 486,724 and 30,621 shares issued and outstanding at December 31, 2008 and December 31, 2007, respectively	487	31
Additional paid-in capital	938,775	441,159
Accumulated deficit	(944,126)	(438,288)
Accumulated other comprehensive income		29
Total stockholders (deficit)/equity	(4,864)	2,931
Total liabilities and stockholders (deficit)/equity	$ 12,693	$ 29,293

See accompanying notes to consolidated financial statements.

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GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)	Years Ended December 31, 2008	2007	2006
Product sales net	$ 363	$ 580	$ 708
Cost of goods sold	102	90	108
Gross margin	261	490	600
Operating expenses:			
Research and development	19,991	13,491	28,064
Selling, general and administrative	10,452	16,865	25,152
Settlement of office lease obligation (Note 5)	3,307		
Provision for settlement of litigation (Note 6 and Note 18)	(340)	(4,240)	5,280
Write-off of prepaid royalty (Note 8)			1,268
Total operating expenses	33,410	26,116	59,764
Other (expense)/income, net:			
Gain on maturity of marketable securities	31	159	310
Interest income and other income, net	252	837	1,216
Interest expense	(1,718)	(160)	(72)
Amortization of deferred financing costs and debt discount (Note 11)	(11,229)		
Fair value conversion feature liability (Note 11)	(460,000)		
Fair value warrant liability (Note 11)	(2,000)		
Total other (expense)/income, net	(474,664)	836	1,454
Loss before income taxes	(507,813)	(24,790)	(57,710)
Income tax benefit (Note 12)	1,975	1,470	929
Net loss	$ (505,838)	$ (23,320)	$ (56,781)
Net loss per basic and diluted common share	$ (9.10)	$ (0.79)	$ (2.52)
Shares used in computing net loss per basic and diluted common share	55,576	29,621	22,553

See accompanying notes to consolidated financial statements.

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GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF STOCKHOLDERS (DEFICIT)/EQUITY
For the Years Ended December 31, 2008, 2007 and 2006

(In thousands)	Convertible Preferred Stock Shares	Amount	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders (Deficit)/Equity
Balance at January 1, 2006	10	$	19,092	$ 19	$ 373,805	$ (358,187)	$ 60	$ 15,697
Net loss						(56,781)		(56,781)
Net change in value of marketable securities							(29)	(29)
Issuance of common stock, net of issuance costs of $3,125			3,167	3	37,722			37,725
Issuance of common stock in connection with conversion of Series A preferred stock	(2)		3					
Issuance of common stock, net of issuance costs of $925			3,333	4	14,871			14,875
Issuance of common stock in connection with exercise of stock options			26		156			156
Stock-based compensation expense					2,999			2,999
Balance at December 31, 2006	8	$	25,621	$ 26	$ 429,553	$ (414,968)	$ 31	$ 14,642
Net loss						(23,320)		(23,320)
Net change in value of marketable							(2)	(2)

securities								
Issuance of common stock, net of issuance costs of $562		5,000	5	10,233				10,238
Stock-based compensation expense				1,373				1,373
Balance at December 31, 2007	8	$ 30,621	$ 31	$ 441,159	$ (438,288)	$ 29	$	2,931
Net loss					(505,838)			(505,838)
Net change in value of marketable securities						(29)		(29)
Issuance of common stock, net of issuance costs of $183		6,120	6	2,870				2,876
Issuance of common stock as interest payment on Senior Convertible Promissory Note		4,000	4	643				647
Issuance of common stock on voluntary conversions of Senior Convertible Promissory Note		445,963	446	4,014				4,460
Transfer of warrant liability to paid-in-capital				9,600				9,600
Transfer conversion feature liability to paid-in-capital				480,000				480,000
Vesting of restricted stock		20						
Stock-based compensation expense				489				489
Balance at December 31, 2008	8	$ 486,724	$ 487	$ 938,775	$ (944,126)	$	$	(4,864)

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GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Years Ended December 31, 2008	2007	2006
Operating activities:			
Net loss	$ (505,838)	$ (23,320)	$ (56,781)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	154	170	942
Loss on disposition of equipment	10		
Amortization of deferred financing costs and debt discount (Note 11)	11,229		
Share-based compensation (Note 14)	489	1,373	2,999
Provision for sales returns	79	(133)	(300)
Gain on maturity of marketable securities	(31)	(159)	(310)
Interest payment settled in shares of common stock (Note 19)	647		
Provision for settlement of litigation, net (Note 6)	(340)	(4,240)	5,280
Write-off of prepaid royalty (Note 8)			1,268
Change in fair value conversion feature liability (Note 11)	460,000		
Change in fair value warrant liability (Note 11)	2,000		
Changes in operating assets and liabilities:			
Accounts receivable	29	(14)	42
Inventory	104	83	88
Prepaid expenses and other current assets	198	627	(142)
Accounts payable and accrued expenses	5,615	(6,071)	2,264
Other assets		(42)	(40)
Net cash used in operating activities	(25,655)	(31,726)	(44,690)
Investing activities:			
Purchase of marketable securities		(13,900)	(56,784)
Maturities of marketable securities	2,000	32,000	49,091
Release of restricted cash deposits (Note 5)	1,731		
Purchase of property and equipment	(141)	(222)	(136)
Net cash provided by (used in) investing activities	3,590	17,878	(7,829)
Financing activities:			
Net proceeds from sale of common stock, net (Note 13)	2,876	10,238	52,691
Issuance of note payable (Note 10)		1,155	1,174
Repayments of note payable (Note 10)	(512)	(1,285)	(1,261)
Issuance of convertible notes net of financing cost of $1,205 (Note 11)	18,795		
Issuance of common stock upon exercise of stock options (Note 15)			155
Net cash provided by financing activities	21,159	10,108	52,759

Increase (decrease) in cash and cash equivalents	(906)	(3,740)	240
Cash and cash equivalents at beginning of year	5,814	9,554	9,314
Cash and cash equivalents at end of year	$ 4,908	$ 5,814	$ 9,554

See accompanying notes to consolidated financial statements.

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GENTA INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended December 31, 2008, 2007 and 2006

1. Organization and Business

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 since its inception. Management expects that such losses will continue at least until its lead product, Genasense® (oblimersen sodium) Injection, receives approval for and begins commercial sale in one or more indications. Achievement of profitability for the Company is currently dependent on the timing of Genasense® regulatory approval. Any adverse events with respect to approvals by the U.S. Food and Drug Administration (FDA) and/or European Medicines Agency (EMEA) could negatively impact the Company s ability to obtain additional funding or identify potential partners.

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

The Company had $4.9 million of cash and cash equivalents on hand at December 31, 2008. Net cash used in operating activities during 2008 was $25.7 million, which represents an average monthly outflow of $2.1 million.

On June 5, 2008, the Company entered into a securities purchase agreement with certain institutional and accredited investors to place up to $40 million of senior secured convertible notes with such investors. On June 9, 2008, the Company placed $20 million of such notes in the initial closing.

The 2-year notes bear interest at an annual rate of 15% payable at quarterly intervals in stock or cash at the Company s option, and are convertible into shares of Genta common stock at a conversion rate of 100,000 shares of common stock for every $1,000 of principal. Holders of the notes have the right, but not the obligation, for the 12 months following the initial closing date to purchase in whole or in part up to an additional $20 million of the notes. The Company shall have the right to force conversion of the notes in whole or in part if the closing bid price of the Company s common stock exceeds $0.50 for a period of 20 consecutive trading days. Certain members of senior management of Genta participated in this offering. The notes are secured by a first lien on all assets of Genta.

The notes included certain events of default, including a requirement that the Company obtain stockholder approval within a specified period of time to amend its certificate of incorporation to authorize additional shares of common stock. 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.

The Company will require additional cash in order to maximize its commercial opportunities and continue its clinical development opportunities. The Company has had discussions with other companies regarding partnerships for the further development and global commercialization of Genasense®. Additional alternatives available to the Company to subsequently sustain its operations include financing arrangements with potential corporate partners, debt financing, asset-based loans, royalty-based financings, equity financing and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available on favorable terms, if at all. Presently, with no further financing, management projects that the Company will run out of funds in the first quarter of 2009. The Company currently does not have any additional financing in place. There can be no assurance that the Company can obtain financing, if at all, on terms acceptable to it.

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If the Company is unable to raise additional funds, it will need to do one or more of the following:

delay, scale back or eliminate some or all of the Company s research and product development programs and sales and marketing activity;

license third parties to develop and commercialize products or technologies that the Company would otherwise seek to develop and commercialize themselves;

attempt to sell the Company;

cease operations; or

declare bankruptcy.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements are presented on the basis of accounting principles generally accepted in the United States of America. 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, 2008, the amounts on deposit that exceeded the $250,000 federally insured limit was $3.9 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.

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Income Taxes

The Company uses the liability method of accounting for income taxes. Deferred income taxes are determined based on the estimated future tax effects of differences between the financial statement and tax bases of assets and liabilities given the provisions of the enacted tax laws. Management records valuation allowances against net deferred tax assets, if based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The 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, 2008 and December 31, 2007, 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.

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109* (FIN 48), which clarifies the accounting and disclosure for uncertainty in tax positions, as defined. The Company adopted the provisions of FIN 48 as of January 1, 2007 and has analyzed filing positions in all of the federal and state jurisdictions where it is required to file income tax returns, as well as all open tax years in these jurisdictions.

The State of New Jersey has taken the position that amounts reimbursed to Genta by Aventis Pharmaceutical Inc. for co-development expenditures during an audit period of 2000 through 2004 were subject to Alternative Minimum Assessment (AMA), resulting in a liability at December 31, 2008 of $841 thousand, (see Note 13 to the Company s Consolidated Financial Statements). The Company believes the State s position is unjustified and is pursuing this matter before the New Jersey Tax Court. Other than this matter, the Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to FIN 48. In addition, the Company did not record a cumulative effect adjustment related to the adoption of FIN 48. If such adjustment was recorded, it would have been fully offset by a change in a valuation allowance.

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

Stock Options

The Company s share-based payments including grants of employee stock options are recognized in the Consolidated Statement of Operations based on their fair values. The amount of compensation cost is measured based on the grant-date fair value of the equity instrument issued. The Company utilizes a Black-Scholes option-pricing model to measure the fair value of stock options granted to employees. See Note 15 to our Consolidated Financial Statements for a further discussion on share-based compensation.

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Deferred Financing Costs and Other Debt-Related Costs

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

Net Loss Per Common Share

Net loss per common share for the year ended December 31, 2008, 2007 and 2006, respectively, are based on the weighted average number of shares of common stock outstanding during the periods. Basic and diluted loss per share are identical for all periods presented as potentially dilutive securities have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would be antidilutive. The potentially dilutive securities include 1.6 billion, 2.3 million and 2.1 million shares in 2008, 2007 and 2006, respectively, reserved for the conversion of convertible notes, convertible preferred stock and the exercise of outstanding options and warrants.

Recent Accounting Pronouncements

In June 2008 the FASB issued EITF 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock* . EITF 07-5 provides guidance in assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity s own stock for purposes of determining whether the appropriate accounting treatment falls under the scope of SFAS 133, *Accounting For Derivative Instruments and Hedging Activities* and/or EITF 00-19, *Accounting For Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock* . EITF 07-05 is effective as of the beginning of our 2009 fiscal year. The Company does not expect the adoption of EITF 07-05 to have a material impact on its consolidated financial position or results of operations.

In May 2008, the FASB issued FASB Staff Position (FSP) APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*. FSP APB14-1 will require us to account separately for the liability and equity components of our convertible debt. The debt would be recognized at the present value of its cash flows discounted using our nonconvertible debt borrowing rate at the time of issuance. The equity component would be recognized as the difference between the proceeds from the issuance of the note and the fair value of the liability. The FSP also requires accretion of the resultant debt discount over the expected life of the debt. The FSP is effective for fiscal years beginning after December 15, 2008, and interim periods within those years. Entities are required to apply the FSP retrospectively for all periods presented. We are currently evaluating FSP APB 14-1 and have not yet determined the impact its adoption will have on our consolidated financial statements. However, the impact of this new accounting treatment may be significant and may result in a significant increase to non-cash interest expense beginning in fiscal year 2009 for financial statements covering past and future periods.

In May 2008, the Financial Accounting Standards Board (FASB) issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* . The statement is intended to improve financial reporting by identifying a consistent hierarchy for selecting accounting principles to be used in preparing financial statements that are prepared in

conformance with generally accepted accounting principles. The statement is effective 60 days following the Securities and Exchange Commission s (SEC) approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with GAAP* , and is not expected to have any impact on the Company s financial statements.

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In March 2008, the FASB issued SFAS 161, *Disclosures about Derivative Instruments and Hedging Activities*, *an amendment of FASB SFAS 133* (SFAS 161), which requires enhanced disclosures for derivative and hedging activities. SFAS 161 will become effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The implementation of this standard did not have a material effect on the Company s consolidated financial statements.

In December 2007, the FASB issued SFAS 141(R), *Business Combinations* (SFAS 141(R)), which replaces SFAS 141. SFAS 141(R) establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any controlling interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141(R) is to be applied prospectively to business combinations for which the acquisition date is on or after an entity s fiscal year that begins after December 15, 2008. The standard will have an impact on our financial statements when an acquisition occurs.

In December 2007, the FASB issued SFAS 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51* (SFAS 160). SFAS 160 establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Specifically, this statement requires the recognition of a noncontrolling interest (minority interest) as equity in the consolidated financial statements and separate from the parent s equity. The amount of net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement. SFAS 160 clarifies that changes in a parent s ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, this statement requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. SFAS 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The implementation of this standard did not have a material effect on the Company s consolidated financial statements.

In December 2007, the SEC issued Staff Accounting Bulletin 110 (SAB 110), which permits entities, under certain circumstances, to continue to use the simplified method of estimating the expected term of plain options as discussed in SAB No. 107 and in accordance with SFAS 123R. The guidance in this release was effective January 1, 2008. The implementation of this standard did not have a material effect on the Company s consolidated financial statements.

In December 2007, the FASB issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, which is effective for calendar year companies on January 1, 2009. The Task Force clarified the manner in which costs, revenues and sharing payments made to, or received by, a partner in a collaborative arrangement should be presented in the income statement and set forth certain disclosures that should be required in the partners financial statements. The implementation of this standard did not have a material effect on the Company s consolidated financial statements.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, which was effective for calendar year companies on January 1, 2008. The Task Force concluded that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. The implementation of this standard did not have a material effect on the Company s consolidated financial statements.

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In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 permits all entities to choose to elect, at specified election dates, to measure eligible financial instruments at fair value. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date and recognize upfront costs and fees related to those items in earnings as incurred and not deferred. SFAS 159 applied to fiscal years beginning after November 15, 2007, with early adoption permitted for an entity that also elected to apply the provisions of SFAS 157, *Fair Value Measurements* . The implementation of this standard did not have a material effect on the Company s consolidated financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements* . SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States of America and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements. The Company was required to adopt SFAS 157 beginning January 1, 2008. In February 2008, the FASB released FASB Staff Position (FSP FAS 157-2 Effective Date of FASB Statement No. 157), which delayed the effective date of SFAS No. 157 for all non-financial assets and liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The adoption of SFAS No. 157 for the Company s financial assets and liabilities did not have a material impact on its consolidated financial statements. The Company does not expect that adoption of SFAS No. 157 for the Company s non-financial assets and liabilities, effective January 1, 2009, will have a material impact on its financial statements.

3. Marketable Securities

The carrying amounts of the Company s marketable securities, which are primarily securities of government-backed agencies, approximate fair value due to the short-term nature of these instruments. The fair value of available-for-sale marketable securities was as follows ($ thousands):

	December 31, 2007
Cost	$ 1,970
Gross unrealized gains	29
Gross unrealized losses	
Fair value	$ 1,999

The fair value of each marketable security was compared to its cost and therefore, unrealized gains of approximately $29 thousand were recognized in accumulated other comprehensive income in the Company s Consolidated Balance Sheets at December 31, 2007.

4. Inventory

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

	December 31,

	2008	2007
Raw materials	$ 24	$ 24
Work in process		
Finished goods	97	201
	$ 121	$ 225

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.

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5. Settlement of Office Lease Obligation and Operating Leases

In May 2008, the Company entered into an amendment of its Lease Agreement with The Connell Company (Connell), whereby the lease for one floor of office space in Berkeley Heights, New Jersey was terminated. Connell received a termination payment of $1.3 million, comprised solely of the Company s security deposits and the Company agreed to a future payment from the Company of $2.0 million upon the earlier of July 1, 2009 or the receipt of at least $5.0 million in upfront cash from a business development deal. In January 2009, the Company entered into an amendment of its agreement with Connell whereby the Company s future payment of $2.0 million is now payable on January 1, 2011. The Company will pay 6.0% interest in arrears to Connell from July 1, 2009 through the new payment date.

At December 31, 2007, the Company had maintained $1.7 million in restricted cash balances with financial institutions related to lease obligations on its corporate facilities. These amounts were included in other assets in the Company s Consolidated Balance Sheets.

Future minimum obligations under operating leases at December 31, 2008 are as follows ($ thousands):

2009	$ 706
2010	146
2011	2,007
2012	
2013	
Thereafter	
	$ 2,859

Annual rent expense incurred by the Company in 2008, 2007 and 2006 was $4.8 million, $2.6 million and $2.5 million, respectively. The annual rent expense in 2008 of $4.8 million includes the termination agreement with Connell for $3.3 million.

6. Provision for Settlement of Litigation, net

The Company reached an agreement to settle a class action litigation in consideration for issuance of 2.0 million shares of common stock of the Company (adjusted for any subsequent event that results in a change in the number of shares outstanding as of January 31, 2007) and $18.0 million in cash for the benefit of plaintiffs and the stockholder class, (see Note 19 to the Consolidated Financial Statements). A Court order approving the settlement was issued on May 27, 2008 and the settlement became final on June 27, 2008. The Company also entered into release and settlement agreements with its insurance carriers, pursuant to which insurance will cover the settlement fee and various costs incurred in connection with the action. Under FASB Statement No. 5, *Accounting for Contingencies* and FASB Interpretation No. 14, *Reasonable Estimation of the Amount of a Loss, an interpretation of FASB Statement No. 5,* the Company recorded an expense of $5.3 million, comprised of 2.0 million shares of the Company s common stock valued at a market price of $2.64 on December 31, 2006. At December 31, 2007, the revised estimated value of the common shares portion of the litigation settlement was $1.0 million, based on a closing price of Genta s common stock of $0.52 per share, resulting in a reduction in the provision of $4.2 million recognized in the year ended December 31, 2007. At June 27, 2008, the date that the settlement became final, the revised value of the common stock portion of the litigation settlement was $0.7 million, based on a closing price of Genta s common stock of $0.35

per share, resulting in a reduction in the provision of $0.3 million for the year ended December 31, 2008. The liability for the settlement of litigation, originally recorded at $23.2 million at December 31, 2006, was measured at $19.0 million at December 31, 2007 and $0.7 million at December 31, 2008 and is included in accounts payable and accrued expenses in the Company s Consolidated Balance Sheets. An insurance receivable of $18.0 million was included in prepaid expenses and other current assets in the Company s Consolidated Balance Sheets at December 31, 2007. As a result of the Court approving the settlement on May 27, 2008 and it being deemed final on June 27, 2008, the Company no longer had any interest in the insurance proceeds held in escrow or the associated liability.

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7. Property and Equipment, Net

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

	Estimated Useful Lives	December 31, 2008	2007
Computer equipment	3	$ 2,298	$ 2,855
Software	3	3,206	3,211
Furniture and fixtures	5	899	936
Leasehold improvements	Life of lease	463	420
Equipment	5	182	182
		7,048	7,604
Less accumulated depreciation and amortization		(6,748)	(7,281)
		$ 300	$ 323

8. Write-off of Prepaid Royalty

In December 2000, the Company recorded $1.3 million as the fair value for its commitment to issue shares of common stock to a major university as consideration for an amendment to a license agreement initially executed in August 1991 related to antisense technology licensed from the university. The amendment provided for a reduction in the royalty percentage rate to be paid to the university based on the volume of sales of the Company s products containing the antisense technology licensed from such university. These shares were issued in 2001. The Company planned to amortize the prepaid royalties upon the commercialization of Genasense®. In December 2006, the Company received a non-approvable notice from the FDA for its NDA for the use of Genasense® plus chemotherapy in patients with CLL. As a result, in December 2006, the Company accounted for the impairment of these prepaid royalties by recording a write-off of this asset.

9. Workforce reduction

In December 2006, due to FDA s non-approval of the Company s NDA for CLL, the Company initiated a series of steps that are designed to conserve cash in order to focus on its oncology development operations. The Company reduced its workforce by 34 positions, or approximately 35%, including the elimination of 18 positions classified as research and development, 9 in sales and marketing and 7 in administration. Severance costs of $0.7 million were recognized in operating expenses in December 2006, including $0.3 million in research and development expenses and $0.4 million in selling, general and administrative expenses in the Company s Consolidated Statements of Operations. Payment of the severance began in January 2007 and was completed by June 30, 2007.

10. Accounts Payable and Accrued Expenses

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

	December 31,

	2008	2007
Accounts payable	$ 4,654	$ 2,519
Accrued compensation	574	488
Reserve for settlement of litigation obligation	700	19,040
License obligations to Daiichi Sankyo	2,125	
State of New Jersey (AMA) tax liability	841	776
Other accrued expenses	2,330	3,027
	$ 11,224	$ 25,850

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

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11. Notes Payable

During 2007, the Company issued notes payable to finance premiums for its corporate insurance policies of $1.1 million. Payments were scheduled for seven or ten equal monthly installments for the notes initiated in 2007. The notes payable balance at December 31, 2007 was $0.5 million. The carrying amount of notes payable approximates fair value due to the short-term nature of these instruments.

