GENTA INC DE/
Form 10-K
March 30, 2011

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, 2010

Or

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

For the Transition Period from _____ to _____

Commission File Number 000-19635

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

Delaware	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: None

Securities registered pursuant to Section 12(g) 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	

Indicate by check mark if a registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yeso Nox

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the

Act. Yeso Nox

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. Yesx Noo

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

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

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

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $29,131,402 as of June 30, 2010 (the last business day of the registrant's most recently completed second fiscal quarter).

As of March 30, 2011, the registrant had 53,499,182 shares of Common Stock outstanding.

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

- the Company's financial projections;
- the Company's projected cash flow requirements and estimated timing of sufficient cash flow;
- the Company's current and future license agreements, collaboration agreements, and other strategic alliances;
- the Company's ability to obtain necessary regulatory approval for Genasense® (oblimersen sodium) Injection from the U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA);
- the safety and efficacy of the Company's products;
- the timing of commencement and completion of clinical trials;
- the Company's ability to develop, manufacture, license and sell its products or product candidates;
- the Company's ability to enter into and successfully execute license and collaborative agreements, if any;
- the adequacy of the Company's capital resources and cash flow projections, and the Company's ability to obtain sufficient financing to maintain the Company's planned operations, or the Company's risk of bankruptcy;
- the adequacy of the Company's patents and proprietary rights;
- the impact of litigation that has been brought against the Company and its officers and directors and any proposed settlement of such litigation; and
- the other risks described under "Certain Risk Factors".

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

We make available free of charge on our internet website (http://www.genta.com) our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. The content on 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.

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 the drug, Genasense®); and “Small Molecules” (which includes our marketed product, Ganite®, and tesetaxel and oral gallium-containing compounds).

Genta was a pioneering company in the development of modified DNA and RNA compounds (or oligonucleotides) as potential human medicines. 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 blocks 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 have developed the drug primarily as a means of amplifying the cytotoxic effects of other anticancer treatments.

Our principal goal is to secure regulatory approval for the marketing of our products. For example, Genasense® has been studied in combination with a wide variety of anticancer drugs in a number of different cancer indications. We have reported results from randomized trials of Genasense® in various diseases. We have been especially interested in the development of Genasense® in three specific diseases: melanoma, chronic lymphocytic leukemia, referred to herein as CLL and non-Hodgkin’s lymphoma, referred to herein as NHL.

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

As noted, AGENDA was designed based on data obtained from a similarly designed Phase 3 trial that was published in 2006. Results from that study showed that treatment with Genasense® plus dacarbazine compared with dacarbazine alone was associated with a statistically significant increase in the secondary endpoints of overall response, CR, durable response and PFS. However, the primary endpoint of overall survival approached but did not reach statistical significance (P=0.077) in the entire “intent-to-treat” population. Further analysis of this trial showed that there was a significant treatment interaction effect related to blood levels of LDH. Survival was significantly superior for patients with a non-elevated LDH who received Genasense® (P=0.018). Moreover, this benefit was particularly noteworthy for patients whose baseline LDH did not exceed 80% of the upper limit of normal. LDH had also been previously described by others as the single most important prognostic factor in advanced melanoma. Thus, the AGENDA trial sought to prospectively confirm these observations of potentially improved survival in this biomarker-defined patient population.

A total of 315 patients were enrolled into AGENDA. In October 2009, we announced that AGENDA did not show a statistically significant increase in its co-primary endpoint of PFS, or for secondary endpoints of overall response rate and disease control rate (which includes complete and partial responses, plus stable disease greater than 3 months duration). However, the differences in PFS, overall response and disease control all numerically favored the group that received Genasense®.

As prospectively specified, AGENDA was statistically powered to detect an improvement in overall survival, which is a late endpoint. At the time the early endpoints of the study were released (i.e. PFS response rate), the data on late endpoints of survival and durable response were too early to analyze. An analysis for futility, which was defined as greater than 50% conditional power to observe a statistically significant increase under the prospectively assumed hazard ratio of 0.69, was conducted for the co-primary endpoint of overall survival. AGENDA passed this futility analysis, and an Independent Data Monitoring Committee recommended that the trial continue to completion. The safety profile in patients who received Genasense® plus dacarbazine in AGENDA was consistent with prior studies. Followup of all patients for survival will terminate on March 31, 2011. We project that the survival information will be available shortly thereafter. If the final analysis for overall survival is statistically significant, we believe that Genasense® could receive regulatory approval for marketing in this indication. Under such circumstance, we would confer with the FDA regarding resubmission of our New Drug Application, or NDA, regarding approval for treatment of patients with advanced melanoma.

We have conducted other trials of Genasense® in melanoma, including a Phase 2 trial of Genasense® plus chemotherapy consisting of Abraxane® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus temozolomide (Temodar®). In this trial, we examined whether different dosing regimens could be used to improve convenience. We project that data from that trial will be presented in the second quarter of 2011.

We have also conducted extensive trials in patients with advanced CLL. We completed a randomized Phase 3 trial in 241 patients with relapsed or refractory CLL who were treated with fludarabine and cyclophosphamide, also known as Flu/Cy, with or without Genasense®. The trial achieved its primary endpoint: a statistically significant increase (17% vs. 7%; P=0.025) in the proportion of patients who achieved a complete response, or CR, defined as a complete or nodular partial response, also known as PR. Patients who achieved this level of response also experienced disappearance of predefined disease symptoms. A key secondary endpoint, duration of CR, was also significantly longer for patients treated with Genasense® (median exceeding 36+ months in the Genasense® group, versus 22 months in the chemotherapy-only group).

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

We submitted a NDA to the FDA that proposed the use of Genasense® in combination with Flu/Cy for the treatment of patients with relapsed or refractory CLL who had previously received fludarabine. However, we received a "non-approvable" notice from the FDA in December 2006 for this NDA. Our appeals of this decision to the FDA were unsuccessful.

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

In March 2008, we obtained an exclusive worldwide license for tesetaxel from Daiichi Sankyo Company, Limited. Tesetaxel is a novel taxane compound that is taken by mouth. Tesetaxel has completed Phase 2 trials in a number of cancer types, and the drug has shown definite evidence of antitumor activity in gastric cancer and breast cancer. Tesetaxel also appears to be associated with a lower incidence of peripheral nerve damage, a common side effect of taxanes that limits the maximum amount of these drugs that can be given to patients.

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

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

The FDA has also designated tesetaxel as an Orphan Drug for treatment of patients with advanced gastric cancer and for patients with advanced melanoma. Orphan Drug designation is designed to facilitate the development of new drugs that are intended to treat diseases that affect a small number of patients. Orphan Drug designation for tesetaxel in gastric cancer was also granted by the EMA in October 2010. We routinely file for both Fast Track and Orphan Drug designations, or similar designations in applicable territories for diseases that fulfill regulatory requirements for such designation.

Our third pipeline project consists of the development of an oral gallium-containing compound. We completed a single-dose Phase 1 clinical study of one such compound (known as G4544[a]). We are currently developing additional experimental compounds of this class with the expectation that we can identify a lead compound for further clinical testing. Some of these compounds are currently being tested in animals to evaluate oral absorption.

If we are able to identify a clinically and commercially acceptable formulation of an oral gallium-containing compound, we believe a drug of this class may also be broadly useful for treatment of other diseases associated with accelerated bone loss. These illnesses include hypercalcemia, bone metastases, Paget's disease and osteoporosis. In addition, new uses of gallium-containing compounds have been identified for treatment of certain infectious diseases. We have supported research conducted by certain academic institutions by providing clinical supplies of our gallium-containing drugs for patients with cystic fibrosis who have severe infections.

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

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 Genasense® as a preferred chemosensitizing drug for use in combination with other cancer therapies in melanoma and other cancers;

- Secure a “first-to-market” position for our oral taxane, tesetaxel;

- Develop a first-in-class oral gallium-containing compound for skeletal diseases and other uses;

- Partner with other companies to defer part of the expenses associated with clinical development of our products; 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. We remain committed to research and development of our key compound Genasense® in cancer medicine, commonly known as oncology. Genasense® involves the use of DNA-based 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, or 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 ability to bind to the intended target. Some of these advanced technologies may be incorporated into future products.

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

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

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

Genasense®

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

Overview of Preclinical and Clinical studies of Genasense®

Preclinical Studies

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

Clinical Studies

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

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

In 2007, we began a new Phase 1 trial of Genasense® administered as an IV infusion over 1-2 hours. This trial showed that the maximally tolerable dose was 900 mg, which can be administered twice per week. Pharmacokinetic and pharmacodynamic data from this trial suggest that prior requirements for treatment by continuous IV infusion can be eliminated by these more convenient dosing regimens.

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Tesetaxel

In March 2008, we obtained an exclusive worldwide license for tesetaxel from Daiichi Sankyo Company, Limited. Tesetaxel is a novel taxane compound that is taken by mouth. Tesetaxel has completed Phase 2 trials in a number of cancer types, and the drug has shown definite evidence of antitumor activity in gastric cancer and breast cancer. Tesetaxel also appears to be associated with a lower incidence of peripheral nerve damage, a common side effect of taxanes that limits the maximum amount of these drugs that can be given to patients.

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Tesetaxel Background Information

Tesetaxel is a structurally novel oral semi-synthetic taxane. Taxanes, such as paclitaxel (Taxol®) and docetaxel (Taxotere®), are mainstays of modern anticancer therapy. These drugs are believed to kill cancer cells by disrupting critical proteins that maintain the structure of cancer cells. More recent research suggests that they may also disrupt the blood supply to malignant tumors (i.e., an "antiangiogenic" effect). Because of their antitumor efficacy, taxanes are the most widely used class of drugs for treatment of patients with advanced cancer.

Certain taxanes have been approved by the FDA for the treatment of breast, lung, ovarian, gastric, and prostate cancers. However, all currently approved taxanes require IV infusion under close medical supervision due to a high level of toxicity. For example, both paclitaxel and docetaxel can cause severe, occasionally fatal hypersensitivity reactions, which require pre-medication with corticosteroids and antihistamines to ameliorate their severity. Other serious reactions associated with taxanes include long-lasting damage to peripheral nerves (neuropathy).

With tesetaxel, we hope to provide patients with an oral taxane that retains the broad anticancer activity of the IV drugs, while providing substantially improved safety. Tesetaxel is administered by mouth, which obviates the risk of taxane-related hypersensitivity reactions and the need for associated premedications and extended medical and nursing observation. Oral dosing provides a high level of convenience for patients, physicians and nurses, and increases dosing flexibility.

Tesetaxel Mechanisms of Action and Preclinical Studies

Tesetaxel stabilizes cytoskeletal structures known as microtubules. This effect induces potent cancer killing effects in a wide range of tumor cell types. Microtubule stabilization occurs when tesetaxel binds the beta-tubulin subunit in

assembled microtubules, thus “locking” them in place.

Preclinical studies have shown that tesetaxel inhibited tubulin depolymerization, which resulted in the inhibition of mitosis by arresting tumor cells at G2/M phase. The cytotoxic activity of tesetaxel against various types of human tumor cell lines was about 10-fold and 3-fold greater than paclitaxel and docetaxel, respectively. In particular, tesetaxel exhibited much greater cytotoxicity against multidrug-resistant cell lines that constitutively over-expressed a substance know as the P-glycoprotein, or Pgp. Pgp acts as a pump that can rapidly eliminate drugs such as taxanes from inside cancer cells, thereby markedly reducing their effectiveness. Over-expression of Pgp is a major cause of so-called “multidrug resistance”, and high levels of Pgp in cancer cells are linked to a lack of clinical sensitivity to standard taxanes. However, tesetaxel is not susceptible to Pgp, and as such can be used in cancers that are generally considered unresponsive to standard taxanes. Experimentally, the anti-tumor activity of tesetaxel against Pgp-expressing cells was greater than paclitaxel and docetaxel both in vitro and in vivo.

Tesetaxel Clinical Development

Tesetaxel has already been studied in a number of Phase 1 and Phase 2 studies, encompassing more than 300 patients. Preliminary activity has been observed in patients with advanced gastric cancer and advanced breast cancer. In these studies, the most common side-effect was neutropenia, a hematological disorder characterized by a low number of white blood cells. We have identified priority indications for clinical development, including gastric, prostate, breast and bladder cancer, and we have initiated new or confirmatory trials in each of these diseases.

We believe that gastric cancer may represent the best opportunity for regulatory approval. Accordingly, we have designed a prospective, randomized, Phase 3 trial, and we have discussed this trial with regulatory authorities in the United States, Europe, and Japan. Pending completion of these discussions, adequacy of funding, and other matters, we believe this trial can be initiated in the second half of 2011. A positive result from this trial that yields regulatory approval may enable us to commercially launch tesetaxel by 2014.

Ganite®

Ganite® as a Treatment for Cancer-Related Hypercalcemia

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

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

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

Other Pipeline Products and Technology Platforms

Oral Gallium-Containing Compounds

We have sought to develop novel formulations of gallium-containing compounds that can be taken orally and that will have extended patent protection. Such formulations might be useful for diseases in which long-term low-dose therapy is deemed desirable, such as bone metastases, Paget's disease and osteoporosis. A number of candidate formulations have been developed in this collaboration. In August 2007, we submitted an Investigational New Drug Application, or IND, to the Endocrinologic and Metabolic Drugs Division of the FDA for an experimental compound known as G4544. G4544 is a new tablet formulation that enables oral absorption of the active ingredient contained in Ganite®. We were not satisfied with results obtained with G4544 and have decided to pursue further discovery work. Several patents related to new gallium-containing products have been filed or issued. 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.

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 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.

We have licensed several U.S. patents relating to the composition and methods of use related to Genasense® from the University of Pennsylvania. Related ex-U.S. patent applications have been issued or are pending. The most important of these "composition of matter" patents in the U.S. expires in 2015. We believe this patent may be eligible for up to 5 years of extension under Waxman-Hatch provisions, (i.e. to 2020). We also own U.S. patent applications relating to methods of using Genasense® that are expected to expire in 2020 and 2026, all of which have corresponding foreign patent applications and granted patents.

We licensed certain rights licensed from the U.S. NIH that covered phosphorothioate antisense oligonucleotides. However, this patent expired in 2010. We did not pay royalties on sales from any products under this patent and we do not believe its expiration will have a material adverse impact on our overall intellectual property position for Genasense®.

Tesetaxel, its potential uses, composition, and methods of manufacturing are covered under a variety of patents licensed exclusively from Daiichi Sankyo Company, Limited. 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. We have also filed several patents on manufacturing methods and compositions of intermediate compounds formed during manufacturing processes.

The principal patent covering the use of Ganite® for its approved indication, including extensions expired in April 2005. We have filed several applications on novel gallium-containing compounds. At least two of these patents have been issued in the U.S.

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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.

In addition, there may be patents which are unknown to us and which may block our ability to make, use or sell our products. We may be forced to defend ourselves against charges of infringement or we may need to obtain expensive licenses to continue our business. See the Risk Factor below, entitled “We may be unable to obtain or enforce patents, other proprietary rights and licenses to protect our business; we could become involved in litigation relating to our patents or licenses that could cause us to incur additional costs and delay or prevent our introduction of new drugs to market”.

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

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

License Agreements

Our license agreement with the University of Pennsylvania, dated August 1, 1991, as most recently amended on October 23, 2003, has a term for the duration of our royalty obligations to the University of Pennsylvania. We are required to pay royalties to the University of Pennsylvania until the later of 12 years from (i) the date of first commercial sale of licensed product (which has not yet occurred) or (ii) the date of expiration of the last to expire licensed patent with a valid claim covering the licensed product (which is currently scheduled to expire in 2015). We may terminate this agreement upon notice to the University of Pennsylvania. The University of Pennsylvania may

terminate this agreement upon an event of default that we have not cured. The royalty rate that we may be obligated to pay to the University of Pennsylvania ranges from 2% to 4% of the net sales price, with an additional royalty for compensation we receive from any sublicense of our rights under this agreement. We also may be required to pay certain milestone payments and certain additional fees in the aggregate of $4,770,000 contingent upon certain preclinical, clinical and regulatory events. The aggregate payments we made to the University of Pennsylvania under this agreement from the date of execution of the agreement through December 31, 2010 are approximately $1.4 million.

Our license agreement with Daiichi Sankyo Company, Limited, dated March 7, 2008, has a term that continues until when we have no remaining royalty payment obligations to Daiichi Sankyo. Either party may terminate the agreement as a result of a material breach by the other party. The royalty rate that we may be obligated to pay to Daiichi Sankyo ranges in the low to mid teens of aggregate annual net sales, on a sliding scale depending on sales volume. We are required to pay royalties to Daiichi Sankyo on a country-by-country basis until the later of (i) 10 years from the first commercial sale of such product in such country (which has not yet occurred) or (ii) expiration of the last to expire issued patent (or pending patent application) within the Daiichi Sankyo patents with a valid claim covering such product in such country (which is currently scheduled to expire in 2020). We also may be required to pay certain milestone payments in the aggregate of $68,000,000 contingent upon certain clinical thresholds and a number of regulatory approvals. The aggregate payments we made to Daiichi Sankyo under the agreement from the date of execution of the agreement through December 31, 2010 were $3.5 million.

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 $10.0 million during the year ended December 31, 2010 and $15.1 million during the year ended December 31, 2009.

Sales and Marketing

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

On March 6, 2007, we entered into a distribution and supply agreement with IDIS Limited (a privately owned company based in the United Kingdom). The term of the agreement lasts for three years with automatic one-year renewals unless adequate notice of intent not to renew is provided by either party. This agreement was renewed pursuant to its terms through March 6, 2012. The agreement will continue on a product-by-product and country-by-country basis until that product has been granted a marketing authorization for an indication within that country of the territory and we have provided written notice of termination for such product in that country. We may terminate this agreement upon notice to IDIS. Either party may terminate the agreement (i) as a result of a material breach by the other party, (ii) upon the other party's bankruptcy, insolvency, liquidation, or similar events, (iii) upon any distrait, execution or other process levied or enforced against the property of the other party, or (iv) in the event the other party ceases, or threatens to cease to carry on its business. There are no minimum purchase requirements, but we pay IDIS certain scheduled pricing for product that we order. The amount we pay to IDIS is reflected in our results of operations for each respective period.

Manufacturing and Raw Materials

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

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®. Avecia was recently purchased by Nitto Denko Corporation, Japan's leading diversified materials manufacturer. At present, we do not believe this transfer of ownership will materially affect the supply of Genasense®.

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

For tesetaxel, we have purchased all remaining quantities of bulk drug substance and finished capsules from Daiichi Sankyo Company, Limited. This quantity totals approximately 11,000 drug doses, an amount that we project will be sufficient for our projected needs for at least the next 2 years. We are currently evaluating new suppliers of both bulk drug substance and finished goods with the intent of completely replacing the supply chain that was previously used to manufacture this compound.

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®, tesetaxel and Ganite® and to meet future customer demand.

Human Resources

As of December 31, 2010, we had 22 employees, 8 of whom hold doctoral degrees. As of that date, there were 14 employees engaged in research, development and other technical activities and 8 in administration. None of our employees are represented by a union. Most of our management and professional employees have had prior experience and positions with pharmaceutical and biotechnology companies. We believe we maintain satisfactory relations with our employees and have not experienced interruptions of operations due to employee relations issues.

Government Regulation

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

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

Clinical trials are generally categorized into four phases.

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

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

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

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

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

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

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

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

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

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

Competition

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

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

Our competitive position also depends upon our ability to attract and retain qualified personnel, obtain patent protection, or otherwise develop proprietary products or processes and secure sufficient capital resources for the often-substantial period between technological conception and commercial sales.

Item 1A. Risk Factors

You should carefully consider the following risks and all of the other information set forth in this Form 10-K before deciding to invest in shares of our common stock. The risks described below are not the only ones facing us. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

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

Risks Related to Our Business

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

Our operations to date have required significant cash expenditures. Our future capital requirements will depend on the results of our research and development activities, preclinical studies and clinical trials, competitive and technological advances, and regulatory activities of the FDA and other regulatory authorities. In order to commercialize our products, seek new product candidates and continue our research and development programs, we will need to raise additional funds. We have historically financed our activities from the sale of shares of common stock, convertible notes, warrants and proceeds from partnerships with other companies.

Presently, with no further financing, we project that we will run out of funds in the third quarter of 2011. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase additional notes with similar terms. We currently do not have any additional financing in place. If we are unable to raise additional funds, we could be required to reduce our spending plans, reduce our workforce, license one or more of our products or technologies that we would otherwise seek to commercialize ourselves, or sell certain assets. There can be no assurance that we can obtain financing, if at all, on terms acceptable to us.

We will require additional cash in order to maximize the commercial opportunity and continue clinical development of our product candidates. Alternatives available to us to sustain our operations include collaborative agreements, equity financing, debt and other financing arrangements with potential corporate partners and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available to us on favorable terms, if at all.

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

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

- our ability to demonstrate clinically that our products are useful and safe in particular indications;
- delays or refusals by regulatory authorities in granting marketing approvals;
- our limited financial resources and sales and marketing experience relative to our competitors;
- actual and perceived differences between our products and those of our competitors;
- the availability and level of reimbursement for our products by third-party payors;
- incidents of adverse reactions to our products;
- side effects or misuse of our products and the unfavorable publicity that could result; and
- the occurrence of manufacturing, supply or distribution disruptions.

We cannot assure you that our product candidates will receive FDA or EMA approval. For example, the recent results in the Phase 3 AGENDA trial of Genasense® in advanced melanoma were not sufficient to submit a NDA in the U.S., and our prior regulatory applications for Genasense® in melanoma were unsuccessful. Our NDA for Genasense® plus chemotherapy in patients with relapsed or refractory CLL was also unsuccessful.

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

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

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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, 2010 with respect to this uncertainty. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of the common shares of our stock and we may have a more difficult time obtaining financing.

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

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

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

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

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

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

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

- subjects may drop out of our clinical trials;

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

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

In October 2009, we announced that AGENDA did not show a statistically significant increase in its co-primary endpoint of PFS, or for secondary endpoints of overall response rate and disease control rate (which includes complete and partial responses, plus stable disease greater than 3 months duration).

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

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

We have a significant amount of debt. As of December 31, 2010, we had a face amount of debt outstanding of $29.8 million, consisting of the face value of 2008 Notes of $1.9 million, the face value of April 2009 Notes of $0.2 million, the face value of July 2009 Notes issued in July 2009 of $36 thousand, the face value of the September 2009 Notes and July 2009 Notes issued in September 2009 of $2.5 million and the face value of March 2010 Notes of $25.1 million.

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

- making it more difficult for us to meet our payment and other obligations under our outstanding debt;
- resulting in an event of default if we fail to comply with the restrictive covenants contained in our debt agreements, which could result in all of our debt becoming due and payable;
- limiting our flexibility in planning for, or reacting to, and increasing our vulnerability to, changes in our business, the industry in which we operate and the general economy; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or are less leveraged.

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

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

Our convertible notes contain various provisions regarding the adjustment of their applicable conversion prices. Conversion price resets were effected on October 9, 2010, January 1, 2011 and March 12, 2011. There are no other scheduled adjustments to the conversion prices of our convertible notes.

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

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

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

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

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

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

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

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.

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, 2010, we have incurred a cumulative net deficit of $1,197.7 million. Achieving profitability is unlikely unless one or more of our product candidates is approved by the FDA or EMA for commercial sale in one or more indications.

Our business depends heavily on a small number of products.

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

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

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

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

- obtain U.S. and foreign patent or other proprietary protection for our technologies, products and processes;
- preserve trade secrets; and
- operate without infringing the patent and other proprietary rights of third parties.

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

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

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

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

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

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

We have devoted considerable resources to the development of potential antisense pharmaceutical products such as Genasense®, based upon oligonucleotide technology. Genasense® is our only antisense product to have been tested in humans. Tesetaxel has completed several clinical Phase 2 studies, and we plan to conduct additional clinical studies with the drug. Our products may prove to have undesirable and unintended side effects or other characteristics that may prevent our obtaining FDA or foreign regulatory approval for any indication. In addition, it is possible that research and discoveries by others will render our products obsolete or noncompetitive. Similar types of limitations apply to all our product candidates.

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

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

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

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

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

The FDA in the United States and regulatory authorities in international markets impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve lengthy and detailed preclinical and clinical testing and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more depending upon the type, complexity and novelty of the product. We cannot apply for regulatory approval to market any of our products under development until preclinical and clinical trials on the product are successfully completed. Several factors could prevent successful completion or cause significant delays of these trials, including an inability to enroll the required number of patients or failure to

demonstrate adequately that the product is safe and effective for use in humans. If safety concerns develop, the FDA or international regulatory authorities could stop our trials before completion. We may not market or sell any product for which we have not obtained regulatory approval.

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

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

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

In addition to product approval, any facility in which our product candidates are manufactured or tested for its ability to meet required specifications must be approved by the FDA and/or the EMA before a commercial product can be manufactured. Failure of such a facility to be approved could delay the approval of our product candidates.

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

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

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

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

material adverse effect on our business, results of operations and financial condition. Such failures or restrictions may also prompt regulatory recalls of one or more of our products, which could have material and adverse effects on our business.

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

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

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

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

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

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

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

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

- difficulties in assimilating the operations and personnel of acquired companies;

- diversion of our management's attention from ongoing business concerns;

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

- additional expense associated with amortization of acquired assets;

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

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

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

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

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

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

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

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

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

Risks Related to Outstanding Litigation

The outcome of and costs relating to pending litigation are uncertain.

In September 2008, several of our stockholders, on behalf of themselves and all others similarly situated, filed a class action complaint against us, our Board of Directors, and certain of our executive officers in Superior Court of New Jersey, captioned Collins v. Warrell, Docket No. L-3046-08. The complaint alleged that in issuing convertible notes in June 2008, our Board of Directors, and certain officers breached their fiduciary duties, and we aided and abetted the breach of fiduciary duty. On March 20, 2009, the Superior Court of New Jersey granted our motion to dismiss the class action complaint and dismissed the complaint with prejudice. On April 30, 2009, the plaintiffs filed a notice of appeal with the Appellate Division. On May 13, 2009, the plaintiffs filed a motion for relief from judgment based on a claim of new evidence, which was denied on June 12, 2009. The plaintiffs also asked the Appellate Division for a temporary remand to permit the Superior Court judge to resolve the issues of the new evidence plaintiffs sought to raise and the Appellate Division granted the motion for temporary remand. Following the briefing and a hearing, the Superior Court denied the motion for relief from judgment on August 28, 2009. Thus, this matter proceeded in the Appellate Division. Plaintiffs' brief before the Appellate Division was filed on October 28, 2009, and our responsive brief was filed on January 27, 2010. The plaintiffs' reply brief was filed on March 15, 2010. We are currently awaiting a decision from the Appellate Division on this matter. At this time, we cannot estimate when the Appellate Division will rule on the appeal. We intend to continue our vigorous defense of this matter.

Risks Related to Our Common Stock

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

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

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

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

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

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

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

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

Our stock price is volatile.

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

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

At December 31, 2010, we had 3.3 million shares of common stock outstanding and 311.4 million shares reserved for the conversion of our outstanding convertible preferred stock, convertible notes, warrants, debt warrants, outstanding restricted stock units and shares issuable upon the exercise of purchase rights of our noteholders. Future sales of shares of our common stock by existing stockholders, holders of preferred stock who might convert such preferred stock into common stock, holders of convertible notes who might convert such convertible notes into common stock and option and warrant holders who may exercise their options and warrants to purchase common stock also could adversely affect the market price of our common stock. Moreover, the perception that sales of substantial amounts of our common stock might occur could adversely affect the market price of our common stock.

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

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

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

number of short sales generally causes the price of common stock to decline, in part because it indicates that a number of market participants are taking a position that will be profitable only if the price of the common stock declines.

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

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

Item 1B. Unresolved Staff Comments

None

Item 2. Properties

We lease approximately 25,000 square feet of office space in Berkeley Heights, New Jersey. Our annual rental costs for this space are approximately $0.7 million. Our lease on this space terminates in August 2015.

Item 3. Legal Proceedings

In September 2008, several of our stockholders, on behalf of themselves and all others similarly situated, filed a class action complaint against us, our Board of Directors, and certain of our executive officers in Superior Court of New Jersey, captioned Collins v. Warrell, Docket No. L-3046-08. The complaint alleged that in issuing convertible notes in June 2008, our Board of Directors, and certain officers breached their fiduciary duties, and we aided and abetted the breach of fiduciary duty. On March 20, 2009, the Superior Court of New Jersey granted our motion to dismiss the class action complaint and dismissed the complaint with prejudice. On April 30, 2009, the plaintiffs filed a notice of appeal with the Appellate Division. On May 13, 2009, the plaintiffs filed a motion for relief from judgment based on a claim of new evidence, which was denied on June 12, 2009. The plaintiffs also asked the Appellate Division for a temporary remand to permit the Superior Court judge to resolve the issues of the new evidence plaintiffs sought to raise and the Appellate Division granted the motion for temporary remand. Following the briefing and a hearing, the Superior Court denied the motion for relief from judgment on August 28, 2009. Thus, this matter proceeded in the Appellate Division. Plaintiffs' brief before the Appellate Division was filed on October 28, 2009, and our responsive brief was filed on January 27, 2010. The plaintiffs’ reply brief was filed on March 15, 2010. We are currently awaiting a decision from the Appellate Division on this matter. At this time, we cannot estimate when the Appellate Division will rule on the appeal. We intend to continue our vigorous defense of this matter.

In November 2008, a complaint against us and our transfer agent, BNY Mellon Shareowner Services, was filed in the Supreme Court of the State of New York by an individual stockholder. The complaint alleges that we and our transfer agent caused or contributed to losses suffered by the stockholder. On July 20, 2009, the stockholder moved for summary judgment. The summary judgment motion was fully briefed, and oral argument was heard on December 3, 2009. On May 18, 2010, the Court denied the stockholder's motion for summary judgment. Although we deny the allegations of this complaint, in order to hold down the cost of our legal expenses, on September 27, 2010, we settled this case with the individual stockholder for an amount that was not material to our Consolidated Financial Statements.

Item 4. Removed and Reserved

PART II

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

Market Information

From January 1, 2009 through July 13, 2009, our common stock traded on the OTC Bulletin Board under the symbol "GNTA.OB", from July 14, 2009 through October 17, 2010, our common stock traded on the OTC Bulletin Board under the symbol "GETA.OB" and from October 18, 2010 through December 31, 2010, our common stock traded on the OTC Bulletin Board under the symbol "GNTA.OB". The following table sets forth the high and low daily closing prices per share of our common stock for the periods indicated.

2009	High*	Low*
First Quarter	$ 77,500.00	$ 725.00
Second Quarter	$ 5,800.00	$ 1,350.00
Third Quarter	$ 5,750.00	$ 1,675.00
Fourth Quarter	$ 5,500.00	$ 415.00
2010		
First Quarter	$ 647.00	$ 220.00
Second Quarter	$ 780.00	$ 176.50
Third Quarter	$ 186.00	$ 20.00
Fourth Quarter	$ 21.50	$ 0.98

* All figures have been retroactively adjusted to reflect all applicable reverse stock splits.

Holders

There were 50 holders of record of our common stock as of March 30, 2011. We estimate that there are approximately 21,900 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.

Performance Graph

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

The following table compares total stockholder returns for Genta over the last five years to the NASDAQ Composite Index and the NASDAQ Biotechnology Index assuming a $100 investment made on December 31, 2005. The stock performance shown on the graph below is not necessarily indicative of future price performance.

	12/05	12/06	12/07	12/08	12/09	12/10
Genta Incorporated	100.00	30.31	5.94	0.03	0.02	0.00007
NASDAQ Composite	100.00	111.74	124.67	73.77	107.12	125.93
NASDAQ Biotechnology	100.00	99.71	103.09	96.34	106.49	114.80

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities

Any disclosure required by Item 701 of Regulation S-K has been previously disclosed in our Current Reports on Form 8-K.

Purchases of equity securities by the issuer and affiliated purchasers

None

Item 6. Selected Financial Data

Not applicable.

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, 2010, we have incurred a cumulative net deficit of $1,197.7 million. We expect that such losses will continue at least until one or more of our product candidates are approved by one or more regulatory authorities for commercial sale in one or more indications.

Our principal goal is to secure regulatory approval for the marketing of our products. For example, Genasense® has been studied in combination with a wide variety of anticancer drugs in a number of different cancer indications. We have reported results from randomized trials of Genasense® in various diseases. We have been especially interested in the development of Genasense® in three specific diseases: melanoma, chronic lymphocytic leukemia, referred to herein as CLL and non-Hodgkin's lymphoma, referred to herein as NHL.

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

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

A total of 315 patients were enrolled into AGENDA. In October 2009, we announced that AGENDA did not show a statistically significant increase in its co-primary endpoint of PFS or for secondary endpoints of overall response rate and disease control rate (which includes complete and partial responses, plus stable disease greater than 3 months duration). However, the differences in PFS, overall response and disease control all numerically favored the group that received Genasense®.

As prospectively specified, AGENDA was statistically powered to detect an improvement in overall survival, which is a late endpoint. At the time the early endpoints of the study were released (i.e. PFS, response rate), the data on late endpoints of survival and durable response were too early to analyze. An analysis for futility, which was defined as greater than 50% conditional power to observe a statistically significant increase under the prospectively assumed hazard ratio of 0.69, was conducted for the co-primary endpoint of overall survival. AGENDA passed this futility analysis, and an Independent Data Monitoring Committee recommended that the trial continue to completion for the determination of the overall survival endpoint. The safety profile in patients who received Genasense® plus dacarbazine in AGENDA was consistent with prior studies. Followup of all patients for survival will terminate on March 31, 2011. We currently project that the survival information will be available shortly thereafter. If the final analysis for overall survival is statistically significant, we believe that Genasense® could receive regulatory approval for marketing in this indication. Under such circumstance, we would confer with the FDA regarding resubmission of our New Drug Application, or NDA, regarding approval for treatment of patients with advanced melanoma.

We have conducted other trials of Genasense® in melanoma, including a Phase 2 trial of Genasense® plus chemotherapy consisting of Abraxane® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus temozolomide (Temodar®). In this trial, we examined whether different dosing regimens could be used to improve convenience. We project that data from that trial will be presented in the second quarter of 2011.

We have also conducted extensive trials in patients with advanced CLL. We completed a randomized Phase 3 trial in 241 patients with relapsed or refractory CLL who were treated with fludarabine and cyclophosphamide, also known as Flu/Cy, with or without Genasense®. The trial achieved its primary endpoint: a statistically significant increase (17% vs. 7%; P=0.025) in the proportion of patients who achieved a complete response, or CR, defined as a complete or nodular partial response. Patients who achieved this level of response also experienced disappearance of predefined disease symptoms. A key secondary endpoint, duration of CR, was also significantly longer for patients treated with Genasense® (median exceeding 36+ months in the Genasense® group, versus 22 months in the chemotherapy-only group).

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

We submitted a NDA to the FDA that proposed the use of Genasense® in combination with Flu/Cy for the treatment of patients with relapsed or refractory CLL who had previously received fludarabine. However, we received a "non-approvable" notice from the FDA in December 2006 for this NDA. Our appeals of this decision to the FDA were unsuccessful.

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

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In March 2008, we obtained an exclusive worldwide license for tesetaxel from Daiichi Sankyo Company Limited. Tesetaxel is a novel taxane compound that is taken by mouth. Tesetaxel has completed Phase 2 trials in a number of cancer types, and the drug has shown definite evidence of antitumor activity in gastric cancer and breast cancer. Tesetaxel also appears to be associated with a lower incidence of peripheral nerve damage, a common side effect of taxanes that limits the maximum amount of these drugs that can be given to patients.

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

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

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

Our third pipeline project consists of the development of an oral gallium-containing compound. We completed a single-dose Phase 1 clinical study of one such compound (known as G4544[a]). We are currently developing additional experimental compounds of this class with the expectation that we can identify a lead compound for further clinical testing. Some of these compounds are currently being tested in animals to evaluate their oral absorption.

If we are able to identify a clinically and commercially acceptable formulation of an oral gallium-containing compound, we currently intend to evaluate whether an expedited regulatory approval may be possible. We believe a drug of this class may also be broadly useful for treatment of other diseases associated with accelerated bone loss. These illnesses include hypercalcemia, bone metastases, Paget's disease and osteoporosis. In addition, new uses of gallium-containing compounds have been identified for treatment of certain infectious diseases. We have supported research conducted by certain academic institutions by providing clinical supplies of our gallium-containing drugs for patients with cystic fibrosis who have severe infections.

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

Results of Operations

	Summary Operating Results For the years ended December 31,		
($ thousands)	2010	2009	2010 vs. 2009
Product sales - net	$257	$218	$39
Cost of goods sold	47	40	7
Gross margin	210	178	32
Operating expenses:			
Research and development	10,015	15,144	(5,129)
Selling, general and administrative	9,764	17,233	(7,469)
Total operating expenses	19,779	32,377	(12,598)
Interest income and other income, net	544	3	541
Interest expense	(3,389)	(1,191)	(2,198)
Amortization of deferred financing costs and debt discount	(34,931)	(29,092)	(5,839)
Fair value – conversion feature liability	(55,813)	(19,040)	(36,773)
Fair value – warrant liability	(54,638)	(7,655)	(46,983)
Total other income/(expense), net	(148,227)	(56,975)	(91,252)
Loss before income taxes	(167,796)	(89,174)	(78,622)
Income tax benefit	497	2,873	(2,376)
Net loss	$(167,299)	$(86,301)	$(80,998)

Product sales - net

Product sales - net increased in 2010 to $257 thousand from $218 thousand in 2009, primarily due to a lower level of returns during 2010, partially offset by lower unit sales of Ganite® of 5% in 2010.

Cost of goods sold

During 2009, 37% of the units sold of Ganite® were from product that had been previously accounted for as excess inventory; however, a lower level of product returns during 2010 resulted in a similar gross margin percentage in both years.

Research and development expenses

Research and development expenses declined to $10.0 million in 2010, compared with $15.1 million in 2009, primarily due to lower expenses resulting from lower spending on the AGENDA clinical trial and lower share-based compensation expense of $2.2 million recorded in 2010. During 2009, with the establishment of the 2009 Stock Incentive Plan, or the 2009 Plan, and implementation of two Equity Award Exchange programs, outstanding stock option awards granted under the 1998 Non-Employee Directors Plan, as amended, and 1998 Stock Incentive Plan, as amended, were exchanged for grants of new restricted stock units, or RSUs. Incremental compensation cost for the new RSUs was measured as the excess of the fair value of the RSUs over the fair value of the stock option awards on the date of exchange. Share-based compensation expense recognized for the year ended December 31, 2010 was $1.7 million and for the year ended December 31, 2009 was $3.9 million, for those employees categorized as research and development.

Research and development expenses incurred on the tesetaxel project in 2010 were approximately $5.0 million, representing 50% of research and development expenses in 2010, and research and development expenses incurred on the Genasense® project in 2010 were approximately $3.9 million, representing 39% of research and development expenses in 2010. During 2009, expenses incurred on the Genasense® project were approximately $12.9 million, representing 85% 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 $9.8 million in 2010, compared with $17.2 million in 2009, primarily due to a reduction in share-based compensation expense. Share-based compensation expense recognized for the year ended December 31, 2010 was $2.7 million and for the year ended December 31, 2009 was $9.4 million, for employees categorized as selling, general and administrative.

Interest income and other income, net

In November 2010, we were awarded cash grants totaling approximately $489 thousand under the U.S. Government's Qualifying Therapeutic Discovery Project program. The awards are intended for projects designed to treat or prevent diseases by conducting studies for the purpose of securing approval from the FDA.

Interest expense

Interest expense of $3.4 million for the year ended December 31, 2010 increased from $1.2 million for the year ended December 31, 2009, primarily due to the inclusion of interest on the March 2010 Notes.

Amortization of deferred financing costs and debt discount

Amortization of deferred financing costs and debt discount of $34.9 million during 2010 increased from $29.1 million during 2009 primarily due to the inclusion of amortization related to our March 2010 Notes and a full year’s worth of amortization related to our September 2009 Notes, mostly offset by lower amortization on the 2008 Notes resulting from a lower amount of notes outstanding.

Fair value – conversion feature liability

On March 9, 2010, we issued $25 million of units, or the 2010 Units, each 2010 Unit consisting of (i) 40% of a senior unsecured convertible note, or the B Notes, (ii) 40% of a senior unsecured convertible note, or the C Notes and (iii) 20% of a senior secured convertible note, or the D Notes. In connection with the sale of the 2010 Units, we also issued warrants, or the Debt Warrants, to purchase senior unsecured convertible notes, or the E Notes, in an amount equal to 40% of the purchase price paid for each such 2010 Unit. On March 17, 2010, March 22, 2010 and April 9, 2010, four investors who had participated in our April 2009 financing, exercised their rights under the April 2009 securities purchase agreement and the April 2009 consent agreement to acquire senior unsecured convertible notes, or the F Notes, of $1.0 million. On May 6, 2010 and May 10, 2010, two holders of Debt Warrants totaling $1.3 million exercised their warrants using a cashless exercise procedure and received, in total, E Notes for $1.1 million. The B Notes, C Notes, D Notes, E Notes and F Notes are referred to as the March 2010 Notes.

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

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

million, resulting in an expense of $6.4 million.

At the Annual Meeting of Stockholders of Genta Incorporated held on June 15, 2010, the Company's stockholders authorized its Board of Directors to effect a reverse stock split of all outstanding shares of common stock. The Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of 1-for-100 shares on July 9, 2010 and the reverse stock split became effective on August 2, 2010. The approval of the reverse stock split resulted in the Company having enough shares to accommodate the potential number of shares underlying the March 2010 Notes. The fair value of the conversion feature liability of the March 2010 Notes was re-measured at July 9, 2010 at $81.8 million and credited to permanent equity, resulting in expense of $55.8 million for the year ended December 31, 2010.

In the prior-year period, in April 2009, we issued approximately $6 million of April 2009 Notes and corresponding warrants to purchase common stock. When we issued the April 2009 Notes, there were an insufficient number of authorized shares of common stock in order to permit conversion of all of the notes. The conversion feature liability of the April 2009 Notes was marked-to-market until there were enough shares of common stock in order to permit conversion of all the April 2009 Notes, resulting in expense of $19.0 million for the year ended December 31, 2009.

Fair value – warrant liability

In March 2010, in addition to issuing Debt Warrants, we also issued March 2010 Warrants to holders of our outstanding 2008 Notes to extend the maturity of those notes from June 9, 2010 to June 9, 2011. The March 2010 Warrants allow the holder to purchase the same number of shares of our common stock issuable upon conversion of our 2008 Notes. The Debt Warrants and the March 2010 Warrants were also treated as liabilities, due to the insufficient number of authorized shares of common stock at the time that they were issued up until the reverse stock split was implemented in August 2010.

In December 2010, we extended the maturity date of our outstanding 2008 Notes from June 9, 2011 to September 4, 2011 in exchange for December 2010 Warrants. The December 2010 Warrants allow the holder to purchase 10% of the number of shares of our common stock issuable upon conversion of our 2008 Notes and have the same expiration date as the March 2010 Warrants. Both the March 2010 Warrants and the December 2010 Warrants have anti-dilution protection. Warrants with anti-dilution protection are accounted for as liabilities and are marked-to-market throughout their lives. Some of the warrants were initially recorded at a fair value of $125.1 million based upon a Black-Scholes valuation model and re-measured at $35.9 million on July 9, 2010 and credited to permanent equity, resulting in expense of $35.9 million for the year ended December 31, 2010. The March 2010 Warrants and December 2010 Warrants will be marked-to-market over the life of the warrants, and based upon a Black-Scholes valuation model, expense of $18.7 million was recorded for the year ended December 31, 2010.

In the prior-year period, the warrants that were issued with the April 2009 Notes were also treated as liabilities, due to the insufficient number of authorized shares of common stock at the time that they were issued. The warrant liability was marked-to-market until there were enough shares of common stock in order to permit conversion of all of the warrants issued with the April 2009 Notes, resulting in expense of $7.7 million for the year ended December 31, 2009.

Income tax benefit

New Jersey has legislation permitting certain corporations located in the state to sell state tax loss carryforwards and state research and development credits. We sold portions of our New Jersey net operating losses and research and development credits for $0.5 million in 2010, and for $2.9 million in 2009, which are recognized as income tax benefit. New Jersey reduced the size of this program in 2010, resulting in the lower amount that we received.

If still available under New Jersey law, we will attempt to sell our remaining tax losses in 2011. We cannot be assured that the New Jersey program will continue next year, nor can we estimate what percentage of our saleable tax benefits

New Jersey will permit us to sell, how much money will be received in connection with the sale, if we will be able to find a buyer for our tax benefits or if such funds will be available in a timely manner.

Net loss

Genta recorded a net loss of $167.3 million, or net loss per basic and diluted share of $246.04, for 2010 and a net loss of $86.3 million, or net loss per basic and diluted share of $4,200.99, for 2009. All common share and per common share data in this Annual Report on Form 10-K have been retroactively adjusted to account for the effect of the reverse stock splits for all periods presented prior to the reverse stock splits.

The higher net loss for 2010 was primarily due to higher expenses from marking to market the conversion feature liabilities of our notes and our warrant liabilities, as well as increased amortization of financing costs and debt discount and higher interest expense. These increases were slightly offset by lower share-based compensation and lower research and development expenses.

Critical Accounting Policies and Estimates

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

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

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

Valuation of RSUs. RSUs are recognized in the Consolidated Statements of Operations based on their fair values. The amount of compensation cost is measured based on the grant-date fair value of the equity instrument issued.

Liquidity and Capital Resources

At December 31, 2010, we had cash and cash equivalents totaling $12.8 million, compared with $1.2 million at December 31, 2009, reflecting our March 2010 financing offset by funds used in operating our company.

During the year ended December 31, 2010, cash used in operating activities was $14.3 million compared with $21.5 million for the same period in 2009, reflecting lower expenses resulting from lower spending on the AGENDA clinical trial and lower expenses resulting from the reduced size of our company.

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In March 2010 and April 2010, we raised $25.8 million from the sale of various convertible notes and debt warrants. Presently, with no further financing, we project that the Company will run out of funds in the third quarter of 2011. As of December 31, 2010, we had convertible notes with face value of $4.4 million maturing in September 2011. The terms of the April 2009 Notes enable those noteholders, at their option, to purchase additional notes with similar terms. We currently do not have any additional financing in place. If we are unable to raise additional funds, we could be required to reduce our spending plans, reduce our workforce, license one or more of our products or technologies that we would otherwise seek to commercialize ourselves, or sell certain assets. There can be no assurance that we can obtain financing, if at all, on terms acceptable to us.

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

Contractual Obligations

Future contractual obligations at December 31, 2010 are as follows ($ thousands):

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Uncertain tax positions*	$953	$953	$-	$-	$-
Operating lease obligations	3,166	700	2,017	449	-
Office settlement lease obligation	1,950	86	257	1,607	-
Maturity of convertible notes	29,781	4,422	25,359	-	-
Total	$35,850	$6,161	$27,633	$2,056	$-

* see Note 11 to the Consolidated Financial Statements

Virtually all of the operating lease obligations result from our lease of approximately 25,000 square feet of office space in Berkeley Heights, New Jersey. Our lease on this space terminates in August 2015. In addition, as part of an amendment of our lease for office space with our landlord, we are due to pay an office settlement lease obligation of $1.9 million over the term of the lease, including a final payment of $1.6 million in August 2015.

Our 2008 Notes mature on September 4, 2011, our April 2009 Notes mature on April 2, 2012, our July 2009 Notes mature on July 7, 2011, our September 2009 Notes and July 2009 Notes issued in September mature on September 4, 2011 and our March 2010 Notes mature on March 9, 2013, (see Note 10 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, into shares of Genta common stock at a conversion rate of $0.16 per share, adjusted for the 1-for-50 reverse stock split implemented in February 2011. The amount in the table above, $29.8 million, is the face value of convertible notes outstanding at December 31, 2010. This amount would be due on their respective maturity dates assuming no voluntary conversions by noteholders prior to the maturity date. As of March 30, 2011, our total outstanding face value of all of the notes listed above is $31.8 million.

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 other suppliers of services, since such payments are contingent on the occurrence of certain events.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Our carrying values of cash, accounts payable, accrued expenses and debt are a reasonable approximation of their fair value. The estimated fair values of financial instruments have been determined by us using available market information and appropriate valuation methodologies (see Note 2 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, 2010. Therefore, there will be no ongoing exposure to a potential material adverse effect on our business, financial condition or results of operation for sensitivity to changes in interest rates or to changes in currency exchange rates.

Item 8. Financial Statements and Supplementary Data

Genta Incorporated
Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have audited the accompanying consolidated balance sheet of Genta Incorporated and Subsidiaries (the "Company") as of December 31, 2010, and the related consolidated statements of operations, stockholders' deficit, 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropri−ate 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 the Company as of December 31, 2010, and the results of its operations and its cash flows for the year then ended, 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 2 to the consolidated financial statements, the Company's recurring losses from operations, negative cash flows from operations and current maturities of convertible notes payable raise substantial doubt about its ability to continue as a going concern. Management's plans considering these matters are also described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited the adjustments to the 2009 consolidated financial statements to retrospectively apply the adjustments described in Note 1 for the one-for-one hundred reverse stock split which became effective on August 2, 2010, and for the one-for-fifty reverse stock split which became effective on February 18, 2011. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2009 consolidated financial statements of the Company other than with respect to the adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2009 consolidated financial statements taken as a whole.

/s/ EisnerAmper LLP

Edison, New Jersey
March 30, 2011

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Genta Incorporated and Subsidiaries

We have audited, before the effects of the adjustments to retrospectively apply the changes described in Note 1 for the one-for-one hundred reverse stock split which became effective on August 2, 2010, and for the one-for-fifty reverse stock split which became effective on February 18, 2011, the accompanying consolidated balance sheet of Genta Incorporated and Subsidiaries (the "Company") as of December 31, 2009, and the related consolidated statements of operations, stockholders' deficit, and cash flows for the year then ended. The 2009 consolidated 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, before the effects of the adjustments to retrospectively apply the changes described in Note 1, the 2009 consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2009, and the results of its operations and its cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

We were not engaged to audit, review, or apply any procedures to the adjustments for the reverse stock splits described in Note 1 and, accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by EisnerAmper LLP.

/s/ Amper, Politziner & Mattia, LLP

Edison, New Jersey
March 29, 2010

GENTA INCORPORATED
CONSOLIDATED BALANCE SHEETS

(In thousands, except par value data)

ASSETS	December 31, 2010	December 31, 2009
Current assets:		
Cash and cash equivalents	$12,835	$1,216
Accounts receivable - net of allowances of $21 at December 31, 2010 and $23 at December 31, 2009	-	2
Receivable on sale of New Jersey tax losses	-	2,873
Inventory (Note 5)	31	81
Prepaid expenses and other current assets	890	971
Total current assets		