GENTA INC DE/
Form 10-K
March 14, 2005

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

FORM 10-K
FOR ANNUAL AND TRANSITIONAL REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

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

For the Fiscal Year Ended December 31, 2004

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

Commission File Number 0-19635

GENTA INCORPORATED

(Exact name of Registrant as specified in its certificate of incorporation)

Delaware	**33-0326866**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification Number)**
Two Connell Drive **Berkeley Heights, New Jersey** **(Address of principal executive offices)**	**07922** **(Zip Code)**

(908) 286-9800
(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act: NONE

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $.001 par value
(Title of Class)

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 ý No o

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ý No o

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $159,885,000 as of June 30, 2004 (the last business day of the registrant s most recently completed second fiscal quarter). For purposes of determining this number, 16,416,341 shares of common stock held by affiliates as of June 30, 2004 are excluded. For purposes of making this calculation, the registrant has defined affiliates as including all directors, executive officers and beneficial owners of more than ten percent of the common stock of the Company.

As of March 9, 2005, the registrant had 95,358,215 shares of Common Stock outstanding.

Documents Incorporated by Reference

Certain provisions of the registrant s definitive proxy statement to be filed not later than April 30, 2005 pursuant to Regulation 14A are incorporated by reference in Items 10 through 13 of Part III of this Annual Report on Form 10-K.

Genta Incorporated
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(1) The information required in these items is incorporated by reference from the Company s definitive proxy statement to be filed not later than April 30, 2005 pursuant to Regulation 14A of the General Rules and Regulations under the Securities Exchange Act of 1934, as amended.

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The statements contained in this Annual Report on Form 10-K that are not historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. The Company intends 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 the Company s views as of the date they are made with respect to future events and financial performance, but are subject to many risks and uncertainties, which could cause actual results to differ materially from any future results expressed or implied by such forward-looking statements. Forward-looking statements include, without limitation, statements about:

- the Company s ability to obtain necessary regulatory approval, especially U.S. Food and Drug Administration (FDA) approval or failure to approve Genasense®;
- the safety and efficacy of the Company s products;
- the commencement and completion of clinical trials;
- the Company s ability to develop, manufacture and sell its products;
- the adequacy of the Company s capital resources and the Company s ability to obtain sufficient financing to maintain
- the Company s planned operations;
- 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;
- the other risks described under Certain Risks and Uncertainties Related to the Company s Business.

The Company does not undertake to update any forward-looking statements.

We make available free of charge on our internet website (http://www.genta.com) our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. The content on the Company s website is available for informational purposes only. It should not be relied upon for investment purposes, nor is it incorporated by reference into this Form 10-K.

PART I

Item 1. ***Business***

A. Overview

Genta Incorporated (Genta or the Company) was incorporated in Delaware on February 4, 1988. Genta is a biopharmaceutical company dedicated to the identification, development and commercialization of novel drugs for cancer and related diseases. Our research portfolio consists of two major areas of focus:

- DNA/RNA Medicines, which include drugs that are based on chemical modifications of oligonucleotides; and
- Small Molecules

The DNA/RNA Medicines program includes drugs that are based on technologies known as antisense, decoys and RNA interference. The Company s lead drug from this program is an investigational antisense compound known as Genasense® (oblimersen sodium injection). Genasense® is designed to block the production of a protein known as Bcl-2. Current science suggests that Bcl-2 is a fundamental (although not sole) cause of the inherent resistance of cancer cells to current anticancer treatments, such as chemotherapy, radiation, or monoclonal antibodies. While Genasense® has displayed some anticancer activity when used by itself, the Company is developing the drug primarily as a means of amplifying the cytotoxic effects of other anticancer treatments.

Genasense® has been studied in combination with a wide variety of anticancer drugs in a number of different cancer indications. Three randomized Phase 3 trials of Genasense® have been completed in malignant melanoma, chronic lymphocytic leukemia (CLL), and multiple myeloma. Under its own sponsorship or in collaboration with the U.S. National Cancer Institute (NCI), Genta is currently conducting a number of additional trials.

In May 2004, the Company s New Drug Application (NDA) for Genasense® plus chemotherapy in malignant melanoma failed to gain a majority vote for marketing approval by the Oncology Drug Advisory Committee (ODAC) of the U.S. Food and Drug Administration (FDA). Genta subsequently withdrew the NDA from further consideration. The Company has continued long-term follow-up of patients who were enrolled into the melanoma trial. Genta is conducting additional analyses of those data and expects to provide an update of these results in 2005. The Company is also exploring the feasibility of filing similar regulatory applications in the European Union.

In December 2004, the Company released initial results from its other Phase 3 trials. The trial in multiple myeloma failed to meet endpoints that would be sufficient for regulatory approval. The trial in CLL met its primary endpoint of significantly increasing the proportion of patients who achieved a complete or nodular partial remission, as determined by blinded expert review of clinical data and bone marrow biopsies. A significant increase in disease-free survival was also observed. No difference was observed in overall response rate, time-to-disease progression, or overall survival. Adverse events (irrespective of relation to study drugs) during treatment or within 30 days from last dose of treatment that resulted in death occurred in 9 patients treated with Genasense® plus chemotherapy compared with 5 patients treated with chemotherapy alone. The percentage of patients who experienced serious adverse events was increased in the Genasense® arm; however, the percentages of patients who discontinued treatment due to adverse events were equal in the treatment arms. The incidence of certain serious adverse reactions, including but not limited to nausea, fever and catheter-related complications, was increased in patients treated with Genasense®.

Genta is currently conducting additional analyses of data from this trial and is exploring the feasibility of filing a NDA for this indication based on existing data. Such an application would be filed using the Fast Track designation previously granted by the FDA, which allows approval of a drug based on a surrogate endpoint that is reasonably likely to be predictive of clinical benefit. Approval under this mechanism is contingent upon a company conducting one or more additional trials that would conclusively document that benefit. The Company is also exploring the feasibility of filing similar regulatory applications in the European Union.

In April 2002, we entered into a series of agreements with Aventis, a member of the sanofi-aventis Group (Aventis), regarding the development and commercialization of Genasense®. On November 8, 2004, the Company received from Aventis a notice of termination of these agreements. Pursuant to those agreements, Aventis is required to fund substantial portions of the development costs of Genasense® until May 8, 2005. Genta has initiated discussions with other potential marketing and development partners for Genasense®.

The Company has two additional programs in the DNA/RNA Medicines program. The first is an antisense drug (LR3001) directed against an oncogene called c-myb. LR3001 has been tested in a clinical Phase 1 trial, and the Company is currently seeking to restart that study, which is currently being sponsored by an independent investigator. The second is a drug called the CRE-BP Decoy, which remains in the laboratory testing stage.

The Small Molecules Program currently includes drugs that are based on gallium-containing compounds. The lead drug from this Program is Ganite® (gallium nitrate injection), which was approved by FDA in October 2003 for the treatment of cancer-related hypercalcemia that is resistant to hydration. In Phase 2 studies, Ganite® has been reported to demonstrate direct anticancer activity, particularly in patients with malignant lymphoma and bladder cancer. Following the adverse outcome of the ODAC meeting in May 2004 for Genasense®, the Company markedly reduced spending on the development, sale and marketing of Ganite® resulting in significantly lower sales of Ganite®. A number of side effects have been reported related to treatment with Ganite®. These side effects are described in the Product Insert for the drug. Genta has also been engaged in developing new formulations of gallium-containing compounds that may be orally absorbed; to date, however, these efforts have not yielded a compound that the Company has advanced into late-stage preclinical testing.

The Company seeks to acquire additional drugs in these two Programs that will enhance the value of its pipeline to shareholders.

B. 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 as direct marketers of our products in the United States. Our key strategies in this regard are:

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

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

Establish our lead antisense compound, Genasense®, as the preferred chemosensitizing drug for use in combination with other cancer therapies in a variety of human cancer types.

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

Research and Development Programs

DNA/RNA Medicines

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

Antisense Technology

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

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

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

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

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

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

Bcl-2 as an Inhibitor of Programmed Cell Death

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

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

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

Genasense®

Genasense® has been designed to block the production of Bcl-2. Current science suggests that Bcl-2 is a fundamental cause of the inherent resistance of cancer cells to current cancer treatments, such as chemotherapy, radiation or monoclonal antibodies. Blocking Bcl-2, therefore, may enable cancer treatments to be more effective. While Genasense® has displayed some anticancer activity when used by itself, we believe the drug can be optimally used as a means of amplifying the effectiveness of other cancer therapies, most of which function by triggering apoptosis, which as noted is relatively blocked in cancer cells to over-production of Bcl-2.

Overview of Preclinical and Clinical studies of Genasense®

Preclinical Studies

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

Clinical Studies

Genasense® has been in clinical trials since 1995 in both the United States and Europe. We currently have efficacy and safety data on over 1,400 patients in Phase 1, Phase 2 or Phase 3 clinical trials. These studies have been conducted in patients with a wide variety of tumor types, including advanced malignant melanoma, several types of leukemia, non-Hodgkin s lymphoma (NHL) and cancers of the prostate, colon, lung, breast and other tumor types. Since 2001, Genta and the National Cancer Institute (NCI) have jointly approved the initiation of approximately twenty clinical trials. In addition to making Genasense® available to more physicians and patients, these trials allow us to evaluate Genasense® in certain diseases (and in combination with other chemotherapy drugs) that would otherwise be outside our initial priorities for clinical development. The overall results of clinical trials performed to date suggest that Genasense® can be administered to cancer patients with acceptable side-effects, and that such treatment may reduce the level of Bcl-2 protein in cancer cells.

The following chart sets forth the progress of our clinical trials with respect to various potential indications for Genasense®:

Indication	Status
Malignant Melanoma	Phase 3 completed; NDA filed; On May 3, 2004, the FDA Oncology Drugs Advisory Committee voted not to recommend; NDA withdrawn; analysis of data continues
Chronic Lymphocytic Leukemia	Phase 3 completed; results of trial met primary endpoint; analysis of data continues
Multiple Myeloma	Phase 3 completed; trial did not meet primary endpoint
Acute Myelocytic Leukemia	Phase 3 (randomized)
Non-Small-Cell Lung Cancer	Phase 2 (randomized), fully enrolled
Prostate Cancer	Phase 2 (randomized)
Small-Cell Lung Cancer	Phase 2 (randomized), fully enrolled
Breast Cancer	Phase 1-2
Colorectal Cancer	Phase 1-2
non-Hodgkin s lymphoma	Phase 1-2 and Phase 2
Kidney Cancer	Phase 2
Pancreatic Cancer (and other solid tumors)	Phase 1-2
Waldenstrom s macroglobulinemia	Phase 1-2
Hepatocellular Carcinoma	Phase 1-2
Childhood Solid Tumors	Phase 1

Highlights of the randomized trials sponsored directly by the Company follow:

Phase 3 Trial of Genasense® Plus Chemotherapy in Patients with Malignant Melanoma

In late 2003, we filed an NDA for Genasense® to be used in combination with dacarbazine for the treatment of patients with melanoma who had not previously received chemotherapy. The FDA accepted our NDA filing on February 5, 2004 and granted Priority Review status to the application, which targeted an agency action on or before June 8, 2004. On February 10, 2004, we were invited by the FDA to meet on May 3, 2004 with ODAC. On May 3, 2004 we presented results of our Phase 3 trial of Genasense® in combination with dacarbazine versus dacarbazine alone to the ODAC. A majority of the committee members voted that the increased number of clinical responses were indicative of the clinical activity of Genasense® in melanoma. However, in the absence of increased survival, a majority of the committee members voted that the evidence presented did not provide substantial evidence of effectiveness, as measured by response rate and progression-free survival, to outweigh the increased toxicity of administering Genasense® for the treatment of patients with metastatic melanoma who have not received prior chemotherapy. On May 13, 2004 the Company announced that it had withdrawn its NDA. Genta continues to track data from patients enrolled in this trial and to analyze its results. The Company expects to present updated information from this trial in 2005. The Company is currently reviewing the possibility for filing the updated data for marketing approval in Europe. The Company has not yet determined what, if any, additional clinical trials may be undertaken with Genasense® in patients with melanoma.

Phase 3 Trial of Genasense® Plus Chemotherapy in Patients with Chronic Lymphocytic Leukemia

In November 2004, the Company reported results from a randomized Phase 3 clinical trial of Genasense® in patients with relapsed or refractory chronic lymphocytic leukemia (CLL). Patients were eligible for this trial if they had failed standard treatment for CLL that had included fludarabine. Two hundred forty one patients were randomized to receive standard chemotherapy with fludarabine and cyclophosphamide with or without Genasense®. The primary objective of the study was to evaluate whether the addition of Genasense® would increase the proportion of patients who attained major objective responses (defined as complete remission or a nodular partial remission), as determined by review of clinical data and bone marrow biopsies using experts who were blinded as to treatment assignment. Analysis of study results has shown that the addition of Genasense® to chemotherapy was associated with a statistically significant increase in the major objective response rate compared with the rate observed in patients who were treated with chemotherapy alone. A significant increase in disease-free survival was also observed. No difference was observed in overall response rate, time-to-disease progression, or overall survival. The incidence of certain serious adverse reactions, including but not limited to nausea, fever and catheter-related complications, was increased in patients treated with Genasense®. Adverse events (irrespective of relation to study drugs) during treatment or within 30 days from last dose of treatment that resulted in death occurred in 9 patients treated with Genasense® plus chemotherapy compared with 5 patients treated with chemotherapy alone. The percentage of patients who experienced serious adverse events was increased in the Genasense® arm; however, the percentages of patients who discontinued treatment due to adverse events were equal in the treatment arms.

Genta plans to discuss the feasibility of submitting an NDA for Accelerated Approval based on this data with the FDA. The CLL trial has both Fast Track and Orphan Drug designations from the FDA. The Company is also exploring the feasibility of filing similar regulatory applications in the European Union.

In mid-2004, the Company became aware of an episode of employee misconduct that involved an unauthorized attempt by the employee to analyze data from the Company s Phase 3 trial of Genasense® in patients with CLL. The episode, which was undertaken prior to assessment of the external expert clinical review of response, was fully investigated by the Company and the Company reported the incident to the FDA. While there can be no assurance, the Company does not currently believe this episode will have a material impact on the analysis or interpretation of the study results, nor that it will affect whether or not the Company will receive marketing approval for Genasense® in CLL.

Phase 3 Trial of Genasense® Plus Chemotherapy in Patients with Multiple Myeloma

In November 2004, Genta reported that the Company's randomized Phase 3 clinical trial of Genasense® in patients with multiple myeloma did not meet its primary endpoint. The trial had been designed to evaluate whether the addition of Genasense® to standard therapy with high-dose dexamethasone could increase the time to development of progressive disease in patients who previously had received extensive therapy. Based on the results of the Phase 3 trial, the Company has no plans to submit an NDA in this indication at the current time. The Company has not yet determined what additional clinical trials, if any, may be undertaken in patients with multiple myeloma.

Other Trials

Other randomized trials are being conducted by either the Company or by oncology cooperative groups. These trials materially differ from previous studies noted above in that they were not prospectively reviewed by FDA for registration suitability prior to initiation. Details of these trials are as follows:

A large U.S. cooperative oncology group, the Cancer and Leukemia Group B (CALGB) is running a Phase 3 trial in patients with acute myelocytic leukemia (AML) over the age of 60 who have not previously received chemotherapy. All patients in this trial receive standard chemotherapy with daunorubicin and cytarabine and they are randomly assigned to receive additional treatment with Genasense® or no other treatment. This trial is currently projected to enroll up to approximately 500 patients. As yet, the CALGB has not released expectations for enrollment completion. While the primary endpoint is overall survival, a variety of secondary endpoints (such as complete remission rate and remission duration) will be sequentially examined during the conduct of this trial.

During June 2004, Genta completed enrollment in a randomized Phase 2 trial of Genasense® plus docetaxel in patients with non-small cell lung cancer. Patients who met a variety of eligibility criteria and who had failed front-line platinum-containing chemotherapy were eligible. Patients were randomly assigned to receive a standard dose of docetaxel with or without Genasense®. A total of 298 patients were enrolled into this study. The primary endpoint of the study was to increase overall survival in patients treated with Genasense® plus chemotherapy compared with patients treated with chemotherapy alone. Key secondary endpoints include comparisons of progression-free survival and objective response.

Two oncology cooperative groups, including the European Organization for Research and Treatment of Cancer (EORTC) and the CALGB, are conducting exploratory randomized trials, as follows:

During the fourth quarter of 2004, the CALGB completed enrollment in a randomized trial of Genasense® in patients with small cell lung cancer. The trial evaluates patients with extensive disease who have not previously received chemotherapy. The trial includes approximately 55 patients and randomly assigns patients to receive Genasense® plus chemotherapy with carboplatin and etoposide or chemotherapy alone. The endpoint of the trial is to determine the proportion of patients who have survived at least twelve months from the date of randomization. Data from this trial are expected to be available in 2006.

The EORTC is conducting a randomized study of Genasense® in patients with hormone-refractory prostate cancer who have not previously received chemotherapy. In this study, all patients receive standard therapy with docetaxel and are randomly assigned to receive Genasense® or no other treatment. The current sample size is projected at 102 patients; the primary objective is to compare response rates of prostate specific antigen (PSA).

In addition to these randomized trials, the Company, either under its own sponsorship or in collaboration with the NCI is also conducting a number of non-randomized clinical trials in patients with various types of cancer.

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

Ganite®

Ganite® as a Treatment for Cancer-Related Hypercalcemia

On October 6, 2003, we began marketing Ganite® for the treatment of cancer-related hypercalcemia. Ganite® is our first drug to receive marketing approval.

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

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

The extension for an important patent covering the use of Ganite® for its approved indication will expire in April 2005. Genta has filed patent applications seeking additional patent protection for Ganite®.

In May 2004, the Company eliminated its sales force and significantly reduced its marketing support for Ganite®. After evaluating various options, we decided during the third quarter of 2004 to continue selective marketing support of the product. In December 2004, a wholesaler contacted the Company to return a significant portion of its inventory of Ganite®. The Company agreed to the return of this product and recorded a provision for sales returns, as well as provided for potential returns from other wholesalers. Our provision for sales returns increased by $1.2 million in 2004.

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

Based on previously published data, we believe that Ganite® may also be a useful treatment for patients with certain types of cancer, particularly non-Hodgkin s lymphoma (NHL). Approximately 54,000 new cases of NHL are diagnosed in the United States each year. We have been granted an investigational new drug exemption, or IND, and we have commenced clinical trials of Ganite® for the treatment of patients with relapsed NHL. In December 2004, we announced the results of a Phase 2 clinical trial in patients with NHL. The results showed that Ganite® displayed antitumor activity in patients with various types of advanced NHL who had failed to respond or had relapsed from other types of treatment. However, the use of Ganite® for these indications entailed the use of higher doses than were used in the hypercalcemia trials and as a result, an increased number of serious adverse events were recorded in this trial. In particular, several patients experienced optic neuritis and optic atrophy associated with visual loss, along with other side effects. As a result of the cost savings actions announced in May 2004, spending on the clinical development of Ganite® as a chemotherapy agent was also reduced. When sufficient resources become available, we may resume clinical development of Ganite® in NHL and other indications by initiating new clinical trials. Previous clinical trials of Ganite® showed that the drug has not been associated with significant myelosuppression, a decrease of bone marrow activity often associated with cancer therapy, which can cause increased susceptibility to bleeding and infection. We believe this feature may allow Ganite® to be incorporated into combination chemotherapy regimens that employ other drugs that cause myelosuppression, thereby potentially increasing the utility of such therapy for patients.

Other Pipeline Products and Technology Platforms

Oral Gallium

For several years, we have been attempting to develop novel formulations of gallium-containing compounds that can be taken orally. 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. Such patients are commonly afflicted by bone pain and susceptibility to fractures. To date, a suitable oral formulation that would be available for clinical development has not yet been identified.

Decoys

In addition to antisense compounds from the DNA/RNA Medicines Program, we have explored the development of compounds known as decoys that are short strands of DNA or RNA which bind proteins known as transcription factors. Normally, transcription factors bind to specific portions of DNA known as response elements and regulate the functions of genes in a positive or negative fashion (i.e., they can turn genes on or off). When a cell is flooded with an excess of decoys, these decoys compete with normal DNA response elements to bind transcription factors and inactivate them. By selectively inactivating the transcription factor, the function of the gene can be regulated in a positive or negative manner. This type of control could potentially be used to regulate genes that are critically involved in the cause, metastasis, or progression of cancer.

In December 2000, Genta licensed patents and technology relating to decoys from the National Institutes of Health (NIH). This technology targets a transcription factor known as the cyclic adenosine monophosphate response element binding protein, or CRE-BP. Pre-clinical studies conducted at the NIH have shown broad anticancer activity for this compound, with very low toxicity to normal cells. Due to the financial constraints described above, the Company has sharply reduced current spending on the Decoy program and is currently reviewing whether or not to retain this compound within its research portfolio.

c-myb Antisense

In December 2004, