GENTA INC DE/ Form 10-K March 28, 2012

#### **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, 2011

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

(I.R.S. Employer Identification No.)

organization)

200 Connell Drive

Berkeley Heights, New Jersey

07922

(Zip Code)

(Address of principal executive offices)

(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. Yes o No x

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

#### Act. Yes o No x

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

Accelerated filer o
Smaller reporting

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

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was \$43,104,028 as of June 30, 2011 (the last business day of the registrant's most recently completed second fiscal quarter).

As of March 28, 2012, the registrant had 2,090,399,725 shares of Common Stock outstanding.

# Genta Incorporated Table of Contents

| Part I    |                                                                                            |    |
|-----------|--------------------------------------------------------------------------------------------|----|
| Item 1.   | Business                                                                                   | 4  |
| Item 1A.  | Risk Factors                                                                               | 12 |
| Item 1B.  | Unresolved Staff Comments                                                                  | 24 |
| Item 2.   | Properties                                                                                 | 24 |
| Item 3.   | Legal Proceedings                                                                          | 25 |
| Item 4.   | Mine Safety Disclosures                                                                    | 25 |
| Part II   |                                                                                            |    |
| Item 5.   | Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of |    |
|           | Equity Securities                                                                          | 26 |
| Item 6.   | Selected Financial Data                                                                    | 27 |
| Item 7.   | Management's Discussion and Analysis of Financial Condition and Results of Operations      | 28 |
| Item 7A.  | Quantitative and Qualitative Disclosure about Market Risk                                  | 34 |
| Item 8.   | Consolidated Financial Statements and Supplementary Data                                   | 35 |
| Item 9.   | Changes in and Disagreements with Accountants on Accounting and Financial Disclosure       | 58 |
| Item 9A.  | Controls and Procedures                                                                    | 58 |
| Item 9B.  | Other Information                                                                          | 58 |
| Part III  |                                                                                            |    |
| Item 10.  | Directors, Executive Officers and Corporate Governance                                     | 59 |
| Item 11.  | Executive Compensation                                                                     | 64 |
| Item 12.  | Security Ownership of Certain Beneficial Owners and Management and Related Stockholder     |    |
|           | Matters                                                                                    | 75 |
| Item 13.  | Certain Relationships and Related Transactions and Director Independence                   | 78 |
| Item 14.  | Principal Accounting Fees and Services                                                     | 79 |
| Part IV   |                                                                                            |    |
| Item 15.  | Exhibits and Financial Statement Schedules                                                 | 80 |
| Signature | S                                                                                          | 86 |
|           |                                                                                            |    |
|           |                                                                                            |    |
| 2         |                                                                                            |    |

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. 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 its products from the U.S. Food and Drug Administration, or FDA, or European Medicines Agency, or EMA;
  - the safety and efficacy of the Company's products;
  - the timing of commencement and completion of clinical trials;
  - the Company's ability to develop, manufacture, license and sell its products or product candidates;
  - the Company's ability to enter into and successfully execute license and collaborative agreements, if any;
- •the adequacy of the Company's capital resources and cash flow projections, and the Company's ability to obtain sufficient financing to maintain the Company's planned operations, or the Company's risk of bankruptcy;
  - the adequacy of the Company's patents and proprietary rights;
- the impact of litigation that has been brought against the Company and its officers and directors and any proposed settlement of such litigation; and
  - •the other risks described under "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 that are chiefly intended for the treatment of cancer and related diseases.

Our principal goals are to secure marketing approval and to profit from subsequent sales of our products. Our lead compound is tesetaxel, a novel taxane compound that is taken by mouth. Tesetaxel has completed Phase 2 trials in a number of cancer types. Clinical trials conducted by us have confirmed that the drug has definite antitumor activity in gastric cancer and breast cancer. Tesetaxel appears to be associated with a substantially lower incidence of side effects, particularly hypersensitivity reactions and peripheral nerve damage, both of which are common side effects of taxanes.

We have initiated and completed a number of clinical trials with tesetaxel, including Phase 2 trials of tesetaxel in patients with advanced gastric cancer, breast cancer, bladder cancer, prostate cancer and melanoma. Our ongoing trials are currently open to enrollment at major cancer centers in the U.S., Europe and Asia.

The FDA granted our request for "Fast Track" designation of tesetaxel for treatment of patients with advanced gastric cancer. Fast Track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The designation typically enables a company to submit a New Drug Application, or 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 the FDA at the time of submission.

The FDA has also granted our request for designation of tesetaxel as an "Orphan Drug" for treatment of patients with advanced gastric cancer. 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 requests for both Fast Track and Orphan Drug designation, and similar designations in applicable territories, for diseases that fulfill regulatory requirements for such designation.

Our other pipeline project consists of the development of an orally bioavailable gallium-containing compound. We believe the class of gallium compounds may have broad utility to treat diseases associated with accelerated bone loss. These illnesses include cancer-related hypercalcemia (i.e., life-threatening elevation of blood calcium), bone metastases, Paget's disease and osteoporosis. In addition, new uses of gallium-containing compounds have been identified for treatment of certain infectious diseases. We have supported research conducted by certain academic institutions by providing clinical supplies of our gallium-containing drugs for patients with cystic fibrosis who have severe infections.

We completed a single-dose Phase 1 clinical study of one such oral gallium compound, known as G4544a. Since then, we have synthesized additional compounds of this class with the goal of identifying a potential lead compound for further clinical testing. Some of these compounds have been tested in animals to evaluate their oral absorption. If we are able to identify a potentially acceptable formulation of an oral gallium-containing compound, we may evaluate whether an expedited regulatory approval may be possible.

In 2011, we reported results from a Phase 3 randomized trial of Genasense® in advanced melanoma. This trial, known as AGENDA, failed to achieve its primary endpoint of improving overall survival. Given these results, we terminated further internal development of Genasense® and redirected our resources to other programs.

In the U.S. we are currently marketing Ganite®, which is an intravenous formulation of gallium nitrate, for treatment of cancer-related hypercalcemia that is resistant to hydration. Sales of Ganite® have been very low due to our under-investment in its marketing and an inconvenient dosing schedule. Since the relevant patents on Ganite® have expired, we do not plan to substantially increase our investment in the drug. We believe the product may have strategic importance for our franchise of gallium-containing compounds, especially regarding the previously noted oral gallium compounds.

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;
  - 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

#### **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. Clinical trials conducted by us have confirmed that the drug has definite antitumor activity in gastric cancer and breast cancer. Tesetaxel appears to be associated with a substantially lower incidence of side effects, particularly hypersensitivity reactions and peripheral nerve damage, both of which are common side effects of taxanes.

We have initiated and completed a number of clinical trials with tesetaxel, including Phase 2 trials of tesetaxel in patients with advanced gastric cancer, breast cancer, bladder cancer, prostate cancer, and melanoma. Our ongoing 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 the 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, and similar designations in applicable territories, for diseases that fulfill regulatory requirements for such designation.

#### **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 known 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 400 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 during 2012. A positive result from this trial that yields regulatory approval may

enable us to commercially launch tesetaxel by 2015.

#### 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 non-Hodgkin's lymphoma, or 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 our products and technology, including novel compositions of matter, methods of synthesis and manufacture, methods of controlling gene expression and methods of treating disease.

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. Provisions for patent-term extensions beyond 2020 may also be available in the U.S., Europe and Japan that may further their periods of exclusivity once the product is approved for commercialization. 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 the manufacturing process of tesetaxel.

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.

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 for tesetaxel 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 million 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, 2011 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 \$12.4 million during the year ended December 31, 2011 and \$10.0 million during the year ended December 31, 2010.

#### Sales and Marketing

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

On March 6, 2007, we entered into a distribution and supply agreement with IDIS Limited (a privately owned company based in the United Kingdom). The term of the agreement lasts for three years with automatic one-year renewals unless adequate notice of intent not to renew is provided by either party. The agreement will continue on a product-by-product and country-by-country basis until that product has been granted a marketing authorization for an indication within that country of the territory and we have provided written notice of termination for such product in that country. We may terminate this agreement upon notice to IDIS. Either party may terminate the agreement (i) as a result of a material breach by the other party, (ii) upon the other party's bankruptcy, insolvency, liquidation, or similar events, (iii) upon any 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 Johnson Matthey Inc. whereby we will purchase a minimum of 80% of our requirements for quantities of Ganite®;

however, there are no minimum purchase requirements. The agreement renews automatically at the end of each year, unless either party gives one-year notice.

For tesetaxel, we purchased all remaining quantities of bulk drug substance and finished capsules from Daiichi Sankyo Company, Limited. Current inventory totals approximately 6,000 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. We believe that we have adequately addressed our needs for suppliers of raw materials to manufacture tesetaxel and Ganite® and to meet future customer demand.

#### **Human Resources**

As of December 31, 2011, we had 21 full-time employees, 6 of whom hold doctoral degrees. As of that date, there were 13 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 a NDA. In responding to a 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 U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, 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 April 2012. 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, sell all or some of our assets, cease operations or even declare bankruptcy. There can be no assurance that we can obtain financing, if at all, or raise such additional funds, on terms acceptable to us.

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

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

Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements for the year ended December 31, 2011 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 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 and an oral gallium compound, 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 results of the AGENDA trial that were released in May 2011 did not show a significant increase in overall survival for patients treated with Genasense®, and this failure meant that we would not be able to file any application for regulatory approval in any territory.

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

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

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

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

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

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

We cannot assure you that our ongoing preclinical studies and clinical trials will produce successful results in order to support regulatory approval of our products in any territory or for any indication. Failure to obtain approval, or a substantial delay in approval of our products for any indication 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.

As of December 31, 2011, we had a face amount of convertible notes outstanding of \$44.3 million. Our aggregate level of debt could have significant consequences on our future operations, including:

• making it more difficult for us to meet our payment and other obligations under our outstanding debt;

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

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

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

Our convertible notes contain various provisions regarding the adjustment of their applicable conversion prices. Conversion price resets went into effect on January 1, 2011, March 12, 2011, September 2, 2011 and December 17, 2011. There are two other scheduled adjustments to the conversion prices of our convertible notes.

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

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

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

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

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

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

Our convertible notes mature on various dates in 2013 and 2021, and bear interest payable quarterly or semi-annually at rates of 8.0%, 12.0% or 15.0% per annum. However, virtually all of our notes allow the holder, at various dates throughout 2012, to require us to redeem their note upon 10 days prior written notice. Absent additional financing, we will likely not have sufficient funds to pay the principal upon maturity, a holder requiring us to redeem their note 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, 2011, we have incurred a cumulative net deficit of \$1,267.1 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 tesetaxel or oral gallium 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 manufacturing and 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.

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 a third-party manufacturer to manufacture Ganite®. 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.

Tesetaxel and oral gallium (if they obtain regulatory approval), and Ganite®, as well as 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 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. On August 3, 2011, the Appellate Division affirmed the decision of the Superior Court in part and reversed the decision of the Superior Court in part. The Appellate Division held that the Superior Court properly dismissed the complaint, but should have permitted the plaintiffs to file an amended complaint. The Appellate Division remanded the case to the Superior Court. On August 15, 2011, the defendants moved for reconsideration by the Appellate Division, but their motion was denied on August 26, 2011. The plaintiffs then filed an Amended Complaint on October 12, 2011 which the defendants answered on November 15, 2011. We, our Board of Directors and officers deny these allegations and intend to vigorously defend this lawsuit.

#### Risks Related to Our Common Stock

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

Provisions in our restated certificate of incorporation and bylaws may discourage third parties from seeking to obtain control of us and, therefore, could prevent our stockholders from receiving a premium for their shares. Our restated certificate of incorporation gives our Board of Directors the power to issue shares of preferred stock without approval of the holders of common stock. Any preferred stock that is issued in the future could have voting rights, including voting rights that could be superior to that of our common stock. The affirmative vote of 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 two reverse stock splits prior to December 31, 2012.

At a Special Meeting of Stockholders held on October 21, 2011, our stockholders authorized our Board of Directors to implement up to two reverse stock splits prior to December 31, 2012, with each stock split having an exchange ratio from 1-for-2 up to 1-for-500. Our Board may decide to implement one or two reverse stock splits prior to December 31, 2012. Even if our Board decides to implement a reverse stock split, we may be unable to obtain the requisite approval from the Financial Industry Regulatory Authority ("FINRA") in order to effect such reverse split. Although our Board of Directors believes that a reverse stock split may increase the price of our common stock, in many cases, because of variables outside of a company's control (such as market volatility, investor response to the news of a proposed reverse stock split and the general economic environment), the market price of a company's shares of common stock may in fact decline in value after a reverse stock split. The implementation of a reverse stock split does not have an effect on the actual or intrinsic value of our business or our stockholders' proportional ownership. However, should the overall value of our common stock decline after the proposed reverse stock splits, then the actual or intrinsic value of the shares of our common stock will also proportionately decrease as a result of the overall decline in value.

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, 2011, we had 1,344 million shares of common stock outstanding and 60,223 million shares reserved for the conversion of our outstanding convertible preferred stock, convertible notes, warrants, debt warrants and restricted stock units. 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 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. On August 3, 2011, the Appellate Division affirmed the decision of the Superior Court in part and reversed the decision of the Superior Court in part. The Appellate Division held that the Superior Court properly dismissed the complaint, but should have permitted the plaintiffs to file an amended complaint. The Appellate Division remanded the case to the Superior Court. On August 15, 2011, the defendants moved for reconsideration by the Appellate Division, but their motion was denied on August 26, 2011. The plaintiffs then filed an Amended Complaint on October 12, 2011 which the defendants answered on November 15, 2011. We, our Board of Directors and officers deny these allegations and intend to vigorously defend this lawsuit.

Item 4. Mine Safety Disclosures

Not applicable.

#### **PART II**

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

#### **Market Information**

From July 14, 2009 through October 17, 2010, our common stock was quoted on the OTC Bulletin Board under the symbol "GETA.OB" and from October 18, 2010 through December 31, 2011, our common stock was quoted 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.

|                | 2010 | High*        | Low*         |
|----------------|------|--------------|--------------|
| First Quarter  |      | \$<br>647.00 | \$<br>220.00 |
| Second Quarter |      | \$<br>780.00 | \$<br>176.50 |
| Third Quarter  |      | \$<br>186.00 | \$<br>20.00  |
| Fourth Quarter |      | \$<br>21.50  | \$<br>0.98   |
|                |      |              |              |
|                | 2011 |              |              |
| First Quarter  |      | \$<br>1.1500 | \$<br>0.0275 |
| Second Quarter |      | \$<br>0.0989 | \$<br>0.0152 |
| Third Quarter  |      | \$<br>0.0204 | \$<br>0.0013 |
| Fourth Quarter |      | \$<br>0.0068 | \$<br>0.0013 |

<sup>\*</sup> All figures have been retroactively adjusted to reflect all applicable reverse stock splits.

#### Holders

We estimate that there are approximately 3,885 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, 2006. The stock performance shown on the graph below is not necessarily indicative of future price performance.

|                      | 12/06  | 12/07  | 12/08 | 12/09  | 12/10  | 12/11   |
|----------------------|--------|--------|-------|--------|--------|---------|
| Genta Incorporated   | 100.00 | 19.59  | 0.10  | 0.07   | 0.0002 | 0.00004 |
| NASDAQ Composite     | 100.00 | 110.26 | 65.65 | 95.19  | 112.10 | 110.81  |
| NASDAQ Biotechnology | 100.00 | 102.53 | 96.57 | 110.05 | 117.19 | 124.54  |

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 and Quarterly Reports on Form 10-Q.

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 that are chiefly intended 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, 2011, we have incurred a cumulative net deficit of \$1,267.1 million. Our recurring losses from operations and our negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. 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 goals are to secure marketing approval and to profit from subsequent sales of our products. Our lead compound is tesetaxel, a novel taxane compound that is taken by mouth. Tesetaxel has completed Phase 2 trials in a number of cancer types. Clinical trials conducted by us have confirmed that the drug has definite antitumor activity in gastric cancer and breast cancer. Tesetaxel appears to be associated with a substantially lower incidence of side effects, particularly hypersensitivity reactions and peripheral nerve damage, both of which are common side effects of taxanes.

We have initiated and completed a number of clinical trials with tesetaxel, including Phase 2 trials of tesetaxel in patients with advanced gastric cancer, breast cancer, bladder cancer, prostate cancer and melanoma. Our ongoing trials are currently open to enrollment at major cancer centers in the U.S., Europe and Asia.

The FDA granted our request for "Fast Track" designation of tesetaxel for treatment of patients with advanced gastric cancer. Fast Track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The designation typically enables a company to submit a New Drug Application, or 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 the FDA at the time of submission.

The FDA has also granted our request for designation of tesetaxel as an "Orphan Drug" for treatment of patients with advanced gastric cancer. 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 requests for both Fast Track and Orphan Drug designation, and similar designations in applicable territories, for diseases that fulfill regulatory requirements for such designation.

Our other pipeline project consists of the development of an orally bioavailable gallium-containing compound. We believe the class of gallium compounds may have broad utility to treat diseases associated with accelerated bone loss. These illnesses include cancer-related hypercalcemia (i.e., life-threatening elevation of blood calcium), bone metastases, Paget's disease and osteoporosis. In addition, new uses of gallium-containing compounds have been identified for treatment of certain infectious diseases. We have supported research conducted by certain academic institutions by providing clinical supplies of our gallium-containing drugs for patients with cystic fibrosis who have severe infections.

We completed a single-dose Phase 1 clinical study of one such oral gallium compound, known as G4544a. Since then, we have synthesized additional compounds of this class with the goal of identifying a potential lead compound for further clinical testing. Some of these compounds have been tested in animals to evaluate their oral absorption. If we are able to identify a potentially acceptable formulation of an oral gallium-containing compound, we may evaluate whether an expedited regulatory approval may be possible.

In 2011, we reported results from a Phase 3 randomized trial of Genasense® in advanced melanoma. This trial, known as AGENDA, failed to achieve its primary endpoint of improving overall survival. Given these results, we terminated further internal development of Genasense® and redirected our resources to other programs.

In the U.S. we are currently marketing Ganite®, which is an intravenous formulation of gallium nitrate, for treatment of cancer-related hypercalcemia that is resistant to hydration. Sales of Ganite® have been very low due to our under-investment in its marketing and an inconvenient dosing schedule. Since the relevant patents on Ganite® have expired, we do not plan to substantially increase our investment in the drug. We believe the product may have strategic importance for our franchise of gallium-containing compounds, especially regarding the previously noted oral gallium compounds.

#### Results of Operations

|                                                   | Summary Operating Results For the years ended December 31, 2011 vs. |             |          |   |
|---------------------------------------------------|---------------------------------------------------------------------|-------------|----------|---|
| (\$ thousands)                                    | 2011                                                                | 2010        | 2010     |   |
| Product sales - net                               | \$194                                                               | \$257       | \$(63    | ) |
| Cost of goods sold                                | 7                                                                   | 47          | (40      | ) |
| Gross margin                                      | 187                                                                 | 210         | (23      | ) |
|                                                   |                                                                     |             |          |   |
| Operating expenses:                               |                                                                     |             |          |   |
| Research and development                          | 12,434                                                              | 10,015      | 2,419    |   |
| Selling, general and administrative               | 6,347                                                               | 9,764       | (3,417   | ) |
| Total operating expenses                          | 18,781                                                              | 19,779      | (998     | ) |
|                                                   |                                                                     |             |          |   |
| Interest income and other income, net             | 18                                                                  | 544         | (526     | ) |
| Interest expense                                  | (4,094)                                                             | (3,389)     | (705     | ) |
| Amortization of deferred financing costs and debt |                                                                     |             |          |   |
| discount                                          | (27,546)                                                            | (34,931)    | 7,385    |   |
| Fair value – conversion feature liability-        | -                                                                   | (55,813)    | 55,813   |   |
| Fair value – warrant liability                    | (20,406)                                                            | (54,638)    | 34,232   |   |
| Total other income/(expense), net                 | (52,028)                                                            | (148,227)   | 96,199   |   |
|                                                   |                                                                     |             |          |   |
| Loss before income taxes                          | (70,622)                                                            | (167,796)   | 97,174   |   |
| Income tax benefit                                | 1,202                                                               | 497         | 705      |   |
| Net loss                                          | \$(69,420)                                                          | \$(167,299) | \$97,879 |   |

#### Product sales - net

Product sales-net, of Ganite®, were \$194 thousand for the year ended December 31, 2011, a 25% decrease from the prior year. Unit sales for the year ended December 31, 2011 declined 55%; however, this was offset by a decline in the level of product returns.

#### Cost of goods sold

Cost of goods sold declined from the prior year due to the decline in unit sales and because sales of Ganite® from April 2011 through December 2011 were from product that had been previously accounted for as excess inventory.

#### Research and development expenses

Research and development expenses of \$12.4 million for the year ended December 31, 2011 increased from \$10.0 million for the year ended December 31, 2010. The increase was primarily due to the recognition in June 2011 of \$2.7 million in remaining contractual obligations related to Genasense®, as all further internal development of Genasense® was terminated. Research and development expenses incurred on the tesetaxel project during 2011 were approximately \$7.1 million, or 57% of research and development expenses during 2011. Research and development expenses incurred on the Genasense® project during 2011 were approximately \$4.2 million, including the June 2011 recognition, representing 34% of research and development expenses during 2011. During 2010, research and development expenses incurred on the tesetaxel project were approximately \$5.0 million, representing 50% of research and development expenses incurred on the Genasense® project were approximately \$3.9 million, or 39% of research and development expenses during 2010.

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 \$6.3 million for the year ended December 31, 2011, compared with \$9.8 million for the year ended December 31, 2010, primarily due to a reduction in share-based compensation expense, as well as lower payroll costs during 2011. Share-based compensation expense recognized for employees categorized as selling, general and administrative for the year ended December 31, 2011 was \$0.2 million, a decrease from the prior year expense of \$2.7 million, due to the final recognition of expense in 2010 related to restricted stock units, or RSUs, granted in 2009 and no new RSUs being granted in 2011.

#### 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 were 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 \$4.1 million for the year ended December 31, 2011 increased from \$3.4 million for the year ended December 31, 2010, primarily due to the inclusion of interest on the September 2011 Notes.

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

In September 2011, we issued a series of convertible notes totaling \$12.7 million, referred to as September 2011 Notes, along with warrants, referred to as September 2011 Debt Warrants, to purchase \$12.7 million of senior secured convertible notes. In December 2011, three holders of September 2011 Debt Warrants totaling \$2.9 million, exercised their warrants using a cashless exercise procedure and received September 2011 G Notes in the amount of \$2.1 million.

In March 2010, we issued a series of convertible notes totaling \$25 million, referred to as March 2010 Notes. In connection with the sale of the notes, we also issued warrants, referred to as March 2010 Debt Warrants, to purchase \$10 million of senior unsecured convertible notes. In March and April 2010, four investors who had participated in our April 2009 financing, exercised their rights under that financing to acquire March 2010 Notes in the amount of \$1.0 million. In May 2010, two holders of March 2010 Debt Warrants totaling \$1.3 million exercised their warrants using a cashless exercise procedure and received March 2010 Notes in the amount of \$1.1 million. In October 2010, two holders of March 2010 Debt Warrants totaling \$4.0 million exercised their warrants using a cashless exercise procedure and received March 2010 Notes in the amount of \$3.6 million. In January 2011, two holders exercised March 2010 Debt Warrants of \$2.7 million using a cashless exercise procedure and received March 2010 Notes in the amount of \$2.4 million.

In conjunction with the issuance of the September 2011 Notes, the March 2010 Notes and convertible notes issued in September 2009, July 2009, April 2009 and June 2008, we incurred certain financing costs, including, for several of the financings, the issuance of warrants to purchase our common stock. These financing costs are being amortized

over the term of the notes through their respective maturity dates. As notes have been converted, the amortization of deferred financing costs has been accelerated.

The accounting for the issuance of all of our convertible notes also required that we record a debt discount against each of these notes, as the beneficial conversion feature embedded in the notes was valued in excess of the face value of the notes. The resultant debt discount is amortized over the respective lives of the notes; however, as notes are converted, the amortization of the respective debt discount is accelerated. In addition, with each conversion price reset, we have recorded a debt discount equal to the face value of the notes (at the time of the reset), as the beneficial conversion feature embedded in the notes has been valued in excess of face value of notes at the time of each conversion price reset. Conversion price resets went into effect during 2011 on January 1, March 12, September 2 and December 17.

Amortization of deferred financing costs and debt discount declined to \$27.5 million for the year ended December 31, 2011 compared with \$34.9 million for the year ended December 31, 2010. Amortization during 2010 was higher due to a significantly increased level of voluntary conversions of notes during 2010.

Fair value – conversion feature liability

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

In March 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. In March and April 2010, in connection with the issuance of \$1.0 million in March 2010 Notes, the conversion features of the notes were recorded as a derivative liability of \$5.4 million, resulting in an expense of \$4.4 million. In May 2010, in connection with the \$1.1 million issuance of March 2010 Notes, the conversion features of the notes were recorded as a derivative liability of \$7.5 million, resulting in an expense of \$6.4 million.

The fair value of the conversion feature liability of the March 2010 Notes was re-measured at \$81.8 million on July 9, 2010, the date that we could accommodate the potential number of shares underlying the March 2010 Notes, and credited to permanent equity, resulting in expense of \$55.8 million for the year ended December 31, 2010.

#### Fair value – warrant liability

Concurrent with the sale of the September 2011 Notes, we extended the maturity date of our outstanding convertible notes from our financings in June 2008, referred to as June 2008 Notes, April 2009, referred to as April 2009 Notes, and September 2009, referred to as September 2009 Notes. The extension of the maturity was in exchange for three-year warrants, referred to as September 2011 Warrants, to purchase the same number of shares of our common stock issuable upon conversion of such outstanding notes on that date. The September 2011 Warrants and September 2011 Debt Warrants both have anti-dilution protection and can be exercised using a cashless exercise procedure; warrants with these characteristics are accounted for as liabilities and marked-to-market over their lives.

Similarly, with the sale of the March 2010 Notes, we also extended the maturity date of our outstanding June 2008 Notes, in exchange for three-year warrants, referred to as March 2010 Warrants, to purchase the same number of shares of our common stock issuable upon conversion of such June 2008 Notes. In December 2010, we extended the maturity date of our outstanding June 2008 Notes in exchange for December 2010 Warrants. The December 2010 Warrants allow the holder to purchase 10% of the number of shares of common stock issuable upon conversion of June 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 and are marked-to-market over their lives.

Based upon a Black-Scholes valuation model, a liability of \$72.3 million was recorded for the value, in total, of the September 2011 Warrants and the September 2011 Debt Warrants on the date of their issuance. At December 31, 2011, the September 2011 Warrants and the September 2011 Debt Warrants were valued, in total, at \$36.5 million based upon a Black-Scholes valuation model, resulting in a net expense of \$35.4 million on the Consolidated Statement of Operations for the year ended December 31, 2011. Based upon a Black-Scholes valuation model, a liability of \$18.7 million was recorded at December 31, 2010 for the value, in total, of the March 2010 Warrants and December 2010 Warrants. At December 31, 2011, the March 2010 Warrants and December 2010 Warrants were valued, in total, at \$3.8 million based upon a Black-Scholes valuation model, resulting in income of \$15.0 million on the Consolidated Statements of Operations for the year ended December 31, 2011.

In the prior year, the fair value of the warrant liabilities related to the March 2010 transactions was measured at \$35.9 million on July 9, 2010 and credited to permanent equity, resulting in expense of \$35.9 million on the Consolidated Statements of Operations for the year ended December 31, 2010. The March 2010 Warrants and December 2010 Warrants were re-measured at December 31, 2010 based upon a Black-Scholes valuation model, resulting in expense of \$18.7 million being recorded for 2010.

#### 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 for \$1.2 million in 2011 and for \$0.5 million in 2010 which are recognized as income tax benefit.

If still available under New Jersey law, we will attempt to sell additional tax losses in 2012. 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 \$(69.4) million, or net loss per basic and diluted share of \$(0.20), for the year ended December 31, 2011 and a net loss of \$(167.3) million, or net loss per basic and diluted share of \$(246.04), for the year ended December 31, 2010. The lower net loss was primarily due to the recognition in the prior year of significant expense from marking-to-market the conversion feature liability and warrant liabilities.

#### 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, 2011 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 valuation 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. The compensation cost of the RSUs is being recognized over the vesting period of the RSUs. Under the terms of virtually all of the Company's outstanding RSUs, the holders of the RSUs are entitled to anti-dilution protection in the form of additional shares of stock to be issued on the vesting dates of the underlying RSUs. The Company re-measures these RSUs to fair value, including the obligation to issue incremental shares under anti-dilution provisions, at each reporting period until the shares are issued. See Note 12 to the consolidated financial statements for a further discussion on share-based compensation.

#### Liquidity and Capital Resources

At December 31, 2011, we had cash and cash equivalents and restricted cash totaling \$10.6 million, compared with \$12.8 million at December 31, 2010, reflecting funds used in operating our company, partially offset by our September 2011 financing. The restricted cash represents funds received from the September 2011 financing that were placed in a blocked account as collateral security for a specific series of notes, the September 2011 H Notes. The restricted cash will be released if over any consecutive ten day trading period, the trading volume and price of our common stock meet certain levels. The security interest will also be released dollar for dollar upon conversion of any part of the September 2011 H Notes or upon the approval of each holder of the then outstanding September 2011 H Notes with respect to such holder's September 2011 H Notes only.

Net cash used in operating activities for the year ended December 31, 2011 was \$14.4 million, virtually unchanged from the year ended December 31, 2010. However, the prior year included the receipt of funds of \$2.9 million from the sale in 2009 of portions of New Jersey net operating losses and research and development credits.

In September 2011, we issued \$12.7 million of units, consisting of \$4.2 million of senior secured convertible notes and \$8.5 million of senior secured cash collateralized convertible notes. In connection with the sale of the units, we also issued two types of debt warrants in an amount equal to 100% of the purchase price for each unit. We had direct access to \$4.2 million of the proceeds, and the remaining \$8.5 million of the proceeds were placed in a blocked account as collateral security for the \$8.5 million senior secured cash collateralized convertible notes. Presently, with no further financing, we project that the Company will run out of funds in April 2012. 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, sell some or all of our assets, cease operations or even declare bankruptcy. There can be no assurance that we can obtain financing, if at all, or raise such additional funds, on terms acceptable to us.

In August 2011, we submitted a request to the Financial Industry Regulatory Authority, or FINRA, to process documentation related to a reverse stock split pursuant to Rule 10b-17 of the Securities Exchange Act of 1934, as amended. After continual correspondence between us and FINRA, on January 23, 2012, we received notice of FINRA's final denial of our request to process the documentation related to the reverse split. Failure to implement a reverse split comprises an event of default under the terms of our September 2011 G Notes, unless specifically waived by two-thirds of the holders of those notes. An amendment agreement between us and certain of our noteholders has extended the deadline for the implementation of the reverse split until April 16, 2012.

#### **Contractual Obligations**

Future contractual obligations at December 31, 2011 are as follows (\$ thousands):

Less than 1 More
Total year 1 - 3 years 3 - 5 years than 5 years

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| Uncertain tax positions*           | \$1,014  | \$1,014 | \$-      | \$- | \$-      |
|------------------------------------|----------|---------|----------|-----|----------|
| Operating lease obligations        | 2,540    | 698     | 1,842    | -   | -        |
| Office settlement lease obligation | 1,864    | 86      | 1,778    | -   | -        |
| Maturity of convertible notes      | 44,345   | -       | 29,567   | -   | 14,778   |
| Total                              | \$49,763 | \$1,798 | \$33,187 | \$- | \$14,778 |

<sup>\*</sup> see Note 10 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 remaining term of the lease, including a final payment of \$1.6 million in August 2015.

Our March 2010 Notes mature on March 9, 2013, our June 2008 Notes, April 2009 Notes, and our September 2009 Notes and July 2009 Notes issued in September 2009 mature on September 9, 2013 and our September 2011 Notes mature on September 9, 2021, (see Note 9 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 \$0.001. The amount in the table above, \$44.3 million, is the face value of convertible notes outstanding at December 31, 2011. This amount would be due on their respective maturity dates assuming no voluntary conversions by noteholders prior to the maturity date. As of March 28, 2012, our total outstanding face value of all of the notes listed above is \$46.1 million.

Not included in the above table are potential milestone payments to be made to Daiichi Sankyo Company, Limited and other suppliers of services, since such payments are contingent on the occurrence of certain events.

**Off-Balance Sheet Arrangements** 

We have no off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Our carrying values of cash, accounts payable, accrued expenses and debt are a reasonable approximation of their fair value. The estimated fair values of financial instruments have been determined by us using available market information and appropriate valuation methodologies (see Note 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, 2011. Therefore, there will be no ongoing exposure to a potential material adverse effect on our business, financial condition or results of operation for sensitivity to changes in interest rates or to changes in currency exchange rates.

### Item 8. Consolidated Financial Statements and Supplementary Data

## Genta Incorporated Index to Consolidated Financial Statements

| Report of Independent Registered Public Accounting Firm                           | 36 |
|-----------------------------------------------------------------------------------|----|
| Consolidated Balance Sheets as of December 31, 2011 and 2010                      | 37 |
| Consolidated Statements of Operations for the years ended December 31, 2011 and   |    |
| 2010                                                                              | 38 |
| Consolidated Statements of Stockholders' Deficit for the years ended December 31, |    |
| 2011 and 2010                                                                     | 39 |
| Consolidated Statements of Cash Flows for the years ended December 31, 2011 and   |    |
| 2010                                                                              | 40 |
| Notes to Consolidated Financial Statements                                        | 41 |
|                                                                                   |    |

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Genta Incorporated and Subsidiaries (the "Company") as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2011. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Genta Incorporated and Subsidiaries as of December 31, 2011 and 2010, and the consolidated results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's recurring losses from operations and negative cash flows from operations 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 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ EisnerAmper LLP

Edison, New Jersey March 28, 2012

## GENTA INCORPORATED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value data)

| (iii tilousalius, except pai value data)                                             | December 31, | December 31, |
|--------------------------------------------------------------------------------------|--------------|--------------|
| ASSETS                                                                               | 2011         | 2010         |
| Current assets:                                                                      | 2011         | 2010         |
| Cash and cash equivalents                                                            | \$2,116      | \$12,835     |
| Receivable on sale of New Jersey tax losses (Note 10)                                | 1,202        | \$12,033     |
|                                                                                      | 24           | 31           |
| Inventory (Note 3)                                                                   |              |              |
| Prepaid expenses and other current assets                                            | 859          | 890          |
| m · 1                                                                                | 4.001        | 10.756       |
| Total current assets                                                                 | 4,201        | 13,756       |
|                                                                                      | •            | 224          |
| Property and equipment, net (Note 4)                                                 | 288          | 334          |
| Deferred financing costs (Note 9)                                                    | 1,538        | 1,459        |
| Restricted cash account (Note 5)                                                     | 8,470        | -            |
|                                                                                      |              |              |
| Total assets                                                                         | \$14,497     | \$15,549     |
|                                                                                      |              |              |
| LIABILITIES AND STOCKHOLDERS' DEFICIT                                                |              |              |
|                                                                                      |              |              |
| Current liabilities:                                                                 |              |              |
| Accounts payable and accrued expenses (Note 6)                                       | \$10,246     | \$5,813      |
| Notes payable for financing insurance policies (Note 8)                              | 384          | 421          |
| Convertible notes due July 7, 2011, \$36 outstanding, net of debt discount of (\$36) |              |              |
| at December 31, 2010 (Note 9)                                                        |              | -            |
| Convertible notes due September 4, 2011, \$4,386 outstanding, net of debt            |              |              |
| discount of (\$4,386) at December 31, 2010 (Note 9)                                  |              | _            |
| Convertible notes due April 2, 2012, \$229 outstanding, net of debt discount of      |              |              |
| (\$229) at December 31, 2010 (Note 9)                                                |              | _            |
| Convertible notes due March 9, 2013, \$25,385 outstanding, net of debt discount of   |              |              |
| (\$24,466) at December 31, 2011 and \$25,130 outstanding, net of debt discount of    |              |              |
| (\$25,130) at December 31, 2010 (Note 9)                                             | 919          | _            |
| Convertible notes due September 9, 2013, \$2,153 outstanding, net of debt            | 717          |              |
| discount of (\$2,099) at December 31, 2011 (Note 9)                                  | 54           |              |
| Convertible notes due September 9, 2021, \$14,778 outstanding, net of debt           | 34           |              |
| discount of (\$14,718) at December 31, 2011 (Note 9)                                 | 60           |              |
| discount of (\$14,716) at December 31, 2011 (Note 9)                                 | 00           |              |
| Total current liabilities                                                            | 11,663       | 6,234        |
| Total current naomities                                                              | 11,005       | 0,234        |
| I and tame lightification                                                            |              |              |
| Long-term liabilities:                                                               | 1 705        | 1 070        |
| Office lease settlement obligation (Note 7)                                          | 1,795        | 1,872        |
| Convertible June 2008 notes due September 9, 2013, \$2,030 outstanding, net of       | <b>5</b> 0   |              |
| debt discount of (\$1,980) at December 31, 2011 (Note 9)                             | 50           | 10.720       |
| Warrant liability (Note 9)                                                           | 40,235       | 18,738       |
|                                                                                      |              |              |
| Total long-term liabilities                                                          | 42,080       | 20,610       |

### Commitments and contingencies (Note 14)

| Stockholders' deficit:                                                               |            |   |            |   |
|--------------------------------------------------------------------------------------|------------|---|------------|---|
| Preferred stock, 5,000 shares authorized:                                            |            |   |            |   |
| Series A convertible preferred stock, \$.001 par value; 8 shares issued and          |            |   |            |   |
| outstanding, liquidation value of \$385 at December 31, 2011 and December 31,        |            |   |            |   |
| 2010, respectively                                                                   | -          |   | -          |   |
| Series G participating cumulative preferred stock, \$.001 par value; 0 shares issued |            |   |            |   |
| and outstanding at December 31, 2011 and December 31, 2010, respectively             |            |   |            |   |
| (Note 11)                                                                            | -          |   | -          |   |
| Common stock, \$.001 par value; 100,000,000 shares authorized, 1,344,292 and         |            |   |            |   |
| 3,306 shares issued and outstanding at December 31, 2011 and December 31,            |            |   |            |   |
| 2010, respectively (Note 11)                                                         | 1,344      |   | 3          |   |
| Additional paid-in capital                                                           | 1,226,556  |   | 1,186,428  |   |
| Accumulated deficit                                                                  | (1,267,146 | ) | (1,197,726 | ) |
|                                                                                      |            |   |            |   |
| Total stockholders' deficit                                                          | (39,246    | ) | (11,295    | ) |
|                                                                                      |            |   |            |   |
| Total liabilities and stockholders' deficit                                          | \$14,497   |   | \$15,549   |   |

See accompanying notes to consolidated financial statements.

## GENTA INCORPORATED CONSOLIDATED STATEMENTS OF OPERATIONS

|                                                                     |           | ded December 31, |   |
|---------------------------------------------------------------------|-----------|------------------|---|
| (In thousands, except per share data)                               | 2011      | 2010             |   |
| Product sales - net                                                 | \$194     | \$257            |   |
| Cost of goods sold                                                  | 7         | 47               |   |
| Gross margin                                                        | 187       | 210              |   |
| Operating expenses:                                                 |           |                  |   |
| Research and development                                            | 12,434    | 10,015           |   |
| Selling, general and administrative                                 | 6,347     | 9,764            |   |
| Total operating expenses                                            | 18,781    | 19,779           |   |
| - van spermang en penase                                            | 23,. 32   | -24,             |   |
| Other income/(expense), net:                                        |           |                  |   |
| Interest income and other income, net                               | 18        | 544              |   |
| Interest expense                                                    | (4,094    | ) (3,389         | ) |
| Amortization of deferred financing costs and debt discount (Note 9) | (27,546   | ) (34,931        | ) |
| Fair value - conversion feature liability (Note 9)                  | -         | (55,813          | ) |
| Fair value - warrant liability (Note 9)                             | (20,406   | ) (54,638        | ) |
| Total other income/(expense), net                                   | (52,028   | ) (148,227       | ) |
|                                                                     |           |                  |   |
| Loss before income tax benefit                                      | (70,622   | ) (167,796       | ) |
| Income tax benefit (Note 10)                                        | 1,202     | 497              |   |
| Net loss                                                            | \$(69,420 | ) \$(167,299     | ) |
|                                                                     |           |                  |   |
| Net loss per basic and diluted share                                | \$(0.20   | ) \$(246.04      | ) |
|                                                                     |           |                  |   |
| Shares used in computing net loss per basic and diluted share       | 344,015   | 680              |   |

See accompanying notes to consolidated financial statements.

## GENTA INCORPORATED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT

For the Years Ended December 31, 2011 and 2010

|                                                                        | Convertib<br>Preferred | Stock  | Common Stock |        | Additional<br>Paid-in |                   | Total<br>tockholders' |
|------------------------------------------------------------------------|------------------------|--------|--------------|--------|-----------------------|-------------------|-----------------------|
| (In thousands)                                                         | Shares                 | Amount | Shares       | Amount | Capital               | Deficit           | Deficit               |
| Balance at January 1, 2010                                             | 8                      | \$ -   | 39           | \$ -   | \$ 1,027,565          | \$ (1,030,427) \$ | 6 (2,862 )            |
| Net loss                                                               | -                      | -      | -            | -      | -                     | (167,299 )        | (167,299)             |
| Issuance of common stock on voluntary conversion of convertible notes  | -                      | -      | 3,261        | 3      | 17,408                | -                 | 17,411                |
| Issuance of common stock on settlement of class action lawsuit         | -                      | -      | -            | -      | 700                   | -                 | 700                   |
| Adjustment of conversion prices on outstanding Notes                   | -                      | -      | _            | -      | 18,712                | _                 | 18,712                |
| Transfer of warrant liability to paid-in-capital                       | -                      | -      | -            | -      | 35,900                | -                 | 35,900                |
| Transfer beneficial conversion feature to paid-in-capital              | -                      | -      | -            | -      | 81,793                | -                 | 81,793                |
| Vesting of restricted stock                                            | -                      | -      | 6            | -      | -                     | -                 | -                     |
| Stock-based<br>compensation expense<br>Balance at December<br>31, 2010 | - 8                    | -      | 3,306        | - 3    | 4,350<br>1,186,428    | -<br>(1,197,726)  | 4,350<br>(11,295 )    |
| Net loss                                                               | -                      | -      | -            | -      | -                     | (69,420 )         | (69,420 )             |
| Issuance of common stock on voluntary conversion of convertible notes  |                        |        | 1 220 042    | 1 220  | 4 760                 |                   | 6,108                 |
| conventible notes                                                      | -                      | -      | 1,338,842    | 1,339  | 4,769                 | -                 | 0,108                 |
|                                                                        | -                      | -      | 2,144        | 2      | (2)                   | -                 | -                     |

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| Issuance of common   |   |      |           |          |              |                |             |
|----------------------|---|------|-----------|----------|--------------|----------------|-------------|
| stock on exercise of |   |      |           |          |              |                |             |
| March 2010 Warrants  |   |      |           |          |              |                |             |
|                      |   |      |           |          |              |                |             |
| Adjustment of        |   |      |           |          |              |                |             |
| conversion prices on |   |      |           |          |              |                |             |
| outstanding Notes    | _ | -    | _         | -        | 22,445       | _              | 22,445      |
| Č                    |   |      |           |          |              |                |             |
| September 2011       |   |      |           |          |              |                |             |
| financing            | _ | _    | _         | _        | 12,700       | _              | 12,700      |
|                      |   |      |           |          | 12,700       |                | 12,700      |
| Stock-based          |   |      |           |          |              |                |             |
|                      |   |      |           |          | 216          |                | 216         |
| compensation expense | - | -    | -         | -        | 210          | -              | 210         |
| Balance at December  |   |      |           |          |              |                |             |
| 31, 2011             | 8 | \$ - | 1,344,292 | \$ 1,344 | \$ 1,226,556 | \$ (1,267,146) | \$ (39,246) |

See accompanying notes to consolidated financial statements.

## GENTA INCORPORATED CONSOLIDATED STATEMENTS OF CASH FLOWS

|                                                                                      | Years Ended    | December 31, |   |
|--------------------------------------------------------------------------------------|----------------|--------------|---|
| (In thousands)                                                                       | 2011           | 2010         |   |
|                                                                                      |                |              |   |
| Operating activities:                                                                |                |              |   |
| Net loss                                                                             | \$(69,420      | ) \$(167,299 | ) |
| Adjustments to reconcile net loss to net cash and cash equivalents used in operation | ng activities: |              |   |
| Depreciation and amortization                                                        | 186            | 147          |   |
| Amortization of deferred financing costs and debt discount (Note 9)                  | 27,546         | 34,931       |   |
| Share-based compensation (Note 12)                                                   | 405            | 4,350        |   |
| Sale of New Jersey tax losses - proceeds not received until 2012 (Note 10)           | (1,202         | ) -          |   |
| Change in fair value - conversion feature liability (Note 9)                         | -              | 55,813       |   |
| Change in fair value - warrant liability (Note 9)                                    | 20,406         | 54,638       |   |
| Changes in operating assets and liabilities:                                         |                |              |   |
| Receivable on sale of New Jersey tax losses (Note 10)                                | -              | 2,873        |   |
| Inventory                                                                            | 7              | 50           |   |
| Prepaid expenses and other current assets                                            | 31             | 83           |   |
| Accounts payable and accrued expenses (Note 6)                                       | 7,630          | 104          |   |
|                                                                                      |                |              |   |
| Net cash and cash equivalents used in operating activities                           | (14,411        | ) (14,310    | ) |
| Investing activities:                                                                |                |              |   |
| Release of restricted cash deposits (Note 5)                                         | -              | 5,008        |   |
| Interest earned on restricted cash deposits                                          | (3             | ) (8         | ) |
| Purchase of property and equipment                                                   | (140           | ) (276       | ) |
|                                                                                      |                |              |   |
| Net cash and cash equivalents (used in) provided by investing activities             | (143           | ) 4,724      |   |
| Financing activities:                                                                |                |              |   |
| Sale of units, net of financing costs (Note 9)                                       | 12,339         | 25,784       |   |
| Deposits in restricted cash account (Note 5)                                         | (8,467         | ) (5,000     | ) |
| Issuance of note payable for financing insurance policies (Note 8)                   | 544            | 531          |   |
| Repayments of note payable for financing insurance policies (Note 8)                 | (581           | ) (110       | ) |
|                                                                                      |                |              |   |
| Net cash and cash equivalents provided by financing activities                       | 3,835          | 21,205       |   |
|                                                                                      |                |              |   |
| (Decrease)/increase in cash and cash equivalents                                     | (10,719        | ) 11,619     |   |
| Cash and cash equivalents at beginning of year                                       | 12,835         | 1,216        |   |
|                                                                                      |                |              |   |
| Cash and cash equivalents at end of year                                             | \$2,116        | \$12,835     |   |
|                                                                                      |                |              |   |

See accompanying notes to consolidated financial statements.

# GENTA INCORPORATED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS For the years and all December 21, 2011 and 2010

For the years ended December 31, 2011 and 2010

1. Organization and Liquidity

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

The Company has had recurring annual operating losses and negative cash flows from operations since its inception. The Company expects that such losses will continue at least until one or more of its product candidates are approved by one or more regulatory authorities for commercial sale in one or more indications. For the year ended December 31, 2011, the Company had a net loss of \$69.4 million and a net cash outflow from operations of \$14.4 million. As of December 31, 2011, the Company had an accumulated deficit of \$1,267.1 million and held cash and cash equivalents of \$2.1 million. In recent years, the Company has financed its operations from the sale of convertible notes, shares of common stock and warrants.

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

In September 2011, the Company issued \$12.7 million of units, consisting of \$4.2 million of senior secured convertible notes and \$8.5 million of senior secured cash collateralized convertible notes. In connection with the sale of the units, the Company also issued two types of debt warrants in an amount equal to 100% of the purchase price for each unit. The Company had direct access to \$4.2 million of the proceeds, and the remaining \$8.5 million of the proceeds were placed in a blocked account as collateral security for the \$8.5 million senior secured cash collateralized convertible notes. Presently, with no further financing, the Company projects that it will run out of funds in April 2012. The Company currently does not have any additional financing in place. If it is unable to raise additional funds, the Company could be required to reduce its spending plans, reduce its workforce, license one or more of its products or technologies that it would otherwise seek to commercialize itself, sell some or all of its assets, cease operations or even declare bankruptcy. There can be no assurance that the Company can obtain financing, if at all, or raise such additional funds, on terms acceptable to it.

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

2. Summary of Significant Accounting Policies

#### **Accounting Standards Updates**

In May 2011, the Financial Accounting Standards Board ("FASB") issued ASU 2011-04, Fair Value Measurement (Topic 820), "Amendments to Achieve Common Fair Value Measurements and Disclosure Requirements in U.S. GAAP and IFRS" ("ASU 2011-04"). ASU 2011-04 amends the wording used to describe many of the requirements for measuring fair value to achieve the objective of developing common fair value measurement and disclosure requirements, as well as improving consistency and understandability. Some of the requirements clarify the FASB's intent about the application of existing fair value measurement requirements while other amendments change a

particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. ASU 2011-04 is effective for calendar years beginning after December 15, 2011. Early adoption is prohibited. The Company is currently evaluating the potential impact of ASU 2011-04 on the consolidated financial statements and related disclosures but does not anticipate a material impact to the Company on the consolidated financial statements.

Other Accounting Standards Updates not effective until after December 31, 2011 are not expected to have a significant effect on the Company's consolidated financial statements.

#### **Basis of Presentation**

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

#### Use of Estimates

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

#### Cash and Cash Equivalents

Cash and cash equivalents consists of highly liquid instruments with maturities of three months or less from the date acquired and are stated at cost that approximates their fair market value.

#### Revenue Recognition

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

#### Research and Development

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

#### Income Taxes

The Company uses the liability method of accounting for income taxes. Deferred income taxes are determined based on the estimated future tax effects of differences between the financial statement and tax bases of assets and liabilities given the provisions of the enacted tax laws. Management records valuation allowances against net deferred tax assets, if based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and when temporary differences become deductible. The Company considers, among other available information, uncertainties surrounding the recoverability of deferred tax assets, scheduled reversals of deferred tax liabilities, projected future taxable income and other matters in making this assessment. The Company reviewed its deferred tax assets and at both December 31, 2011 and December 31, 2010, recorded a valuation allowance to reduce these assets to zero to reflect that, more likely than not, they will not be realized. Utilization of the Company's net operating loss ("NOL") and research and development ("R&D") credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended, (the "Code"), as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups.

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

#### Restricted Stock Units

Restricted stock units ("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. The compensation cost of the RSUs is being recognized over the vesting period of the RSUs. Under the terms of virtually all of the Company's outstanding RSUs, the holders of the RSUs are entitled to anti-dilution protection in the form of additional shares of stock to be issued on the vesting dates of the underlying RSUs. The Company re-measures these RSUs to fair value, including the obligation to issue incremental shares under anti-dilution provisions, at each reporting period until the shares are issued. See Note 12 to the consolidated financial statements for a further discussion on share-based compensation.

#### **Deferred Financing Costs**

In conjunction with the issuance of the June 2008 Notes, the April 2009 Notes, the September 2009 Notes, the March 2010 Notes and the September 2011 Notes (as described in Note 9 to the consolidated financial statements), the Company incurred certain financing costs, including, for several of the financings, the issuance of warrants to purchase the Company's common stock. This additional consideration is being amortized over the term of the notes through their respective maturity dates. If the maturity of the notes is accelerated because of conversions or defaults, then the amortization is accelerated. The fair value of the warrants issued as placement fees in connection with these financings are calculated utilizing the Black-Scholes valuation model.

#### Net Loss Per Common Share

Net loss per common share for the years ended December 31, 2011 and December 31, 2010 are based on the weighted average number of shares of common stock outstanding during the periods. Basic and diluted loss per share are identical for both periods presented as potentially dilutive securities have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would be antidilutive. At December 31, 2011, the potentially dilutive securities included 60,223 million shares reserved for the conversion of convertible notes and convertible preferred stock, the vesting of RSUs and the exercise of outstanding warrants and debt warrants. At December 31, 2010, the potentially dilutive securities included 311 million shares reserved for the conversion of convertible notes and convertible preferred stock, the vesting of RSUs and the exercise of outstanding warrants.

3. Inventory

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

|                | Dece | December 31, |  |  |
|----------------|------|--------------|--|--|
|                | 2011 | 2010         |  |  |
| Raw materials  | \$24 | \$24         |  |  |
| Finished goods | -    | 7            |  |  |
|                | \$24 | \$31         |  |  |

### 4. Property and Equipment, Net

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

|                                   | Estimated     |         | December 31, |
|-----------------------------------|---------------|---------|--------------|
|                                   | Useful Lives  | 2011    | 2010         |
| Computer equipment                | 3             | \$1,927 | \$1,980      |
| Software                          | 3             | 3,062   | 2,940        |
| Furniture and fixtures            | 5             | 896     | 896          |
| Leasehold improvements            | Life of lease | 433     | 433          |
| Equipment                         | 5             | 51      | 51           |
|                                   |               | 6,369   | 6,300        |
| Less accumulated depreciation and |               |         |              |
| amortization                      |               | (6,081  | ) (5,966 )   |
|                                   |               | \$288   | \$334        |

Depreciation and amortization expense was \$186 thousand for the year ended December 31, 2011 and \$147 thousand for the year ended December 31, 2010.

5. Restricted Cash

Restricted cash at December 31, 2011 represents funds received from the September 2011 financing that were placed in a blocked account as collateral security for the H Notes (as defined in Note 9 to the consolidated financial statements).

6. Accounts Payable and Accrued Expenses

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

|                                         | December 31, |         |  |
|-----------------------------------------|--------------|---------|--|
|                                         | 2011         | 2010    |  |
| Accounts payable                        | \$3,635      | \$2,092 |  |
| Accrued compensation                    | 632          | 283     |  |
| Accrued interest                        | 1,630        | 1,081   |  |
| Accrued expenses – Genasense®           | 1,881        | -       |  |
| State of New Jersey (AMA) tax liability | 1,014        | 953     |  |
| Other accrued expenses                  | 1,454        | 1,404   |  |
|                                         | \$10,246     | \$5,813 |  |

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

7. Office Lease Obligation and Operating Leases

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

Future minimum obligations under operating leases at December 31, 2011, are as follows (\$ thousands):

| 2012 | \$784   |
|------|---------|
| 2013 | 783     |
| 2014 | 781     |
| 2015 | 2,056   |
|      | \$4,404 |

Annual rent expense incurred by the Company during both 2011 and 2010 was \$0.7 million for each year.

8. Notes Payable for Financing Insurance Policies

In June 2011 and in October 2011, the Company issued notes payable totaling \$0.5 million to finance premiums for its corporate insurance policies. In October 2010, the Company issued a note payable of \$0.5 million to finance premiums for its corporate insurance policies. Payments on each of the notes payable were scheduled for nine equal monthly installments. The carrying amounts of the notes payable approximate fair value due to the short-term nature of these instruments.

9. Convertible Notes and Warrants

On September 9, 2011, the Company issued \$12.7 million of units (the "2011 Units"), pursuant to a securities purchase agreement dated September 2, 2011 (the "September 2011 Purchase Agreement"), each 2011 Unit consisting of (i) 12% senior secured convertible promissory notes due September 9, 2021, convertible into shares of common stock, at an initial conversion rate of 671,040 shares of common stock for every \$1,000 of principal and accrued interest due under the notes (the "G Notes"), (ii) 12% senior secured cash collateralized convertible promissory notes due September 9, 2021, convertible into shares of common stock, at a rate of 671,040 shares of common stock for every \$1,000 of principal and accrued interest due under the notes (the "H Notes", together with the G Notes, the "September 2011 Notes"), (iii) senior secured convertible promissory note warrants to purchase an amount of G Notes equal to the G Notes purchased at the closing, with a maturity of five years (the "G Warrants"), which purchase price may be paid through a cashless net exercise feature, and (iv) senior secured cash collateralized convertible promissory note warrants to purchase an amount of G Notes equal to the H Notes purchased at closing, with a maturity of five years (the "H Warrants," together with the G Warrants, the "September 2011 Debt Warrants"), which purchase price may also be paid through a cashless net exercise feature. The issuance of the September 2011 Notes and September 2011 Debt Warrants in exchange for \$12.7 million is referred to herein as the "September 2011 Financing."

The September 2011 Notes are secured by all of the assets of the Company. The Company had direct access to \$4.2 million of the proceeds and the remaining \$8.5 million of the proceeds were placed in a blocked account as collateral security for the \$8.5 million in principal amount of H Notes. The security interest in the cash collateral in the blocked account maintained for the benefit of the holders of the H Notes will be released if over any consecutive ten day trading period, the trading volume and price of the Company's common stock meet certain levels. The security interest will also be released dollar for dollar upon conversion of any part of the H Notes or upon the approval of each holder of the then outstanding H Notes with respect to such holder's H Notes only. At any time after the first anniversary of the issuance date, the holder of a G Note can require the Company to redeem the note upon 10 days prior written notice and at any time after the six-month anniversary of the issuance date, the holder of a H Note can require the Company to redeem the note upon 10 days prior written notice. The September 2011 Notes are classified as a short-term liability due to this right of redemption.

Pursuant to the terms of the G Notes, as amended, there are certain provisions providing for the adjustment of the conversion price of the G Notes. If on the last trading day prior to the Saturday that is one week after the Reverse Split Effective Date (as defined in the September 2011 Purchase Agreement), the volume weighted closing price of the Company's common stock for the three consecutive day period prior to that date is less than the conversion price for the G Notes then in effect, the conversion price for the G Notes shall be reduced to a price equal to 10% of that three-day calculation. Also, if on the last trading day prior to the Saturday following the date that is six months after September 9, 2011 the volume weighted closing price of the Company's common stock for the three consecutive trading day period prior to that date is less than the conversion price for the G Notes then in effect, the conversion price for the G Notes shall be reduced to a price equal to 10% of that three-day calculation. In accordance with the terms of all of the Company's other convertible notes, debt warrants, March 2010 Warrants, December 2010 Warrants, and September 2011 Warrants, all described below, the conversion prices of all of the Company's other notes, debt warrants, March 2010 Warrants, December 2010 Warrants and September 2011 Warrants will be adjusted to be the same conversion price of the G Notes.

In connection with the September 2011 Financing, pursuant to an agreement between the Company and certain investors, the maturity dates of the June 2008 Notes, April 2009 Notes and September 2009 Notes, all described below, were extended to September 9, 2013, and the holders of such existing indebtedness acknowledged that the June 2008 Notes, April 2009 Notes and September 2009 Notes are subordinate and subject in right of payment to the prior payment in full of the September 2011 Notes. Additionally, holders of the March 2010 Notes also acknowledged that the March 2010 Notes are subordinate and subject in right of payment to the prior payment in full of the September 2011 Notes.

Also, pursuant to an agreement between the Company and certain investors, effective September 2, 2011, the conversion rate of the April 2009 Notes, defined below, was changed to 671,040 shares of common stock for every \$1,000 of principal or interest that is being converted. In accordance with the terms of all of the Company's other convertible notes, debt warrants, March 2010 Warrants and December 2010 Warrants, the conversion prices of all of the Company's other notes, debt warrants, March 2010 Warrants and December 2010 Warrants were also adjusted to equal \$0.00149, effective September 2, 2011. The Company valued this change in the conversion rate on September 2, 2011; the aggregate intrinsic value of the difference in conversion rates was in excess of the face value of each of its convertible notes. Thus, a full debt discount was recorded in an amount equal to the face value of each of the Company's convertible notes on September 2, 2011 and the Company began amortizing the resultant debt discount over the remaining term of the convertible notes.

As consideration for the amendments above, the Company issued to each of the holders of the then outstanding June 2008 Notes, April 2009 Notes and September 2009 Notes, a three-year warrant, (the "September 2011 Warrants"), to purchase shares of common stock at an exercise price equal to the conversion price of the Company's convertible notes. Each September 2011 Warrant is exercisable for a number of shares of common stock equal to one hundred percent (100%) of the number of shares of common stock that would be issuable if such holder converted all of the outstanding principal and interest underlying all of such holder's June 2008 Notes, April 2009 Notes or September 2009 Notes, on September 2, 2011, or approximately \$29.4 million.

According to another agreement entered between the Company and certain investors, the conversion price of the Company's convertible notes, and the exercise price of the March 2010 Warrants, the December 2010 Warrants and the September 2011 Warrants were reset to \$0.001 effective December 17, 2011. The conversion price reset on all of the Company's convertible notes resulted in a full debt discount being recorded in an amount equal to the face value of the Company's convertible notes on December 17, 2011. The Company is amortizing the resultant debt discounts over the terms of the notes through their maturity dates.

On December 19, 2011, three holders of September 2011 Debt Warrants totaling \$2.9 million, exercised their warrants using a cashless exercise procedure and received September 2011 G Notes for \$2.1 million. The aggregate intrinsic value of the difference between the market price of a share of the Company's stock on December 19, 2011 and the conversion price of the notes was in excess of the face value of the G Notes of \$2.1 million, and a full debt discount was recorded in an amount equal to the face value of the notes. The Company will amortize the resultant debt discount over the term of the notes through their maturity date.

The September 2011 Warrants and the September 2011 Debt Warrants both have anti-dilution protection and can be exercised using a cashless exercise procedure; warrants with these characteristics are accounted for as liabilities and marked-to-market over their lives. Based upon a Black-Scholes valuation model, a liability of \$72.3 million was recorded for the value, in total, of the September 2011 Warrants and the September 2011 Debt Warrants on the date of their issuance. At December 31, 2011, the September 2011 Warrants and the September 2011 Debt Warrants were valued, in total, at \$36.5 million based upon a Black-Scholes valuation model, resulting in a net expense of \$35.3 million on the Consolidated Statement of Operations for the year ended December 31, 2011.

The September 2011 Warrants were valued at December 31, 2011 and September 9, 2011 using the Black-Scholes valuation model with the following assumptions:

|                                       | December 31, | September 9, |
|---------------------------------------|--------------|--------------|
|                                       | 2011         | 2011         |
| Price per share of Genta common stock | \$0.0026     | \$0.0064     |
| Volatility                            | 248          | % 304 %      |
| Risk-free interest rate               | 0.32         | % 0.31 %     |
| Remaining contractual lives           | 2.69         | 3.0          |

The September 2011 Debt Warrants were valued at December 31, 2011 and September 9, 2011 using the Black-Scholes valuation model with the following assumptions:

|                                       | December 31, | September 9, |
|---------------------------------------|--------------|--------------|
|                                       | 2011         | 2011         |
| Price per share of Genta common stock | \$0.0026     | \$0.0064     |
| Volatility                            | 265          | % 251 %      |
| Risk-free interest rate               | 0.78         | % 0.81 %     |
| Remaining contractual lives           | 4.7          | 5.0          |

In connection with the September 2011 Financing, the Company issued warrants to its private placement agents (the "September 2011 Placement Warrants") and incurred financing fees of \$0.4 million. The September 2011 Placement Warrants, after adjustment, are to purchase 254 million shares of common stock at an exercise price of \$0.001 per share, subject to antidilution adjustments. The financing fees and the initial value of the September 2011 Placement Warrants of \$1.1 million are being amortized over the term of the September 2011 Notes.

On October 7, 12, 19, 24, and 31, 2011 and on November 7, 16, 21, and 28, 2011 and on December 4 and 16, 2011, the Company entered into amendment agreements with certain investors in the September 2011 Financing to amend the terms of the G Notes to reflect the adjustments described above and to extend the deadline set forth in the September 2011 Purchase Agreement for the Company to effect a reverse stock split.

On March 9, 2010, the Company issued \$10 million of senior unsecured convertible notes (the "B Notes"), \$10 million of senior unsecured convertible notes (the "C Notes") and \$5 million of senior unsecured convertible notes (the "D Notes"). In connection with the sale of the notes, the Company also issued warrants (the "March 2010 Debt Warrants") to purchase \$10 million of senior unsecured convertible notes (the "E Notes"). In March and April 2010, four investors who had participated in the Company's April 2009 financing, described below, exercised their rights under the April 2009 securities purchase agreement and the April 2009 consent agreement to acquire \$1.0 million of senior unsecured convertible notes (the "F Notes"). In May 2010, two holders of March 2010 Debt Warrants totaling \$1.3 million exercised their warrants using a cashless exercise procedure and received, in total, \$1.1 million of E Notes. In October 2010, two investors exercised March 2010 Debt Warrants totaling \$4.0 million using a cashless exercise procedure and received \$3.6 million of E Notes. In January 2011, two investors exercised March 2010 Debt Warrants totaling

\$2.7 million using a cashless exercise procedure and received \$2.4 million of E Notes. The notes in all of the above transactions, ("the March 2010 Notes"), bear interest at an annual rate of 12% payable semiannually in other convertible notes. At any time after the second anniversary of the issuance date, the holder can require the Company to redeem the note upon 10 days prior written notice. The March 2010 Notes are classified as a short-term liability due to this right of redemption. As of December 31, 2011, the March 2010 Notes were convertible into shares of Genta common stock at a conversion rate of \$0.001.

Concurrent with the sale of the March 2010 Notes, the Company also extended the maturity date of the outstanding June 2008 Notes from June 9, 2010 to June 9, 2011 in exchange for three-year warrants ("March 2010 Warrants") to purchase the same number of shares of the Company's common stock issuable upon conversion of such June 2008 Notes. Subsequently, the maturity of the outstanding June 2008 Notes has been extended several times and is currently September 9, 2013.

Prior to the approval of a reverse stock split in July 2010, there were not enough shares of common stock authorized under the Company's certificate of incorporation to cover the shares underlying all of the March 2010 Notes. The Company accounted for the conversion options embedded in the March 2010 Notes in accordance with "Accounting for Derivative Instruments and Hedging Activities", FASB ASC 815-10, and "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock", FASB ASC 815-40. FASB ASC 815-10 generally requires companies to bifurcate conversion options embedded in convertible notes from their host instruments and to account for them as free standing derivative financial instruments in accordance with FASB ASC 815-40. FASB ASC 815-40 states that if the conversion option requires net cash settlement in the event of circumstances that are not solely within the Company's control, then the notes should be classified as a liability measured at fair value on the balance sheet. In this case, the holder of each March 2010 Note has the right to require the Company to repay 100% of the outstanding principal and accrued interest on each note in cash on the second anniversary of the closing date of the March 2010 financing.

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

In connection with the March 2010 financing, the convertible features of the B, C, and D Notes were recorded as derivative liabilities of \$263.5 million, resulting in an expense of \$238.5 million. The Company recorded an initial discount of \$25.0 million, equal to the face value of the notes, which is being amortized over the life of the notes through their maturity dates. Similarly, in March and April 2010, in connection with a \$1.0 million exercise of purchase rights/options, the convertible features of the F Notes were recorded as a derivative liability of \$5.4 million, resulting in an expense of \$4.4 million. The Company recorded an initial discount of \$1.0 million, equal to the face value of the F Notes, which is being amortized over the life of the notes through their maturity dates. In May 2010, in connection with the issuance of the \$1.1 million of E Notes, the convertible features of the E Notes were recorded as a derivative liability of \$7.5 million, resulting in expense of \$6.4 million. The Company recorded an initial discount of \$1.1 million, equal to the face value of the E Notes, which is being amortized over the life of the notes through their maturity dates.

In July 2010, the Company's Board of Directors approved the implementation of a reverse stock split at a ratio of 1-for-100 shares, resulting in the Company having enough shares to accommodate the potential number of shares underlying the March 2010 Notes and the March 2010 Debt Warrants. The fair value of the conversion feature liability of the March 2010 Notes was re-measured at July 9, 2010 at \$81.8 million and credited to permanent equity, resulting in expense of \$55.8 million for the year ended December 31, 2010.

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

|         |           |          | March  |          |
|---------|-----------|----------|--------|----------|
| July 9, | May 6/10, | April 9, | 17/22, | March 9, |
| 2010    | 2010      | 2010     | 2010   | 2010     |

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| 266  | %   |
|------|-----|
|      |     |
| 1.43 | %   |
| 3.0  |     |
|      | 3.0 |

From January 1, 2011 through December 31, 2011, holders of the B Notes voluntarily converted \$2.1 million, resulting in an issuance of 386 million shares of common stock, holders of C Notes voluntarily converted \$1.1 million, resulting in an issuance of 220 million shares of common stock, holders of D Notes voluntarily converted \$0.2 million, resulting in an issuance of 11 million shares of common stock, holders of E Notes voluntarily converted \$1.6 million, resulting in an issuance of 616 million shares of common stock and holders of F Notes voluntarily converted \$0.2 million, resulting in an issuance of 17 million shares of common stock. At December 31, 2011, the face value outstanding of the B Notes were \$5.8 million, the C Notes were \$7.5 million, the D Notes were \$5.8 million and the E Notes were \$6.3 million.

The Company recorded the liability for the March 2010 Debt Warrants at a fair value of \$105.6 million on March 9, 2010, based upon a Black-Scholes calculation. The debt warrant liability was marked-to-market and charged/credited to expense in a manner similar to the conversion feature at each reporting date until all the criteria for permanent equity were met on July 9, 2010.

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

|                                       | July 9, 2010 | March 9, 2010 |   |
|---------------------------------------|--------------|---------------|---|
| Price per share of Genta common stock | \$152.50     | \$530.00      |   |
| Volatility                            | 237          | % 225         | % |
| Risk-free interest rate               | 1.54         | % 2.15        | % |
| Remaining contractual lives           | 4.3          | 4.6           |   |

In December 2010, the Company extended the maturity date of its outstanding June 2008 Notes from June 9, 2011 to September 4, 2011 in exchange for December 2010 Warrants. The December 2010 Warrants allow the holder to purchase 10% of the number of shares of common stock issuable upon conversion of June 2008 Notes in December 2010 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. Based upon a Black-Scholes valuation model, a liability of \$18.7 million was recorded at December 31, 2010 for the value of the March 2010 Warrants and December 2010 Warrants. At December 31, 2011, the March 2010 Warrants and December 2010 Warrants were valued at \$3.8 million based upon a Black-Scholes valuation model, resulting in income of \$14.9 million on the Consolidated Statements of Operations for the twelve months ended December 31, 2011.

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

|                                       | December 3 | 1, December 3 | 31, |
|---------------------------------------|------------|---------------|-----|
|                                       | 2011       | 2010          |     |
| Price per share of Genta common stock | \$0.0026   | \$1.475       |     |
| Volatility                            | 264        | % 316         | %   |
| Risk-free interest rate               | 0.15       | % 0.70        | %   |
| Remaining contractual lives           | 1.2        | 2.2           |     |

In September 2009, the Company issued \$7 million of July 2009 Notes, common stock, July 2009 Warrants, \$3 million of September 2009 Notes, common stock and September 2009 Warrants to certain accredited institutional investors. The July 2009 Notes and the September 2009 Notes bear interest at an annual rate of 8% payable semi-annually in other senior unsecured convertible promissory notes to the holder, and with the conversion price

reset on December 17, 2011 noted above, are convertible into shares of common stock at a conversion rate of \$0.001.

From January 1, 2011 through December 31, 2011, holders of the September 2009 Notes and July 2009 Notes issued on September 4, 2009 voluntarily converted \$0.7 million, resulting in an issuance of 49 million shares of common stock. At December 31, 2011, \$1.9 million of the September 2009 Notes and July 2009 Notes issued on September 4, 2009 were outstanding.

On July 7, 2009, the Company issued \$3 million of July 2009 Notes, common stock and July 2009 Warrants. At December 31, 2011, due to voluntary conversions by noteholders, there were no July 2009 Notes outstanding.

On April 2, 2009, the Company issued \$6 million of April 2009 Notes and corresponding warrants to purchase common stock. The April 2009 Notes bear interest at an annual rate of 8% payable semi-annually in other senior unsecured convertible promissory notes to the holder. At any time after the second anniversary of the issuance date, the holder can require the Company to redeem the note upon 10 days prior written notice. The April 2009 Notes are classified as a short-term liability due to this right of redemption. With the conversion price reset on December 17, 2011 noted above, the April 2009 Notes are convertible into shares of common stock at a conversion rate of \$0.001. At December 31, 2011, \$0.2 million of the April 2009 Notes were outstanding.

On June 9, 2008, the Company issued \$20 million of June 2008 Notes. The notes bear interest at an annual rate of 15% payable at quarterly intervals in other senior unsecured convertible promissory notes to the holder, and with the conversion price reset on December 17, 2011 noted above, are convertible into shares of common stock at a conversion rate of \$0.001.

From January 1, 2011 through December 31, 2011, holders of the June 2008 Notes voluntarily converted \$0.1 million, resulting in an issuance of 20 million shares of common stock. At December 31, 2011, \$2.0 million of the June 2008 Notes were outstanding.

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

All of the Company's convertible notes contain various provisions regarding the adjustment of their applicable conversion prices. During 2011, conversion price resets went into effect on January 1, March 12, September 2 and December 17. There are two other scheduled adjustments to the conversion prices of the Company's convertible notes.

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

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

| (\$000 face value)                       | 2012 | 2013     | 2021     |
|------------------------------------------|------|----------|----------|
| June 2008 Notes, April 2009 Notes and    |      |          |          |
| September 2009 Notes and July 2009 Notes |      |          |          |
| issued in September 2009                 | \$-  | \$4,182  | \$-      |
| March 2010 Notes                         | -    | 25,385   | -        |
| September 2011 Notes                     | -    | -        | 14,778   |
| Total                                    | \$-  | \$29,567 | \$14,778 |

10. Income Taxes

Significant components of the Company's deferred tax assets as of December 31, 2011 and 2010 and related valuation reserves are presented below (\$ thousands):

| Deferred tax assets:  Net operating loss carryforwards Research and development credit and Orphan Drug credit carryforwards  54,433  50,720 |
|---------------------------------------------------------------------------------------------------------------------------------------------|
| Net operating loss carryforwards Research and development credit and Orphan Drug credit carryforwards  139,192 136,671 54,433 50,720        |
| Research and development credit and Orphan Drug credit carryforwards 54,433 50,720                                                          |
| ·                                                                                                                                           |
|                                                                                                                                             |
| Depreciation and amortization 224 213                                                                                                       |
| Share-based compensation expense 8,229 8,051                                                                                                |
| Write-off of prepaid royalties 558 558                                                                                                      |
| New Jersey Alternative Minimum Assessment (AMA) Tax 730 730                                                                                 |
| New Jersey research and development credits 2,907 3,782                                                                                     |
| Provision for excess inventory 506 520                                                                                                      |
| License agreement 860 933                                                                                                                   |
| Accrued liabilities 1,250 1,269                                                                                                             |
| Other, net 197 245                                                                                                                          |
| Total deferred tax assets 209,086 203,692                                                                                                   |
| Valuation allowance for deferred tax assets (189,585 ) (190,362 )                                                                           |
| Net deferred tax assets \$19,501 \$13,330                                                                                                   |
|                                                                                                                                             |
| Deferred tax liabilities:                                                                                                                   |
| Deferred financing costs \$(1) \$(226)                                                                                                      |
| Debt discount (19,500 ) (13,104 )                                                                                                           |
| Total deferred tax liabilities \$(19,501) \$(13,330)                                                                                        |
|                                                                                                                                             |
| Net deferred tax assets (liabilities) \$- \$-                                                                                               |

A full valuation allowance has been provided at December 31, 2011 and December 31, 2010, to reserve for deferred tax assets, as it appears more likely than not that net deferred tax assets will not be realized.

At December 31, 2011, the Company had unrecognized tax benefits of \$2.1 million, and recorded liabilities for \$1.0 million, which are included in accounts payable and accrued expenses on the Company's Consolidated Balance Sheets. At December 31, 2010, the unrecognized tax benefits were \$2.0 million and recorded liabilities of \$1.0 million. The amount of unrecognized tax benefits that would have an impact on the effective tax rate, if recognized, is \$0.5 million.

A reconciliation of the total amount of unrecognized tax benefits are as follows:

| (\$ in thousands)                                     | 2011    | 2010    |   |
|-------------------------------------------------------|---------|---------|---|
| Unrecognized tax benefits at January 1                | \$1,960 | \$1,922 |   |
| Gross increases: Tax positions taken in prior periods |         |         |   |
| Gross decreases: Tax positions taken in prior periods | (27     | ) (60   | ) |
| Gross Increases- Current period tax positions         | 152     | 98      |   |
| Lapse of Statute of Limitations                       |         |         |   |
| Unrecognized tax benefits: December 31                | \$2,085 | \$1,960 |   |

The Company files corporate tax returns at the federal level and in the State of New Jersey. The open tax years that are subject to examination for these jurisdictions are 2007 through 2011 for federal returns and 2010 through 2011 for tax returns for the State of New Jersey.

New Jersey has enacted legislation permitting certain corporations located in the state to sell state tax loss carryforwards and state research and development credits. In 2011, the Company sold portions of its New Jersey net operating losses and received \$1.2 million in January 2012; the \$1.2 million was included in the Company's Consolidated Balance Sheets at December 31, 2011. In 2010, the Company sold portions of its New Jersey net operating loss carryforwards for \$0.5 million. These sales were accounted for as income tax benefits in the Company's Consolidated Statement of Operations.

If still available under New Jersey law, the Company will attempt to sell its tax loss carryforwards in 2012. The Company cannot be assured that the New Jersey program will continue in 2012, nor can they estimate what percentage of Genta's saleable tax benefits New Jersey will permit it to sell, how much money will be received in connection with the sale, or if the Company will be able to find a buyer for its tax benefits.

The Company's federal tax returns have never been audited. In January 2006, the State of New Jersey concluded its fieldwork with respect to a tax audit for the years 2000 through 2004. The State of New Jersey took the position that amounts reimbursed to Genta by Aventis Pharmaceutical Inc. for co-development expenditures during the audit period were subject to Alternative Minimum Assessment ("AMA"), resulting in a liability at that time of approximately \$0.5 million. Although the Company and its outside tax advisors believe the State's position on the AMA liability is unjustified, there is little case law on the matter and it is probable that the Company will be required to ultimately pay the liability. As of December 31, 2011, the Company had accrued a tax liability of \$0.5 million and penalties and interest of \$0.5 million related to this assessment. The Company appealed this decision to the New Jersey Division of Taxation, and in February 2008, the Division of Taxation notified the Company that its appeal had not been granted. On April 25, 2008, the Company filed a complaint with the Tax Court of the State of New Jersey to appeal the assessment. A bench trial took place on September 18, 2009. After considering the evidence and reviewing the parties' legal briefs, the judge is expected to render a decision in the case.

At December 31, 2011, the Company has federal net operating loss carryforwards of approximately \$345.5 million and state net operating loss carryforwards of approximately \$195.5 million. The federal tax loss carryforward balance at December 31, 2011 begins to expire in 2012 and completely expires in 2031. The Company also has Research and Development credit and Orphan Drug credit carryforwards totaling \$56.4 million; the balance at December 31, 2011 begins to expire in 2012 and completely expires in 2031.

11. Stockholders' Deficit

### Common Stock

At a Special Meeting of Stockholders of the Company held on October 21, 2011, the Company's stockholders authorized its Board of Directors to effect up to two reverse stock splits of all outstanding shares of common stock before December 31, 2012, with each reverse stock split having an exchange ratio from 1-for-2 up to 1-for-500. Even if the Company decides to implement a reverse stock split, it may be unable to obtain the requisite approval from the Financial Industry Regulatory Authority ("FINRA") in order to effect such reverse split.

At a Special Meeting of Stockholders of the Company held on December 29, 2010, the Company's stockholders authorized its Board of Directors to effect up to two reverse stock splits of all outstanding shares of common stock before December 31, 2011, with each reverse stock split having an exchange ratio from 1-for-2 up to 1-for-100. The Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of 1-for-50 shares and the reverse stock split became effective on February 18, 2011. In August 2011, the Company submitted a request to FINRA to process documentation related to a reverse stock split pursuant to Rule 10b-17 of the Securities Exchange Act of 1934, as amended. After continual correspondence between the Company and FINRA, on January 23, 2012, the Company received notice of FINRA's final denial of the Company's request to process the documentation related to the reverse split. In addition, at the meeting, stockholders approved an amendment to the Company's Restated Certificate of Incorporation, as amended, to increase the total number of authorized shares of capital stock available for issuance from 6,005,000,000, consisting of 6,000,000,000 shares of common stock and 5,000,000 shares of preferred stock, to 100,005,000,000, consisting of 100,000,000,000 shares of common stock and 5,000,000 shares of preferred stock.

At the Annual Meeting of Stockholders of the Company held on June 15, 2010, the Company's stockholders authorized its Board of Directors to effect a reverse stock split of all outstanding shares of common stock. The Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of 1-for-100 shares and the reverse stock split became effective on August 2, 2010.

#### Preferred Stock Purchase Right

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

### Series A Preferred Stock

Each share of Series A Preferred Stock is immediately convertible into shares of the Company's common stock, at a rate determined by dividing the aggregate liquidation preference of the Series A Preferred Stock by the conversion price. The conversion price is subject to adjustment for antidilution. As of December 31, 2011, each share of Series A Preferred Stock was convertible into 1.0886 shares of common stock, and on December 31, 2010 each share of Series A Preferred Stock was convertible into 0.0821 shares of common stock. At December 31, 2011 and December 31, 2010, the Company had 7,700 shares of Series A Convertible Preferred Stock issued and outstanding.

In the event of a liquidation of the Company, the holders of the Series A Preferred Stock are entitled to a liquidation preference equal to \$50 per share, or \$0.4 million at December 31, 2011.

#### Series G Preferred Stock

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

#### Warrants

Warrant transactions consisted of the following during the years ended December 31, 2011 and December 31, 2010.

|                                                       | Adjusted       |                |
|-------------------------------------------------------|----------------|----------------|
|                                                       | Number of      | Weighted       |
|                                                       | Shares         | Average        |
|                                                       | (in thousands) | Exercise Price |
|                                                       | at             | at             |
|                                                       | December 31,   | December 31,   |
|                                                       | 2011           | 2011           |
| Outstanding at January 1, 2010                        | 9              | \$4,166.67     |
| March 2010 Warrants issued in March 2010              | 1,377,300      | \$0.001        |
| December 2010 Warrants issued in December 2010        | 192,218        | \$0.001        |
| Warrants outstanding at December 31, 2010             | 1,569,527      |                |
| September 2011 Placement Warrants issued in September |                |                |
| 2011                                                  | 253,915        | \$0.001        |
| September 2011 Warrants issued in September 2011      | 4,131,036      | \$0.001        |
| Warrants outstanding at December 31, 2011             | 5,954,478      | \$0.007        |

The March 2010 Warrants, December 2010 Warrants, September 2011 Placement Warrants and September 2011 Warrants all have antidilution protection and as of December 31, 2011, were exercisable at a price of \$0.001 per share. The exercise rate of these warrants was reduced as the Company issued convertible notes for consideration that was less than the then applicable conversion price and when the conversion price of the convertible notes was adjusted to a price less than the then applicable conversion price.

Warrants outstanding at December 31, 2011 expire as follows:

|      |                                           | Adjusted Number Adjusted E |      | usted Exercise    |  |
|------|-------------------------------------------|----------------------------|------|-------------------|--|
|      |                                           | of Shares (in              | Pric | Price at December |  |
| Year |                                           | thousands)                 |      | 31, 2011          |  |
| 2012 | April 2009 Warrants                       | 3                          | \$   | 2,500.00          |  |
|      | July 2009 Warrants                        | 1                          | \$   | 5,000.00          |  |
|      | September 2009 Warrants and July 2009     |                            |      |                   |  |
|      | Warrants issued in September 2009         | 5                          | \$   | 5,000.00          |  |
| 2013 | March 2010 Warrants                       | 1,377,300                  | \$   | 0.001             |  |
|      | December 2010 Warrants                    | 192,218                    | \$   | 0.001             |  |
|      | September 2011 Warrants issued in         |                            |      |                   |  |
| 2014 | September 2011                            | 4,131,036                  | \$   | 0.001             |  |
|      | September 2011 Placement Warrants issued  |                            |      |                   |  |
| 2016 | in September 2011                         | 253,915                    | \$   | 0.001             |  |
|      | Warrants outstanding at December 31, 2011 | 5,954,478                  |      |                   |  |

#### Common Stock Reserved

At December 31, 2011, the Company had 1,344.3 million shares of common stock outstanding, 123.1 million shares reserved for the conversion of convertible preferred stock and the 2009 Stock Incentive Plan, 15,754.5 million shares reserved for the conversion of outstanding warrants and debt warrants and 44,345.8 million shares reserved for the conversion of convertible notes.

# 12. Stock Incentive Plans and Share-Based Compensation

During 2009, the Company established the 2009 Stock Incentive Plan ("2009 Plan"). At a Special Meeting of Stockholders of Genta Incorporated held on October 21, 2011, the Company's stockholders approved an amendment and restatement of the 2009 Plan, adjusting the number of shares of common stock reserved for issuance under the 2009 Plan to be fifteen percent (15%) of the outstanding shares of the Company's common stock on each of November 1, 2011, April 1, 2012, August 1, 2012, November 1, 2012, April 1, 2013, August 1, 2013, November 1, 2014 August 1, 2014 and September 1, 2014.

To date, the Company has issued restricted stock units, ("RSUs") under the 2009 Plan. The following table summarizes the RSU activity under the 2009 Plan during 2010 and 2011:

|                                                 |            | Weighted       |
|-------------------------------------------------|------------|----------------|
|                                                 | Number of  | Average        |
|                                                 | Shares     | Grant Date     |
|                                                 | (in        | Fair Value per |
| Restricted Stock Units                          | thousands) | Share          |
| Outstanding nonvested RSUs at January 1, 2010   | 9          | \$1,975.00     |
| Granted                                         | 191        | \$2.80         |
| Vested                                          | (7         | \$511.60       |
| Forfeited or expired                            | (1         | \$1,975.00     |
| Outstanding nonvested RSUs at December 31, 2010 | 192        | \$67.21        |
| Granted                                         | 104,367    | \$0.0057       |
| Vested                                          | -          | \$-            |
| Forfeited or expired                            | -          | \$-            |
| Outstanding nonvested RSUs at December 31, 2011 | 104,559    | \$0.1356       |

Based on the closing price of Genta common stock of \$0.0026 per share on December 31, 2011, the intrinsic value of the nonvested RSUs at December 31, 2011 was \$0.3 million. As of December 31, 2011, there was approximately \$0.1 million of total unrecognized compensation cost related to non-vested share-based compensation granted under the 2009 Plan, which is expected to be recognized over a weighted-average period of 1.0 years. Under the terms of virtually all of the Company's outstanding RSUs, the holders of the RSUs are entitled to anti-dilution protection in the form of additional shares of stock to be issued on the vesting dates of the underlying RSUs. During 2011, there were no grants of RSUs to employees; the number of shares in the above table, 104,367, represents the number of shares reserved for antidilution protection during 2011. The Company re-measures these RSUs to fair value, including the obligation to issue incremental shares under anti-dilution provisions, at each reporting period until the shares are issued.

Share-based compensation expense recognized for the years ended December 31, 2011 and December 31, 2010 follows:

| (\$ thousands, except per share data)             | 2011   | 2010    |
|---------------------------------------------------|--------|---------|
| Research and development expenses                 | \$167  | \$1,680 |
| Selling, general and administrative               | 238    | 2,670   |
| Total share-based compensation expense            | \$405  | \$4,350 |
| Share-based compensation expense per common share | \$0.00 | \$6.40  |

13. Employee Savings Plan

In 2001, the Company initiated sponsorship of the Genta Incorporated Savings and Retirement Plan, a defined contribution plan under Section 401(k) of the Internal Revenue Code. The Company's matching contribution to the Plan was \$0.1 million for both 2011 and 2010.

#### 14. Commitments and Contingencies

### Litigation and Potential Claims

In September 2008, several stockholders, on behalf of themselves and all others similarly situated, filed a class action complaint against the Company, the Board of Directors, and certain of its executive officers in Superior Court of New Jersey, captioned Collins v. Warrell, Docket No. L-3046-08. The complaint alleged that in issuing convertible notes in June 2008, our Board of Directors and certain officers breached their fiduciary duties, and the Company aided and abetted the breach of fiduciary duty. On March 20, 2009, the Superior Court of New Jersey granted the Company's motion to dismiss the class action complaint and dismissed the complaint with prejudice. On April 30, 2009, the plaintiffs filed a notice of appeal with the Appellate Division. On May 13, 2009, the plaintiffs filed a motion for relief from judgment based on a claim of new evidence, which was denied on June 12, 2009. The plaintiffs also asked the Appellate Division for a temporary remand to permit the Superior Court judge to resolve the issues of the new evidence plaintiffs sought to raise and the Appellate Division granted the motion for temporary remand. Following the briefing and a hearing, the Superior Court denied the motion for relief from judgment on August 28, 2009. Thus, this matter proceeded in the Appellate Division. Plaintiffs' brief before the Appellate Division was filed on October 28, 2009, and the Company's responsive brief was filed on January 27, 2010. The plaintiffs' reply brief was filed on March 15, 2010. On August 3, 2011, the Appellate Division affirmed the decision of the Superior Court in part and reversed the decision of the Superior Court in part. The Appellate Division held that the Superior Court properly dismissed the complaint, but should have permitted the plaintiffs to file an amended complaint. The Appellate Division remanded the case to the Superior Court. On August 15, 2011, the defendants moved for reconsideration by the Appellate Division, but their motion was denied on August 26, 2011. The plaintiffs then filed an Amended Complaint on October 12, 2011 which the defendants answered on November 15, 2011. The Company, Board of Directors and Officers deny these allegations and intend to vigorously defend this lawsuit.

#### 15. Supplemental Disclosure of Cash Flows Information and Non-Cash Investing and Financing Activities

No interest or income taxes were paid with cash during the years ended December 31, 2011 and December 31, 2010.

During 2011, the Company issued \$282 thousand of June 2008 Notes in lieu of interest due its June 2008 Notes, \$18 thousand of April 2009 Notes in lieu of interest due its April 2009 Notes, \$176 thousand of September 2009 Notes in lieu of interest due its September 2009 Notes, \$750 thousand of March B Notes in lieu of interest due its March B Notes, \$881 thousand of March C Notes in lieu of interest due its March C Notes in lieu of interest due its March D Notes in lieu of interest due its March E Notes and \$9 thousand of March F Notes in lieu of interest due its March F Notes.

During 2010, the Company issued \$270 thousand of June 2008 Notes in lieu of interest due its June 2008 Notes, \$174 thousand of April 2009 Notes in lieu of interest due its April 2009 Notes, \$55 thousand of July 2009 Notes in lieu of interest due its July 2009 Notes, \$385 thousand of September 2009 Notes in lieu of interest due its September 2009 Notes, \$600 thousand of March B Notes in lieu of interest due its March B Notes, \$600 thousand of March C Notes in lieu of interest due its March D Notes in lieu of interest due its March D Notes, \$66 thousand of March E Notes in lieu of interest due its March F Notes in lieu of interest due its March F Notes in lieu of interest due its March F Notes.

From January 1, 2011 through December 31, 2011, holders of the Company's convertible notes voluntarily converted approximately \$6.1 million, resulting in an issuance of 1,339 million shares of common stock.

From January 1, 2010 through December 31, 2010, holders of the Company's convertible notes voluntarily converted approximately \$17.4 million, resulting in an issuance of 3.3 million shares of common stock.

In December 2011, three holders of September 2011 Debt Warrants totaling \$2.9 million, exercised their warrants using a cashless exercise procedure and received September 2011 G Notes for \$2.1 million.

In January 2011, two investors exercised March 2010 Debt Warrants of \$2.7 million using a cashless exercise procedure and received March E Notes of \$2.4 million.

In May 2010, two investors exercised Debt Warrants of \$1.3 million using a cashless exercise procedure and received March E Notes of \$1.1 million. In October 2010, two investors exercised Debt Warrants of \$4.0 million using a cashless exercise procedure and received March E Notes of \$3.6 million.

During 2011, the Company retired approximately \$0.1 million of computer equipment and during 2010, the Company retired \$0.8 million of computer equipment, computer software, leasehold improvements and furniture and fixtures.

16. Related Party Transactions

On June 9, 2008, Dr. Raymond Warrell, Jr., Chief Executive Officer and Chairman of the Board of Directors of the Company, participated in the initial closing of the Company's sale of June 2008 Notes by purchasing \$2.0 million of such notes. Dr. Loretta Itri, President, Pharmaceutical Development and Chief Medical Officer purchased \$0.3 million of such notes. The remaining members of the Board of Directors independently discussed Dr. Warrell and Dr. Itri's participation in the transaction and resolved that such participation would not interfere with Dr. Warrell or Dr. Itri's exercise of independent judgment in carrying out their responsibilities in their respective positions. In connection with the 2008 Note financing and in accordance with the Audit Committee Charter, the Audit Committee reviewed and approved the 2008 Note financing with Dr. Warrell and Dr. Itri.

As described in Note 9 to the consolidated financial statements, the Company issued September 2011 Warrants, December 2010 Warrants and March 2010 Warrants to extend the maturity of various notes, including the June 2008 Notes. Dr. Warrell and Dr. Itri, as holders of outstanding June 2008 Notes, received September 2011 Warrants, December 2010 Warrants and March 2010 Warrants.

17. Subsequent Events

From January 1, 2012 through March 28, 2012, holders of convertible notes have voluntarily converted approximately \$0.7 million of their notes, resulting in an issuance of 746.1 million shares of common stock.

On January 18, 2012 and February 15, 2012, the Company entered into amendment agreements with certain investors in the September 2011 Financing to amend the terms of the G Notes and to extend the deadline set forth in the September 2011 Purchase Agreement for the Company to effect a reverse stock split. Failure to implement a reverse split comprises an event of default under the terms of our G Notes, unless specifically waived by two-thirds of the holders of those notes. The latest amendment agreement between us and certain of our noteholders has extended the deadline for the implementation of the reverse split until April 16, 2012.

In August 2011, the Company submitted a request to the Financial Industry Regulatory Authority ("FINRA") to process documentation related to a reverse stock split pursuant to Rule 10b-17 of the Securities Exchange Act of 1934, as amended (the "Reverse Split"). After continual correspondence between the Company and FINRA, on January 23, 2012, the Company received notice of FINRA's final denial of the Company's request to process the documentation related to the Reverse Split.

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

None

Item 9A. Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As required by Rule 13a-15(b), Genta's Chief Executive Officer and Principal Accounting and Finance Officer conducted an evaluation as of the end of the period covered by this report of the effectiveness of Genta's "disclosure controls and procedures" (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Based on that evaluation, our Chief Executive Officer and Principal Accounting and Finance Officer concluded that as of December 31, 2011, our disclosure controls and procedures were (1) effective in that they were designed to ensure that material information relating to us is made known to our Chief Executive Officer and Principal Accounting and Finance Officer by others within this entity, as appropriate to allow timely decisions regarding required disclosures, and (2) effective in that they provide that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control — Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2011.

This Annual Report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm because smaller reporting companies are exempt from this requirement.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 that occurred during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

| affected, or are reasonably likely to materially affect, our internal control over financial reporting. |
|---------------------------------------------------------------------------------------------------------|
|                                                                                                         |
| Item 9B. Other Information                                                                              |

58

None

#### **PART III**

Item 10. Directors, Executive Officers and Corporate Governance

Our Directors and executive officers, their age and positions are as follows:

| Name                            | Age | Position With The                                      |
|---------------------------------|-----|--------------------------------------------------------|
|                                 |     | Company                                                |
| Raymond P. Warrell, Jr., M.D.   | 62  | Chairman and Chief Executive Officer                   |
| Gary Siegel                     | 54  | Vice President, Finance                                |
| Loretta M. Itri, M.D., F.A.C.P. | 62  | President Pharmaceutical Development and Chief Medical |
|                                 |     | Officer                                                |
| Marvin E. Jaffe, M.D (1)        | 75  | Director                                               |
| Christopher P. Parios           | 71  | Director                                               |
| Ana I. Stancic (1) (2)          | 54  | Director                                               |
| Daniel D. Von Hoff, M.D.,       | 64  | Director                                               |
| F.A.C.P.                        |     |                                                        |

<sup>(1)</sup> Dr. Jaffe and Ms. Stancic joined the Board of Directors, or the Board, on January 20, 2011.

All directors hold office until the next annual meeting following their election and/or until their successors are elected and qualified. Officers serve at the discretion of the Board. Information with respect to the business experience and affiliation of our directors and executive officers is set forth below:

Raymond P. Warrell, Jr., M.D., 62, has been our Chief Executive Officer and a member of our Board since December 1999 and our Chairman since January 2001. From December 1999 to May 2003, he was also our President. From 1978 to 1999, Dr. Warrell was associated with the Memorial Sloan-Kettering Cancer Center in New York, where he held tenured positions as Member, Attending Physician, and Associate Physician-in-Chief, and with the Joan and Sanford Weill Medical College of Cornell University, where he was Professor of Medicine. Dr. Warrell also has more than 30 years of development and consulting experience in pharmaceuticals and biotechnology products. He discovered and patented the activity of gallium nitrate, and directed the clinical development program that was pivotal for FDA approval of Ganite® (gallium nitrate injection), launched by Fujisawa, Inc. (now Astellas, Inc.) and acquired by Genta. He directed the U.S. clinical development program that was pivotal for the FDA approval of all-trans retinoic acid (Vesanoid®; Hoffmann LaRoche, Inc.) in acute promyelocytic leukemia (APL). He developed and patented the formulation for arsenic trioxide, was a co-founder and chairman of the scientific advisory board of PolaRx Biopharmaceuticals, Inc., and directed the U.S. development program that was pivotal for the FDA approval of Trisenox®, (Teva, Inc.) another drug for the treatment of APL. Dr. Warrell holds or has filed numerous other patents and patent applications for biomedical therapeutic or diagnostic agents. He has published more than 100 peer-reviewed papers and more than 240 book chapters and abstracts, most of which are focused upon drug development in oncology, metabolism and skeletal diseases. Dr. Warrell is a member of the American Society of Clinical Investigation, the American Society of Hematology, the American Association for Cancer Research and the American Society of Clinical Oncology. Among many awards, he has received the U.S. Public Health Service Award for Exceptional Achievement in Orphan Drug Development from the FDA. He obtained a B.S. in Chemistry from Emory University, a M.D. from the Medical College of Georgia, and a M.B.A. from Columbia University Graduate School of Business. Dr. Warrell is married to Dr. Loretta M. Itri, President, Pharmaceutical Development and Chief

<sup>(2)</sup> Ms. Stancic resigned from the Board on March 23, 2012.

### Medical Officer of Genta.

The Board believes that Dr. Warrell's leadership of Genta since December 1999, extensive knowledge in the field of oncology and biotechnology products, as well as his educational and business background, position him to make valuable contributions to Genta as the Chairman of its Board of Directors.

Gary Siegel, 54, joined Genta in May 2003 as Director, Financial Services, was appointed Senior Director, Financial Services in April 2004 and was appointed Vice President, Finance in September 2007. During his tenure at Genta, Mr. Siegel has been accountable for our day-to-day accounting and financial operations including public and management reporting, treasury operations, planning, financial controls and compliance. Mr. Siegel became an executive officer of Genta and assumed the role of interim Principal Accounting Officer, interim Principal Financial Officer and interim Corporate Secretary, effective February 29, 2008. On May 7, 2010, Mr. Siegel was named Principal Accounting Officer, Principal Financial Officer and Corporate Secretary. Prior to joining Genta, he worked for two years at Geller & Company, a private consulting firm, where he led the management reporting for a multi-billion dollar client. His 27 years of experience in the pharmaceutical industry include leadership roles at Warner-Lambert Company and Pfizer Inc., where he held positions of progressively increasing levels of responsibility including Director, Corporate Finance and Director, Financial Planning & Reporting.

Loretta M. Itri, M.D., F.A.C.P., 62, has been our President, Pharmaceutical Development and Chief Medical Officer since May 2003, prior to which she was Executive Vice President, Pharmaceutical Research and Development and Chief Medical Officer since joining Genta in March 2001. Previously, Dr. Itri was Senior Vice President, Worldwide Clinical Affairs, and Chief Medical Officer at Ortho Biotech Inc., a Johnson & Johnson company. As the senior clinical leader at Ortho Biotech and previously at J&J's R.W. Johnson Pharmaceutical Research Institute (PRI), she led the clinical teams responsible for NDA approvals for Procrit® (epoetin alpha), that company's largest single product. She had similar leadership responsibilities for the approvals of Leustatin®, Renova®, Topamax®, Levaquin®, and Ultram®. Prior to joining J&J, Dr. Itri was associated with Hoffmann-La Roche, most recently as Assistant Vice President and Senior Director of Clinical Investigations, where she was responsible for all phases of clinical development programs in immunology, infectious diseases, antivirals, AIDS, hematology and oncology. Under her leadership in the areas of recombinant proteins, cytotoxic drugs and differentiation agents, the first successful Product License Application (PLA) for any interferon product (Roferon-A®; interferon alfa) was compiled. Dr. Itri is married to Dr. Warrell, our Chief Executive Officer and Chairman.

Marvin E. Jaffe, M.D., 75, has been a member of our Board since January 20, 2011. He has spent his career in the pharmaceutical industry and has been responsible for the pre-clinical and clinical development of new drugs and biologics in nearly every therapeutic area. He worked for 18 years at Merck & Co., eventually rising to the position of Senior Vice-President of Medical Affairs. After leaving Merck, Dr. Jaffe became the founding President of the R.W. Johnson Pharmaceutical Research Institute (PRI), a Johnson & Johnson Company. PRI was established for the purpose of providing globally integrated research and development support to several companies within the J&J pharmaceutical sector. Dr. Jaffe retired from Johnson & Johnson in 1994 and currently serves as a consultant and board member to the biopharmaceutical and biotechnology industries. He has served on the Board of Immunomedics, Inc., and on the Board of NeoGenomics. He has served on the Boards of Genetic Therapy, Inc., Vernalis Group, plc., Celltech Group, plc. and Matrix Pharmaceuticals -- all of which were acquired by other companies. He is on the Scientific Advisory Boards of the Seaver Foundation and the Jefferson Medical College Hospital for Neuroscience. He is a partner of Naimark Associates, which consults to the biopharmaceutical industry.

The Board believes that Dr. Jaffe's extensive experience at Johnson & Johnson and Merck, as well as his experience as a director on several other biopharmaceutical companies position him to make valuable contributions to Genta as a member of its Board of Directors.

Christopher P. Parios, 71, has been a member of our Board since September 2005. Mr. Parios has more than 37 years of pharmaceutical industry experience, including product development, marketing and promotion, strategy and tactic development, and managing pharmaco-economic and reimbursement issues. He has worked with many of the major companies in the pharmaceutical industry including Hoffmann-LaRoche, Ortho-McNeil, Pfizer, Novartis, Schering Plough, Janssen, Ortho Biotech, and Bristol-Myers Squibb. For the period 1997 to May of 2008, Mr. Parios was Executive Director of The Dominion Group, an independent healthcare consulting firm that specializes in market

research, strategic planning, and competitive intelligence monitoring. In this role, he was responsible for the full range of market research, consulting, and business planning activities to facilitate informed business decisions for clients regarding product development, acquisitions, product positioning, and promotion. Mr. Parios continues to consult with The Dominion Group on a part-time basis. Previously, Mr. Parios was President and Chief Operating Officer of the Ferguson Communication Group, as well as Vice Chairman of the parent company, CommonHealth USA, a leading full-service communications resource for the healthcare industry. Mr. Parios was a partner in Pracon, Inc., a health-care marketing consulting firm from 1982 to 1991, and helped engineer the sale of that firm to Reed-Elsevier in 1989. Over a 20-year period, Mr. Parios held progressively senior positions at Hoffmann-LaRoche, Inc., most recently as Director of New Product Planning and Regulatory Affairs Management. This group established the project management system for drug development at Roche and coordinated developmental activities for such products as Versed®, Rocephin®, Roferon®, Accutane®, Rimadyl®, and Tegison®. Mr. Parios was also a member of the corporate team responsible for domestic and international product and technology licensing activities.

The Board believes that Mr. Parios's 37 years of pharmaceutical industry experience, including experience with product development, marketing and promotion, strategy and tactic development, and managing pharmaco-economic and reimbursement issues, position him to make valuable contributions to Genta as a member of its Board.

Ana I. Stancic, 54, was a member of our Board from January 20, 2011 through March 23, 2012. She is currently senior vice president and chief financial officer at Enzon, Inc. Previously, she was Chief Financial Officer of M2Gen, a wholly owned, for-profit subsidiary of the Moffitt Cancer Center, and at Aureon Bioscience, Inc., an oncology diagnostic company. From 2007 to 2008, she was Executive Vice President and Chief Financial Officer at OMRIX Biopharmaceuticals, Inc., which was acquired by Johnson and Johnson. From 2004 to 2007, Ms. Stancic was at Imclone Systems, Inc., which was acquired by Eli Lilly, Inc. At Imclone, she served in various financial roles, including Senior Vice President, Finance. Prior to joining ImClone, she was Vice President and Controller at Savient Pharmaceuticals, Inc. Ms. Stancic began her career at PricewaterhouseCoopers in the Assurance practice where she had responsibility for international and national companies in the pharmaceutical and services industries. Ms. Stancic is a Certified Public Accountant and holds an M.B.A. degree from Columbia University Graduate School of Business. She currently serves as a member of the Board of Directors of Champions Biotechnology, Inc. and KV Pharmaceutical Co.

Daniel D. Von Hoff, M.D., F.A.C.P., 64, has been a member of our Board since January 2000. Dr. Von Hoff's major interest is in the development of new anticancer agents, both in the clinic and in the laboratory. He and his colleagues were involved in the beginning of the development of many of the agents now used routinely, including: mitoxantrone, fludarabine, paclitaxel, docetaxel, gemcitabine, CPT-11, and others. At present, he and his colleagues are concentrating on the development of molecularly targeted therapies. He and his laboratory are especially focusing on discovery and development of new target agents for the treatment of pancreatic cancer. Dr. Von Hoff has published more than 530 papers, 129 book chapters, and more than 900 abstracts. Dr. Von Hoff served on the President's National Cancer Advisory Board from 2004 to 2010. Dr. Von Hoff is the past President of the American Association for Cancer Research, a Fellow of the American College of Physicians, and a member and past board member of the American Society of Clinical Oncology. He was a founder of ILEX Oncology, Inc. (acquired by Genzyme-Sanofi Aventis). He was also founder and Editor Emeritus of Investigational New Drugs - The Journal of New Anticancer Agents, and Editor-in-Chief of Molecular Cancer Therapeutics. Among other appointments, Dr. Von Hoff is: Professor of Medicine at the University of Arizona College of Medicine; Clinical Professor of Medicine at the Mayo Clinic; Founder Physician-in-Chief and Distinguished Professor at the Translational Genomics Research Institute (TGen) in Phoenix, AZ; and Chief Scientific Officer at Scottsdale Healthcare, Inc. and U.S. Oncology, Inc.

The Board believes that Dr. Von Hoff's background in the development of anti-cancer compounds, along with his extensive medical background, position him to make valuable contributions to Genta as a member of its Board.

### MATTERS RELATING TO OUR GOVERNANCE

#### The Board and its Committees

The Board currently consists of four Directors. They are Raymond P. Warrell, Jr., M.D., Marvin Jaffe, M.D., Christopher P. Parios and Daniel D. Von Hoff, M.D., F.A.C.P. The Board has determined that, except for Dr. Warrell, all of the members of the Board are "independent Directors". Dr. Warrell is not considered independent, as he is an executive officer of the Company.

The Board has an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. The Board held eleven meetings during the year ended December 31, 2011. The Audit Committee held five meetings and the Compensation Committee held one meeting. No formal meetings were held by the Nominating and Corporate Governance Committee, as the independent Directors of the Board acted as a whole on nominating and corporate governance matters. Independent Directors of the Board held four executive sessions at which only independent Directors were present. Each member of the Board attended no fewer than 94% of the total number of meetings of the Board and the committees of which he or she was a member.

### Board of Directors Leadership Structure and Role in Risk Oversight

Our Board evaluates its leadership structure and role in risk oversight on an ongoing basis. Our leadership structure combines the Chairman of the Board and Chief Executive Officer roles into one position. Currently, Dr. Warrell serves as Chairman of the Board and Chief Executive Officer of our company. Our Board determines what leadership structure it deems appropriate based on factors such as the experience of the applicable individuals, the current business environment of the Company, the current stage of development and commercialization of our products and product candidates and other relevant factors. After considering these factors, our Board has determined that the combined role of Chairman of the Board and Chief Executive Officer is an appropriate board leadership structure for our company at this time. We currently do not have a lead independent director. Our former lead independent director, Douglas G. Watson, resigned from the Board of Directors on January 20, 2011. While we are without a lead independent director, non-management directors meet in regularly scheduled executive sessions at the end of every regularly scheduled board meeting. The non-management directors may schedule additional executive sessions as appropriate. Members of management do not attend these executive sessions.

The Board is also responsible for oversight of our risk management practices, while management is responsible for the day-to-day risk management processes. This division of responsibilities is the most effective approach for addressing the risks facing the Company, and the Company's board leadership structure supports this approach. Through our Chairman of the Board and Chief Executive Officer, and other members of management, the Board receives periodic reports regarding the risks facing the Company. In addition, the Audit Committee assists the Board in its oversight role by receiving periodic reports regarding our risk and control environment. Furthermore, the Compensation Committee and Audit Committee work together to review any potential short-term or long-term risks as a result of the current decisions of the Company's management.

#### **Audit Committee**

The Audit Committee was established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended. During ficsal 2011 and until March 23, 2012, the Audit Committee consisted of Christopher P. Parios, Daniel D. Von Hoff, M.D., F.A.C.P. and Ana I. Stancic. Ms. Stancic served as Chair of this Committee, and Mr. Parios currently serves as Chair of this Committee. Each member of the Audit Committee is independent. The Board determined that Ms. Stancic fulfilled the SEC criteria as an audit committee financial expert. Pursuant to the Audit Committee's charter adopted by the Board, the purposes of the Audit Committee include reviewing the procedures and results of our external auditing functions, providing a direct communication link to the Board from our external auditing staff and our Chief Financial Officer or his equivalent and helping assure the quality of our financial reporting and control systems. The Audit Committee has the sole authority to retain and terminate the independent registered public accounting firm that examines our financial statements. A copy of this committee's charter is available on our website at www.genta.com.

#### **Compensation Committee**

The Compensation Committee currently consists of Marvin Jaffe, M.D., Christopher P. Parios and Daniel D. Von Hoff, M.D., F.A.C.P. Mr. Parios serves as Chair of this Committee. Each member of the Compensation Committee is independent. The primary purpose of the Compensation Committee is to review, on an annual basis or more frequently as it deems appropriate, the performance of our executive officers, determine the amount and form of compensation payable to our executive officers and report to the Board on an annual basis regarding compensation of our executive officers. In addition, the Compensation Committee administers our equity compensation plans. The Compensation Committee, along with the Audit Committee of the Board, reviews any potential short-term or long-term risks as a result of its compensation practices. The Committees believe that these risks are not reasonably likely to have a material adverse effect on the Company. Nonetheless, the Compensation Committee, working with the Audit Committee, seeks to mitigate these risks to the extent possible. A copy of this committee's charter is available on our website at www.genta.com.

### Nominating and Corporate Governance Committee

No formal meetings were held by the Nominating and Corporate Governance Committee, as the independent Directors of the Board acted as a whole on nominating and corporate governance matters during meetings of the Board. The purpose of the Nominating and Corporate Governance Committee are to identify and recommend individuals qualified for nomination to serve on our Board and its committees, ensure that the performance of the Board is reviewed, develop and recommend corporate governance principles to the Board and ensure that an appropriate governing structure with respect to the Board and its committees is in place so that the Board can perform a proper review function. A copy of the Nominating and Corporate Governance Committee's charter is available on our website at www.genta.com.

In assessing candidates as Director nominees, whether recommended by this committee or stockholders, the committee considers the following criteria:

- Members of the Board should be individuals of high integrity and independence with substantial accomplishments and prior or current association with institutions noted for their excellence.
- Members of the Board should have demonstrated leadership ability, with broad experience, diverse perspectives, and the ability to exercise sound business judgment.
  - The background and experience of members of the Board should be in areas important to the operation of Genta such as business, education, finance, government, law, medicine or science.
- The composition of the Board should reflect sensitivity to the need for diversity as to gender, ethnic background and experience.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our Directors and executive officers and persons who own more than 10 percent of our common stock to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock.

To our knowledge based solely on a review of the copies of such reports furnished to us and the reporting persons' representations to us that no other reports were required during the year ended December 31, 2011, our Directors and officers complied with their respective filing requirements under Section 16(a) on a timely basis with the following exceptions: Dr. Warrell filed Form 4 on September 23, 2011 to report the conversion of a convertible note on September 8, 2011, Dr. Warrell filed Form 4 on March 25, 2011 to report the conversion of a convertible note on March 22, 2011, Dr. Warrell filed Form 4 on February 3, 2011 to report the conversion of a convertible note on January 31, 2011 and Dr. Warrell filed Form 4 on January 13, 2011 to report the conversion of a convertible note on January 10, 2011.

#### Code of Ethics

The Board has adopted a Code of Ethics that applies to all our Directors and employees, including our principal executive officer and principal financial/accounting officer. A copy of the Code is currently available on our website at www.genta.com.

### Item 11. Executive Compensation

#### Compensation of Directors

During 2011, non-employee Directors earned annual compensation of \$25,000; however, non-employee Directors in their first year of joining the Board earned annual compensation of \$50,000 per year. For 2012, each of our non-employee Directors will earn \$25,000 per year for their services. Any new Director who joins the Board in 2012 would earn annual compensation of \$50,000 per year for their first year on the Board. Each non-employee Director earned an additional \$1,500 for each Board meeting and \$1,000 for each committee meeting attended in person and \$750 for each Board or committee meeting attended telephonically. The Lead Director and each non-employee Chairperson of each committee of the Board earned additional annual cash compensation of \$5,000. Each non-employee Director receives \$2,500 per day for Board or committee activities outside of normal activities.

Currently, under our 2009 Stock Incentive Plan, as amended, on the date of each annual stockholders meeting, each individual who is at that time serving as, and is to continue to serve as, a non-employee Board member will automatically be granted an award in the form of fully vested shares of common stock and/or options with a value not to exceed \$25,000, or at the option of our Board, cash of \$25,000. Our Compensation Committee will have the sole discretion to determine the amount and type of award for each year. The applicable annual amount will be determined by the Compensation Committee on or before the date of the grant, but in no event will such amount exceed \$25,000. There were no equity grants during 2011.

The following table sets forth certain information regarding compensation earned by or paid to the following non-employee Directors of the Company during the year ended December 31, 2011:

|                       |           |             |             | Non-Equity   |               |              |            |
|-----------------------|-----------|-------------|-------------|--------------|---------------|--------------|------------|
|                       | Fees      |             |             | Incentive    | Nonqualified  |              |            |
|                       | earned or |             |             | Plan         | Deferred      | All Other    |            |
|                       | paid in   | Stock       | Option      | Compensation | Compensation  | Compensation |            |
| Name                  | cash (\$) | awards (\$) | awards (\$) | (\$)         | Earnings (\$) | (\$)         | Total (\$) |
| Marvin E. Jaffe, M.D  | \$57,500  | -           | -           | -            | -             | -            | \$57,500   |
| Christopher P. Parios | \$40,500  | -           | -           | -            | -             | -            | \$40,500   |
| Ana I. Stancic        | \$65,500  | -           | -           | -            | -             | -            | \$65,500   |
| Daniel D. Von Hoff,   |           |             |             |              |               |              |            |
| M.D., F.A.C.P.        | \$32,500  | -           | -           | -            | -             | -            | \$32,500   |

Compensation Discussion and Analysis

### Overview of Compensation Program

The Compensation Committee of the Board, or the Committee, has responsibility for overseeing our compensation and benefit policies, evaluating senior executive performance, determining compensation for our senior executives, including our executive officers and Directors, and reviews and discusses the report on executive compensation included in our annual proxy statement.

The individuals who serve as our Chairman of the Board and Chief Executive Officer (CEO) and the Chief Financial Officer (CFO), as well as the other individual included in the Summary Compensation Table below, are referred to as the "named executive officers".

#### Compensation Philosophy and Objectives

Our compensation philosophy is based on our belief that our compensation programs should: be aligned with stockholders' interests and business objectives; reward performance; and be externally competitive and internally equitable. We seek to achieve three objectives, which serve as guidelines in making compensation decisions:

Providing a total compensation package which is competitive and therefore, enables us to attract and retain, high-caliber executive personnel;

Integrating compensation programs with our short-term and long-term strategic plan and business objectives to provide incentives to ensure superior executive performance and successful financial results; and

Encouraging achievement of business objectives and enhancement of stockholder value by providing executive • management long-term incentives through equity ownership, which align the interests of executives with those of our stockholders.

### Role of Executive Officers in the Compensation Decisions

The Committee makes all compensation decisions regarding the compensation of our named executive officers. The CEO reviews the performance of our executive officers (other than himself) and except for the President, Pharmaceutical Development and Chief Medical Officer (who is the spouse of the CEO), the CEO makes recommendations to the Committee based on these reviews, including salary adjustments, variable cash awards and equity awards. The Committee exercises its discretion in modifying any recommended adjustments or awards to executives. With respect to the CEO and President, Pharmaceutical Development and Chief Medical Officer, the Committee in its sole discretion determines the amount of any adjustments or awards.

### **Establishing Executive Compensation**

One of the tools that the CEO and the Committee use in establishing compensation is comparisons with other companies in the biotechnology and pharmaceutical industries, including companies with which we compete for personnel. To determine external competitiveness practices relevant to the executive officers, we review data from two industry surveys of executive compensation: Radford Biotechnology Compensation Survey and Organization Resources Counselors, collectively referred to as External Market Data. Due to macroeconomic factors in the global economy and our financial challenges during 2009, 2010 and 2011, the Committee did not feel that changes in executive compensation required repurchase of these data to establish an updated database for decision-making.

In 2008, the Committee retained Aon Radford Consulting (a nationally recognized compensation consulting firm with specific expertise in dealing with the equity issues of biopharmaceutical companies) to conduct a review of market trends related to equity compensation in consideration of the fact that our 1998 Stock Incentive Plan would be expiring in May 2008. The peer group companies used for that analysis were: Access Pharmaceuticals, Inc., AMDL, Inc., Celsion Corp., Idera Pharmaceuticals, Inc., Infinity Pharmaceuticals, Inc., Opexa Therapeutics, Inc., Oscient Pharmaceuticals Corp., Poniard Pharmaceuticals, Inc., SEQUENOM, Inc. and Targeted Genetics Corp. These companies were selected because, like Genta, they were oncology-focused, public pharmaceutical companies with products in mid to late-stage development. Due to limited resources, the Committee did not retain a compensation consultant to advise the Committee on its compensation decisions during 2009, 2010 or 2011 and rather, relied on External Market Data and analyses provided by Aon Radford Consulting for past years in determining to keep executive compensation levels unchanged for 2009, 2010 and 2011.

In establishing compensation levels, it is the Committee's objective to target total annual compensation of each executive officer at a level between the 50th and 75th percentiles for comparable positions. However, in determining the compensation for each executive officer, the Committee also considers a number of other factors including: an evaluation of the responsibilities required for each respective position, individual experience levels and individual performance and contributions toward achievement of our business objectives. There is no pre-established policy or target for the allocation between either cash and non-cash or short-term and long-term incentive compensation. Instead, the Committee determines the mix of compensation for each executive officer based on its review of the competitive data and its analysis of that individual's performance and contribution to our performance. In addition, in light of our stage of development, considerable emphasis is placed on equity-based compensation in an effort to preserve cash to finance our research and development efforts.

## Other Factors Influencing 2011 Compensation for Executive Officers

Our potential products are in various stages of research and development and limited revenues have as yet been generated from product sales. As a result, the Committee does not believe the use of traditional performance standards, such as corporate profitability, is appropriate in the evaluation of our performance or the performance of our individual executives. The compensation of our executive officers is based, in substantial part, on industry compensation practices, trends noted (in the External Market Data, peer group analysis and by consulting services provided in prior fiscal years), as well as the extent to which the business and individual executive officers' objectives are achieved. Such objectives are established by the Committee and modified as necessary to reflect changes in market conditions and other factors. Individual performance is measured against quantifiable objectives.

Among the significant business objectives achieved during 2011 were the following: continued development of tesetaxel, including initiation, continuation or completion of clinical trials in melanoma, gastric cancer, breast cancer, bladder cancer and prostate cancer; the finalization of the AGENDA trial in patients with advanced melanoma; and the sale of convertible notes and debt warrants resulting in aggregate gross proceeds of \$12.7 million. The failure of the AGENDA trial, which precluded our ability to file regulatory applications for potential commercial approval, was accorded the most significant weight in evaluating our business performance and in making executive compensation decisions. Other factors included the ability to raise additional funds to continue operations, as well as the ongoing maintenance of the promising programs with tesetaxel and oral gallium to offset the failure of the Genasense® program. These factors were considered carefully in evaluating executive performance and making determinations regarding executive compensation.

In December 2011, due to our failure to close a licensing deal and our limited financial resources, Dr. Warrell recommended to the Committee, and the Committee determined that - for the fourth consecutive year - there should not be any annual salary increases, nor should any incentive bonuses be paid to any employee, including any named executive officers.

### **Elements of Executive Compensation**

Our compensation package for executive officers generally consists of annual cash compensation, which includes both fixed (annual salary) and variable (cash incentive bonus program) elements, long-term compensation in the form of restricted stock units and certain perquisites. The main components are annual salary, cash incentive bonus and the award of restricted stock units, all of which are common elements of executive compensation pay in general and throughout the biotechnology and pharmaceutical industry.

#### **Annual Salary**

We pay an annual salary to our employees and the executive officers as consideration for fulfillment of certain roles and responsibilities. Changes in annual salaries for executive officers, if any, are generally effective at the beginning of each year. Increases to annual salary reflect a reward and recognition for successfully fulfilling the position's role and responsibilities, the incremental value of the experience, knowledge, expertise and skills the individual acquires and develops during employment with us and adjustments as appropriate based on external competitiveness and internal equity. In consideration of our cost-reduction and cash conservation measures, there were no annual salary increases for 2009, 2010 or 2011, other than an increase in the annual salary of Mr. Siegel due to increased responsibilities during 2010. During 2011, in order to further conserve our cash resources, we deferred payment of salaries due to Drs. Warrell and Itri for the period from June 19, 2011 through December 17, 2011 for a total unpaid amount of \$414.090.

#### Cash Incentive Bonus Program

As part of their compensation package, our named executive officers have the opportunity to earn annual cash incentive awards. Cash incentive awards are designed to reward superior executive performance while reinforcing our short-term strategic operating goals. If warranted in special circumstances, individual one-time discretionary bonuses may also be awarded to our named executive officers during the course of the year. Typically, we award cash incentive bonuses to employees, including the executive officers, as a reward and recognition for contributing to our achievement of specific annual business objectives established by the Committee at the beginning of the year. All employees are eligible for a form of cash incentive bonus, although payment of a cash incentive bonus is made at an individual level each year contingent upon our overall performance.