12. Convertible Notes and Warrant

On June 5, 2008, the Company entered into a securities purchase agreement with certain institutional and accredited investors to place up to $40.0 million of senior secured convertible notes with such investors. On June 9, 2008, the Company placed $20.0 million of such notes in the initial closing. The notes are due June 9, 2010 and bear interest at an annual rate of 15% payable at quarterly intervals in stock or cash at the Company s option, and are convertible into shares of Genta common stock at a conversion rate of 100,000 shares of common stock for every $1,000 of principal. At the time the notes were issued, the Company recorded a debt discount (beneficial conversion) relating to the conversion feature in the amount of $20.0 million. The aggregate intrinsic value of the difference between the market price of the Company s share of stock on June 9, 2008 and the conversion price of the notes was in excess of the face value of the $20.0 million notes, and thus, a full debt discount was recorded in an amount equal to the face value of the debt. The Company is amortizing the resultant debt discount over the term of the notes through its maturity date using the effective interest method. In addition, the notes prohibit the Company from consummating any additional financing transaction without the approval of holders of more than two-thirds of the principal amount of the notes. The Company is in compliance with all debt-related covenants at December 31, 2008.

Through December 31, 2008, holders of the convertible notes have voluntarily converted approximately $4.5 million, resulting in an issuance of 446.0 million shares of common stock.

The notes included certain events of default, including a requirement that the Company obtain stockholder approval within a specified period of time to amend its certificate of incorporation to authorize additional shares of common stock.

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

In addition, in connection with the placement of the senior secured convertible notes, the Company issued a warrant to its private placement agent to purchase 40,000,000 shares of common stock at an exercise price of $0.02 per share. The warrant was valued at $7.6 million, using a Black-Scholes valuation model. In addition, the Company incurred a financing fee of $1.2 million. The deferred financing costs, including the financing fee and the initial value of the warrant, are being amortized over the two-year term of the convertible notes. At December 31, 2008, the unamortized balances of the financing fee and the warrant are $0.9 million and $5.5 million, respectively.

The Company concluded that it should initially account for conversion options embedded in convertible notes in accordance with SFAS No. 133 *Accounting for Derivative Instruments and Hedging Activities* (*SFAS 133*) and *EITF 00-19 Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock* (EITF 00-19). SFAS 133 generally requires companies to bifurcate conversion options embedded in

convertible notes from their host instruments and to account for them as free standing derivative financial instruments in accordance with EITF 00-19. EITF 00-19 states that if the conversion option requires net cash settlement in the event of circumstances that are not solely within the Company s control, that the notes should be classified as a liability measured at fair value on the balance sheet. In this case, if the Company was not successful in obtaining approval of its stockholders to increase the number of authorized shares to accommodate the potential number of shares that the notes convert into, the Company would have been required to cash settle the conversion option.

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Upon the issuance date, there were an insufficient number of authorized shares of common stock in order to permit conversion of all of the issued convertible notes. In accordance with EITF 00-19, when there are insufficient authorized shares to allow for settlement of convertible financial instruments, the conversion obligation for the notes should be classified as a liability and measured at fair value on the balance sheet. Accordingly, at June 9, 2008, in connection with the $20.0 million initial closing, the convertible features of the notes were recorded as derivative liabilities of $380.0 million. At the recording of the initial closing, the fair value of the conversion feature, $380.0 million, exceeded the proceeds of $20.0 million. The difference of $360.0 million was charged to expense as the change in the fair market value of conversion liability. Accordingly, the Company recorded an initial discount of $20.0 million equal to the face value of the notes, which is being amortized over the two-year term of the notes.

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. The notes were re-measured and credited to permanent equity, resulting in total expense for the year ended December 31, 2008 of $460.0 million.

The conversion option was valued at June 9, 2008 and October 6, 2008 using the Black-Scholes valuation model with the following assumptions:

	October 6, 2008	June 9, 2008
Price of Genta common stock	$ 0.25	$ 0.20
Volatility	137.4%	125.6%
Risk-free interest rate	1.36%	2.73%
Remaining contractual lives	1.68	2.00

The Company also classified the warrant obligation as a liability to be measured at fair value on the balance sheet, in accordance with EITF 00-19. Accordingly, at June 9, 2008, the Company recorded the warrant liability at a fair value of $7.6 million based upon the Black-Scholes valuation model. On October 6, 2008, we re-measured the warrant liability and credited it to permanent equity, resulting in total expense for the year ended December 31, 2008 of $2.0 million.

	October 6, 2008	June 9, 2008
Price of Genta common stock	$ 0.25	$ 0.20
Volatility	128.6%	115.0%
Risk-free interest rate	2.32%	3.41%
Remaining contractual lives	4.68	5.00

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13. Income Taxes

Significant components of the Company s deferred tax assets as of December 31, 2008 and 2007 and related valuation reserves are presented below ($ thousands):

	December 31, 2008	2007
Deferred tax assets:		
Deferred compensation	$ 772	$ 772
Net operating loss carryforwards	135,990	130,111
Research and development credit and Orphan Drug credit carryforwards	51,288	41,484
Purchased technology and license fees	0	4,850
Depreciation and amortization, net	193	261
Share-based compensation expense	911	892
Provision for settlement of litigation, net	308	458
Write-off of prepaid royalties	558	558
New Jersey Alternative Minimum Assessment (AMA) Tax	730	730
New Jersey research and development credits	4,979	5,612
Provision for excess inventory	714	714
Reserve for product returns	0	2
Accrued liabilities	1,576	355
Other, net	197	323
Total deferred tax assets	198,216	187,122
Valuation allowance for deferred tax assets	(190,884)	(187,122)
Net deferred tax assets	$ 7,332	$
Deferred tax liabilities:		
Deferred financing costs	$ (4,922)	$
Debt discount	(2,410)	
Total deferred tax liabilities	$ (7,332)	$
Net deferred tax assets (liabilities)	$	$

A full valuation allowance has been provided at December 31, 2008 and 2007, respectively, to reserve for deferred tax assets, as it appears more likely than not that net deferred tax assets will not be realized.

Effective January 1, 2007 the company adopted FIN 48. As of December 31, 2008 and 2007, the Company recorded a liability for $841 thousand and $776 thousand, respectively, of unrecognized tax benefits (UTB s), of which $841 thousand and $776 thousand is included in accounts payable and accrued expenses on the Company s Consolidated Balance Sheets, respectively. In addition, as of December 31, 2008 and 2007, the Company reduced its deferred tax assets by $1,312 thousand and $1,033 thousand, respectively. However, the Company recorded a full valuation allowance on its net deferred tax assets and reduced its valuation allowance on these respective amounts. 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)	**2008**	**2007**
Unrecognized tax benefits at January 1	$ 1,567	$ 1,388
Gross increases: Tax positions taken in prior periods		
Gross decreases: Tax positions taken in prior periods		
Gross Increases-Current period tax positions	$ 278	$ 179
Lapse of Statute of Limitations		
Unrecognized tax benefits: December 31	$ 1,845	$ 1,567

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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 2005 through 2008 for federal returns and 2002 through 2008 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. The Company sold portions of its New Jersey net operating losses and received approximate payments of $2.0 million in 2008 and $1.5 million in 2007, recognized as income tax benefits.

If still available under New Jersey law, the Company will attempt to sell its tax loss carryforwards in 2008. We cannot be assured that the New Jersey program will continue in 2008, 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, 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, 2008, the Company had accrued a tax liability of $533 thousand, penalties of $27 thousand and interest of $281 thousand related to this assessment. The Company appealed this decision to the State and in February 2008, the State notified the Company that its appeal had not been granted. The Company believes the State s position is unjustified and is pursuing this matter before the New Jersey Tax Court. Upon close of the audit the Company s UTB s should decrease by approximately $841 thousand.

The Company recorded $65 thousand, $139 thousand and $66 thousand in interest expense related to the State of New Jersey assessment during 2008, 2007 and 2006, respectively.

At December 31, 2008, the Company has federal and state net operating loss carryforwards of approximately $324.8 million and $241.9 million, respectively. The federal tax loss carryforward balance at December 31, 2008 begins to expire in 2009 and completely expires in 2028. The Company also has Research and Development credit and Orphan Drug credit carryforwards totaling $49.7 million; the balance at December 31, 2008 begins to expire in 2009 and completely expires in 2028.

14. Stockholders (Deficit)/Equity

Common Stock

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 6.1 million shares of the Company s common stock at a price of $0.50 per share, raising approximately $3.1 million, before estimated fees and expenses.

At the Company s Annual Meeting of Stockholders on July 11, 2007, the Company s shareholders authorized its Board of Directors to effect a reverse stock split of all outstanding shares of common stock, and the Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of one for six shares.

In March 2007, the Company sold 5.0 million shares of the Company s common stock at a price of $2.16 per share, raising $10.2 million, net of fees and expenses.

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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, 2008 and December 31, 2007, each share of Series A Preferred Stock was convertible into 153.4393 and 2.3469 shares of common stock, respectively. At December 31, 2008 and December 31, 2007, 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, 2008.

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.

Warrant

In connection with the June 2008 convertible note financing, the Company issued a common stock purchase warrant to its private placement agent. The warrant is exercisable into 40,000,000 shares of common stock at an exercise price of $0.02 per share.

Common Stock Reserved

At December 31, 2008, the Company had 486.7 million shares of common stock outstanding, 3.4 million shares reserved for the conversion of convertible preferred stock and the exercise of outstanding options, 40.0 million shares reserved for the conversion of an outstanding warrant, 1,554.0 million shares reserved for the conversion of senior convertible notes and 0.2 million additional shares of common stock authorized for issuance and remaining to be granted under the Company s Non-Employee Directors 1998 Stock Option Plan, as amended and restated.

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15. Share-Based Compensation

The Company estimates the fair value of each option award on the date of the grant using the Black-Scholes option valuation model. Expected volatilities are based on the historical volatility of the Company s common stock over a period commensurate with the options expected term. The expected term represents the period of time that options granted are expected to be outstanding and is calculated in accordance with the Securities and Exchange Commission (SEC) guidance provided in the SEC s Staff Accounting Bulletin 107 (SAB 107), using a simplified method. The Company has used the simplified method and 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 post-vesting forfeiture rate is estimated using historical option cancellation information. The post-vesting forfeiture rate assumption was 40% for the years ended December 31, 2007 and 2006, respectively, and was increased to 50% for the year ended December 31, 2008 based on actual historical forfeitures. The following table summarizes the weighted-average assumptions used in the Black-Scholes model for options granted during the years ended December 31, 2008, 2007 and 2006, respectively:

	2008	2007	2006
Expected volatility	115.7%	102%	97%
Expected dividends			
Expected term (in years)	6.25	6.25	6.25
Risk-free rate	2.7%	4.8%	4.6%

The share-based compensation expense recognized for the years ended December 31, 2008, 2007 and 2006, respectively, follows:

($ thousands, except per share data)	2008	2007	2006
Research and development expenses	$ 151	$ 521	$ 997
Selling, general and administrative	338	852	2,002
Total share-based compensation expense	$ 489	$ 1,373	$ 2,999
Share-based compensation expense, per basic and diluted common share	$ 0.01	$ 0.05	$ 0.13

16. Stock Option Plans

As of December 31 2008, the Company has two outstanding share-based compensation plans, which are described below:

1998 Stock Incentive Plan

Pursuant to the Company s 1998 Stock Incentive Plan, as amended (the 1998 Plan), 3.4 million shares were provided for the grant of stock options to employees, directors, consultants and advisors of the Company. Option awards were granted with an exercise price at not less than the fair market price of the Company s common stock on the date of the grant; those option awards generally vested over a four-year period in equal increments of 25%, beginning on the first anniversary of the date of the grant. All options granted had contractual terms of ten years from the date of the grant.

As of May 27, 2008, the authorization to provide grants under the 1998 Plan expired.

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The following table summarizes the option activity under the 1998 Plan as of December 31, 2008 and changes during the three 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 December 31, 2005	1,570	30.24		
Granted	432	11.64		
Exercised				
Forfeited or expired	(66)	25.32		
Outstanding at December 31, 2006	1,936	$ 26.22		
Granted	316	1.40		
Exercised				
Forfeited or expired	(97)	16.38		
Outstanding at December 31, 2007	2,155	$ 23.05		
Granted				
Exercised				
Forfeited or expired	(278)	17.76		
Outstanding at December 31, 2008	1,877	$ 23.83	3.8	$
Vested and exercisable at December 31, 2008	1,299	$ 22.19	1.7	$

There is no intrinsic value to outstanding stock options as the exercise prices of all outstanding options are above the market price of the Company s stock at December 31, 2008.

As of December 31, 2008, there was approximately $0.2 million of total unrecognized compensation cost related to non-vested share-based compensation granted under the 1998 Plan, which is expected to be recognized over a weighted-average period of 1.2 years.

The following table summarizes the restricted stock unit (RSU) activity under the 1998 Plan as of December 31, 2008 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, 2007	0	$	
Granted	60	$	1.42
Vested	0	$	
Forfeited or expired	(40)	$	1.42
Outstanding nonvested RSUs at December 31, 2007	20	$	1.42
Granted	488	$	0.41
Vested	(20)	$	1.42
Forfeited or expired	(235)	$	0.41
Outstanding nonvested RSUs at December 31, 2008	253	$	0.41

As of December 31, 2008, there was approximately $24 thousand of total unrecognized compensation cost related to non-vested share-based compensation resulting from RSUs granted under the 1998 Plan, which is expected to be recognized over the six months ended June 30, 2009.

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1998 Non-Employee Directors Plan

Pursuant to the Company s 1998 Non-Employee Directors Plan as amended (the Directors Plan), 0.6 million shares have been provided for the grant of non-qualified stock options to the Company s non-employee members of the Board of Directors. Option awards must be granted with an exercise price at not less than the fair market price of the Company s common stock on the date of the grant. Initial option grants vest over a three-year period in equal increments, beginning on the first anniversary of the date of the grant. Subsequent grants, generally vest on the date of the grant. All options granted have contractual terms of ten years from the date of the grant.

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

The following table summarizes the option activity under the Directors Plan as of December 31, 2008 and changes during the three 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 December 31, 2005	193	$ 37.56		
Granted	23	12.42		
Exercised	(26)	6.00		
Forfeited or expired	(90)	40.98		
Outstanding at December 31, 2006	100	$ 37.02		
Granted	20	1.80		
Exercised				
Forfeited or expired	(7)	40.08		
Outstanding at December 31, 2007	113	$ 30.61		
Granted	17	0.25		
Exercised				
Forfeited or expired	(28)	41.82		
Outstanding at December 31, 2008	102	$ 22.61	6.2	$
Vested and exercisable at December 31, 2008	102	$ 22.61	6.2	$

There is no intrinsic value to outstanding stock options as the exercise prices of all outstanding options are above the market price of the Company s stock at December 31, 2008. The weighted-average grant-date fair value of options granted during the year ended December 31, 2008 was $0.25.

Stock option grants for a combination of both the 1998 Plan and the 1998 Directors Plan were as follows:

Year	Options Granted (in Thousands)	Weighted Average Grant Date Per Share Fair Value
2008	17	$ 0.25
2007	336	1.42
2006	455	11.70

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An analysis of all options outstanding as of December 31, 2008 is presented below, (option figures are in thousands):

Range of Prices	Options Outstanding	Weighted Average Remaining Life in Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price of Options Exercisable
$0.25 - $1.98	204	9.0	$ 0.78	65	$ 0.86
$2.73 - $9.54	168	7.4	7.07	64	6.95
$9.66 - $12.96	297	7.0	12.24	167	12.09
$14.58 - $16.01	804	0.9	16.00	804	16.00
$34.38 - $56.10	189	2.8	43.24	190	43.24
$59.28 - $109.50	317	4.2	66.29	100	75.23
	1,979	3.9	$ 23.77	1,401	$ 22.22

2007 Stock Incentive Plan

On September 17, 2007, the Company s Board of Directors approved the Company s 2007 Stock Incentive Plan (the 2007 Plan), pursuant to which 8.5 million shares of the Company s common stock would be authorized for issuance, subject to approval of the Company s stockholders. On September 17, 2007 and September 20, 2007, the Board of Directors approved the issuance of a combined total of 5.4 million options under the 2007 Plan. Awards granted under the plan prior to stockholder approval of the plan were subject to and conditioned upon receipt of such approval on or before September 17, 2008. The Company did not obtain stockholder approval of this plan; the plan was terminated and awards granted pursuant to the plan were terminated. The Company did not recognize compensation expense for grants under the 2007 Plan because grants of these options were contingent upon stockholder approval, and therefore, a grant date as defined in SFAS 123R had not occurred.

Acquisition Bonus Program

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

The Acquisition Bonus Program expired on December 31, 2008.

17. 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 $0.2 million, $0.3 million, and $0.4 million for 2008, 2007 and 2006, respectively.

18. Comprehensive Loss

An analysis of comprehensive loss is presented below:

($ in thousands)	Years Ended December 31, 2008	2007	2006
Net loss	$ (505,838)	$ (23,320)	$ (56,781)
Change in market value on available-for-sale marketable securities	(29)	29	31
Total comprehensive loss	$ (505,867)	$ (23,291)	$ (56,750)

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19. Commitments and Contingencies

Litigation and Potential Claims

In February 2007, a complaint against the Company was filed in the Superior Court of New Jersey by Howard H. Fingert, M.D., a former employee of the Company. The complaint alleges, among other things, breach of contract as to the Company s stock option plan and as to a consulting agreement allegedly entered into by the Company and Dr. Fingert subsequent to termination of Dr. Fingert s employment with the Company, breach of implied covenant of good faith and fair dealing with respect to the Company s stock option plan and the alleged consulting agreement, promissory estoppel with respect to the exercise of stock options and provision of consulting services after termination of employment, and fraud and negligent misrepresentation with respect to the exercise of stock options and provision of consulting services after termination of employment. The complaint sought monetary damages, including punitive and consequential damages. The Company and Fingert settled this complaint in January 2009, and the Company accrued the settlement amount as of December 31, 2008. The settlement did not constitute an admission of guilt or liability.

In November 2007, a complaint against the Company was filed in the United States District Court for the District of New Jersey by Ridge Clearing & Outsourcing Solutions, Inc. The complaint alleges, among other things, that the Company caused or contributed to losses suffered by a Company shareholder which have been incurred by Ridge. The Company and Ridge settled this complaint in September 2008. The settlement did not constitute an admission of guilt or liability.

In September 2008, several shareholders of the Company, on behalf of themselves and all others similarly situated, filed a class action complaint against the Company, the Board of Directors, and certain of its executive officers in Superior Court of New Jersey, captioned Collins v. Warrell, Docket No. L-3046-08. The complaint alleges that in issuing convertible notes, the Board of Directors, and certain officers breached their fiduciary duties, and the Company aided and abetted the breach of fiduciary duty. Defendants filed a motion to dismiss on December 29, 2008. Plaintiffs opposition is due on or before February 13, 2009, and Defendants reply is due March 16, 2009. It is possible that oral argument on the motion will be held on March 20, 2009. Discovery has begun. The Company, Board of Directors and Officers deny these allegations and intend to vigorously defend this lawsuit.

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

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

In accordance with the terms of the convertible notes, the Company elected to pay interest due on the notes on December 9, 2008 in shares of its common stock to all noteholders where the issuance of the shares would not cause the noteholder to beneficially own more than 4.999% of the Company s outstanding common stock. Accordingly, the Company issued 4.0 million shares and $0.1 million to satisfy the interest payment on December 9, 2008.

Through December 31, 2008, holders of the convertible notes have voluntarily converted approximately $4.5 million of their notes, resulting in an issuance of 446.0 million shares of common stock.

No interest was paid for the twelve months ended December 31, 2007 and 2006, respectively.

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21. Selected Quarterly Financial Data (Unaudited)

	Quarter Ended			
2008	**Mar. 31**	**Jun. 30**	**Sep. 30**	**Dec. 31**
($ thousands, except per share data)				
Revenues	$ 117	$ 131	$ 115	$
Gross margin	92	102	89	(23)
Operating expenses	9,816	10,268	7,563	5,763
Other income/(expense), net	67	(728,198)	220,087	33,380
Net (loss)/income	(9,657)	(738,364)	212,613	29,569
Net (loss)/income per basic common share**	$ (0.29)	$ (20.10)	$ 5.78	$ 0.26
Net (loss)/income per diluted common share	$ (0.29)	$ (20.10)	$ 0.10	$ 0.02

	Quarter Ended			
2007	**Mar. 31**	**Jun. 30**	**Sep. 30**	**Dec. 31**
($ thousands, except per share data)				
Revenues	$ 94	$ 105	$ 115	$ 266
Gross margin	72	79	95	244
Operating expenses-net	5,875	8,594	8,046	3,601
Net loss	(5,605)	(8,235)	(7,732)	(1,748)
Net loss per common share:				
Basic and diluted	$ (0.21)	$ (0.27)	$ (0.25)	$ (0.06)

** Net (loss)/income per basic common share and net (loss)/income per diluted common share are calculated independently for each quarter and the full year based upon respective average shares outstanding. Therefore, the sum of the quarterly amounts does not equal the annual amounts reported.

The Company has experienced significant quarterly fluctuations in operating results and it expects that these fluctuations will continue.

Quarterly results in 2008 have been impacted by the accounting for the convertible note and warrant issued in June 2008, (see note 12 to the Consolidated Financial Statements).

During the fourth quarter of 2007, the Company revised its estimate of certain accrued expenses in the amount of $4.7 million, since such amount was no longer deemed probable.

Restatement

During the Company s year-end close, it was discovered that the $18.0 million escrow deposit relating to the insurance proceeds and the corresponding liability to settle a 2004 class action lawsuit against the Company should not have been included on the Company s consolidated balance sheets as of June 30, 2008 and September 30, 2008. As a result of the Court approving the settlement on May 27, 2008, and it being deemed final on June 27, 2008, the Company no longer had any interest in the insurance proceeds held in escrow or the associated liability.

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In lieu of filing amendments to the Reports on Form 10Q for the periods ended June 30, 2008 and September 30, 2008, the Company is providing the following unaudited balance sheet captions to show the effect of the restatement. There was no income statement effect resulting from the restatement and the only effect on the Company s statement of cash flows is a non-cash supplemental disclosure.

($ thousands)	Quarter Ended June 30, 2008 (restated)	Quarter Ended September 30, 2008 (restated)
Selected Balance Sheet Data:		
Current assets	$ 17,230	$ 9,450
Total assets	26,029	17,113
Current liabilities	767,403	12,827
Total liabilities	767,986	546,310

	(as previously reported)	(as previously reported)
Current assets	$ 35,230	$ 27,450
Total assets	44,029	35,113
Current liabilities	785,403	30,827
Total liabilities	785,986	564,310

22. Related Party Transactions

Dr. Daniel Von Hoff, one of Genta s directors, holds the position of Physician in Chief and Director of Translational Research at the Translational Genomics Research Institute (TGen), which provides preclinical testing services under direction of and by contract to Genta. During 2008, TGen performed services for which it was compensated by Genta in the amount of approximately $36,419. The Company believes that the payment of these services was on terms no less favorable than would have otherwise been provided by an unrelated party. In the opinion of the Board of Directors, Dr. Von Hoff s relationship with TGen will not interfere with Dr. Von Hoff s exercise of independent judgment in carrying out his responsibilities as a Director of Genta.

On June 5, 2008, the Company entered into a securities purchase agreement with certain institutional and accredited investors to place up to $40 million of senior secured convertible notes with such investors. On June 9, 2008, the Company placed $20 million of such notes in an initial closing. Each of 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 $1,950,000 and $300,000, 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.

23. Subsequent Event

From January 1, 2009 through February 4, 2009, holders of convertible notes have voluntarily converted approximately $4.6 million of their notes, resulting in an issuance of 459.6 million shares of common stock.

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

None.

Item 9A. ***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 our 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, 2008, 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, 2008.

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 July 16, 2008, following an extensive review and request-for-proposal process, the Audit Committee of the Company determined not to renew its engagement of Deloitte & Touche LLP as the Company s independent registered public accounting firm (auditors) and dismissed them as the Company s auditors. On July 16, 2008, the Audit Committee recommended and approved the appointment of Amper, Politziner & Mattia, LLP as the Company s auditors for the fiscal year ending December 31, 2008, commencing immediately.

On August 29, 2008, the Company filed a Form S-1 Registration Statement with the Securities and Exchange Commission for the offer and sale of the Company s common stock. The Form S-1 is not currently effective.

The Form S-1 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-1, these potential expenditures would relate to general corporate funding, completion of existing clinical trials, initiation of new studies, and acceleration of clinical research in our pipelines programs for tesetaxel and G4544, among other uses.

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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, 2009 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, 2009 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, 2009 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, 2009 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, 2009 pursuant to Regulation 14A.

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PART IV

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

Exhibit Number	Description of Document
1.1	Engagement Letter, dated December 6, 2004 between the Company and Rodman & Renshaw, LLC (incorporated by reference to the Company s Current Report on 8-K filed December 16, 2004, Commission File No. 0-19635)
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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Exhibit Number	Description of Document
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)
10.1	Non-Employee Directors 1998 Stock Option Plan, as amended and restated (incorporated by reference to Exhibit 99.B to the Company s Definitive Proxy Statement on Schedule 14A filed on April 30, 2004, Commission File No. 0-19635)
10.2	1998 Stock Incentive Plan, as amended and restated, effective March 19, 2004 (incorporated by reference to Exhibit 99.A to the Company s Definitive Proxy Statement on Schedule 14A filed on April 30, 2004, Commission File No. 0-19635)
10.3	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)
10.4	Asset Purchase Agreement, dated as of March 19, 1999, among JBL Acquisition Corp., JBL Scientific Incorporated and the Company (incorporated by reference to Exhibit 10.2 to the Company s Quarterly Report filed on Form 10-Q for the quarter ended March 31, 1999, Commission File No. 0-19635)
10.5	Stock Option Agreement, dated as of October 28, 1999, between the Company and Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.71 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
10.6	Letter Agreement, dated March 4, 1999, from SkyePharma Plc to the Company (incorporated by reference to Exhibit 10.72 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
10.7	Subscription Agreement executed in connection with the November 26, 2001 sale of common stock to Franklin Small-Mid Cap Growth Fund, Franklin Biotechnology Discovery Fund, and SF Capital Partners Ltd., and the November 30, 2001 sale of common stock to SF Capital Partners Ltd. (incorporated by reference to Exhibit 10.73 to the Company s Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)
10.8	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)
10.8A	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)

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Exhibit Number	Description of Document
10.9*	U.S. Commercialization Agreement dated April 26, 2002, by and between Genta Incorporated and Aventis Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended June, 30, 2002, Commission File No. 0-19635)
10.9A*	Amendment No. 1 dated March 14, 2003 to the U.S. Commercialization Agreement by and between Genta Incorporated and Aventis Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, Commission File No. 0-19635).
10.10*	Ex-U.S. Commercialization Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.2 to the Company s Quarterly Report on Form 10-Q for the quarter ended June, 30, 2002, Commission File No. 0-19635)
10.11*	Global Supply Agreement, dated April 26, 2002, by and among Genta Incorporated, Aventis Pharmaceuticals Inc. and Garliston Limited (incorporated by reference to Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.12*	Securities Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.4 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.13	Standstill and Voting Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.14	Registration Rights Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.6 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.15	Convertible Note Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.7 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.16*	5.63% Convertible Promissory Note, due April 26, 2009 (incorporated by reference to Exhibit 10.8 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.17*	Subordination Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.9 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.18*	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)
10.19*	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)

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Exhibit Number	Description of Document
10.19A*	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)
10.19AA*	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)
10.20	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)
10.21	Securities Purchase Agreement, dated December 14, 2004, among the Company, Riverview Group, LLC and Smithfield Fiduciary LLC (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on December 16, 2004, Commission File No. 0-19635)
10.22	Form of Subscription Agreement, dated August 5, 2005 among the Company and the purchasers of the Shares (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on August 8, 2005, Commission File No. 0-19635)
10.23	Placement Agency Agreement, dated August 5, 2005 between the Company and Piper Jaffray & Co. (incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K filed on August 8, 2005, Commission File No. 0-19635)
10.24	Form of Subscription Agreement, dated March 6, 2006 by and among the Company and the Purchasers (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on March 7, 2006, Commission File No. 0-19635)
10.25	Form of Placement Agent Agreement, dated March 6, 2006 by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K filed on March 7, 2006, Commission File No. 0-19635)
10.26	Form of Confirmation of Purchase, dated March 10, 2006 by and between the Company and certain Investors (incorporated by reference to Exhibit 10.34 to the Company s Annual Report on Form 10-K for the year ended December 31, 2005, Commission File No. 0-19635)
10.27	Form of Amendment No. 1 to Placement Agent Agreement, dated as of March 10, 2006 by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.35 to the Company s Annual Report on Form 10-K for the year ended December 31, 2005, Commission File No. 0-19635)
10.28	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)
10.29	1998 Stock Incentive Plan, as amended and restated, effective April 5, 2006 (incorporated by reference to the company s Definitive Proxy statement on Schedule 14A filed on April 28, 2006, Commission File No. 0-19635)
10.30	

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)

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Exhibit Number	Description of Document
10.31	Form of Securities Purchase Agreement, dated September 19, 2006, between the Company and each Purchaser (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, filed on September 20, 2006, Commission File No. 0-19635)
10.32	Form of Placement Agent Agreement, dated September 19, 2006, by and between the Company and Rodman & Renshaw LLC (incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K, filed on September 20, 2006, Commission File No. 0-19635)
10.33	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)
10.34	Form of Purchase Agreement by and among the Company and the Purchasers, dated March 13, 2007 (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, filed on March 14, 2007, Commission File No. 0-19635)
10.35	Placement Agent Agreement, by and between the Company and Rodman & Renshaw, LLC, dated February 23, 2007 (incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K, filed on March 14, 2007, Commission File No. 0-19635)
10.36	Form of Acquisition Bonus Program Agreement (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, filed on September 21, 2007, Commission File No. 0-19635)
10.37*	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)
10.38	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)
10.39	Form of Securities Purchase Agreement, dated February 8, 2008, by and between the Company each Purchaser (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, filed on February 11, 2008, Commission File No. 0-19635)
10.40	Placement Agent Agreement, dated February 8, 2008, by and between the Company and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K, filed on February 11, 2008, Commission File No. 0-19635)
10.41	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)
10.42	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)
10.43	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)

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Exhibit Number	Description of Document
10.44	Amendment to the Lease Agreement, dated May 27, 2008, between the Company and The Connell Company (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)
10.45*	Supply Agreement, dated May 1, 2008, between the Company and Avecia Biotechnology (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)
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
23.2	Consent of Deloitte & Touche 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.

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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 13th day of February 2009.

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)	February 13, 2009
/s/ GARY SIEGEL Gary Siegel	Vice President, Finance (principal financial and accounting officer)	February 13, 2009
/s/ MARTIN J. DRISCOLL Martin J. Driscoll	Director	February 13, 2009
/s/ CHRISTOPHER P. PARIOS Christopher P. Parios	Director	February 13, 2009
/s/ DANIEL D. VON HOFF, M.D. Daniel D. Von Hoff, M.D.	Director	February 13, 2009
/s/ DOUGLAS G. WATSON Douglas G. Watson	Director	February 13, 2009

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Exhibit Number	Description of Document	Sequentially Numbered Pages
1.1	Engagement Letter, dated December 6, 2004 between the Company and Rodman & Renshaw, LLC (incorporated by reference to the Company s Current Report on 8-K filed December 16, 2004, Commission File No. 0-19635)	
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)	

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Exhibit Number	Description of Document	Sequentially Numbered Pages
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)	
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)	
10.1	Non-Employee Directors 1998 Stock Option Plan, as amended and restated (incorporated by reference to Exhibit 99.B to the Company s Definitive Proxy Statement on Schedule 14A filed on April 30, 2004, Commission File No. 0-19635)	
10.2	1998 Stock Incentive Plan, as amended and restated, effective March 19, 2004 (incorporated by reference to Exhibit 99.A to the Company s Definitive Proxy Statement on Schedule 14A filed on April 30, 2004, Commission File No. 0-19635)	
10.3	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)	
10.4	Asset Purchase Agreement, dated as of March 19, 1999, among JBL Acquisition Corp., JBL Scientific Incorporated and the Company (incorporated by reference to Exhibit 10.2 to the Company s Quarterly Report filed on Form 10-Q for the quarter ended March 31, 1999, Commission File No. 0-19635)	
10.5	Stock Option Agreement, dated as of October 28, 1999, between the Company and Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.71 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
10.6		

Letter Agreement, dated March 4, 1999, from SkyePharma Plc to the Company (incorporated by reference to Exhibit 10.72 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)

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Exhibit Number	Description of Document	Sequentially Numbered Pages
10.7	Subscription Agreement executed in connection with the November 26, 2001 sale of common stock to Franklin Small-Mid Cap Growth Fund, Franklin Biotechnology Discovery Fund, and SF Capital Partners Ltd., and the November 30, 2001 sale of common stock to SF Capital Partners Ltd. (incorporated by reference to Exhibit 10.73 to the Company s Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)	
10.8	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)	
10.8A	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)	
10.9*	U.S. Commercialization Agreement dated April 26, 2002, by and between Genta Incorporated and Aventis Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended June, 30, 2002, Commission File No. 0-19635)	
10.9A*	Amendment No. 1 dated March 14, 2003 to the U.S. Commercialization Agreement by and between Genta Incorporated and Aventis Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, Commission File No. 0-19635).	
10.10*	Ex-U.S. Commercialization Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.2 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.11*	Global Supply Agreement, dated April 26, 2002, by and among Genta Incorporated, Aventis Pharmaceuticals Inc. and Garliston Limited (incorporated by reference to Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.12*	Securities Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.4 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.13	Standstill and Voting Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.14	Registration Rights Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to	

Exhibit 10.6 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)

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Exhibit Number	Description of Document	Sequentially Numbered Pages
10.15	Convertible Note Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.7 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.16*	5.63% Convertible Promissory Note, due April 26, 2009 (incorporated by reference to Exhibit 10.8 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.17*	Subordination Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.9 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.18*	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)	
10.19*	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)	
10.19A*	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)	
10.19AA*	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)	
10.20	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)	
10.21	Securities Purchase Agreement, dated December 14, 2004, among the Company, Riverview Group, LLC and Smithfield Fiduciary LLC (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on December 16, 2004, Commission File No. 0-19635)	
10.22	Form of Subscription Agreement, dated August 5, 2005 among the Company and the purchasers of the Shares (incorporated by reference	

to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on August 8, 2005, Commission File No. 0-19635)

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Exhibit Number	Description of Document	Sequentially Numbered Pages
10.23	Placement Agency Agreement, dated August 5, 2005 between the Company and Piper Jaffray & Co. (incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K filed on August 8, 2005, Commission File No. 0-19635)	
10.24	Form of Subscription Agreement, dated March 6, 2006 by and among the Company and the Purchasers (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on March 7, 2006, Commission File No. 0-19635)	
10.25	Form of Placement Agent Agreement, dated March 6, 2006 by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K filed on March 7, 2006, Commission File No. 0-19635)	
10.26	Form of Confirmation of Purchase, dated March 10, 2006 by and between the Company and certain Investors (incorporated by reference to Exhibit 10.34 to the Company s Annual Report on Form 10-K for the year ended December 31, 2005, Commission File No. 0-19635)	
10.27	Form of Amendment No. 1 to Placement Agent Agreement, dated as of March 10, 2006 by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.35 to the Company s Annual Report on Form 10-K for the year ended December 31, 2005, Commission File No. 0-19635)	
10.28	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)	
10.29	1998 Stock Incentive Plan, as amended and restated, effective April 5, 2006 (incorporated by reference to the company s Definitive Proxy statement on Schedule 14A filed on April 28, 2006, Commission File No. 0-19635)	
10.30	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)	
10.31	Form of Securities Purchase Agreement, dated September 19, 2006, between the Company and each Purchaser (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, filed on September 20, 2006, Commission File No. 0-19635)	
10.32	Form of Placement Agent Agreement, dated September 19, 2006, by and between the Company and Rodman & Renshaw LLC (incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K, filed on September 20, 2006, Commission File No. 0-19635)	
10.33	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)

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Exhibit Number	Description of Document	Sequentially Numbered Pages
10.34	Form of Purchase Agreement by and among the Company and the Purchasers, dated March 13, 2007 (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, filed on March 14, 2007, Commission File No. 0-19635)	
10.35	Placement Agent Agreement, by and between the Company and Rodman & Renshaw, LLC, dated February 23, 2007 (incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K, filed on March 14, 2007, Commission File No. 0-19635)	
10.36	Form of Acquisition Bonus Program Agreement (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, filed on September 21, 2007, Commission File No. 0-19635)	
10.37*	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)	
10.38	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)	
10.39	Form of Securities Purchase Agreement, dated February 8, 2008, by and between the Company each Purchaser (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K, filed on February 11, 2008, Commission File No. 0-19635)	
10.40	Placement Agent Agreement, dated February 8, 2008, by and between the Company and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K, filed on February 11, 2008, Commission File No. 0-19635)	
10.41	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)	
10.42	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)	
10.43	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)	
10.44	Amendment to the Lease Agreement, dated May 27, 2008, between the Company and The Connell Company (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	Sequentially Numbered Pages
10.45*	Supply Agreement, dated May 1, 2008, between the Company and Avecia Biotechnology (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)	
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	
23.2	Consent of Deloitte & Touche 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.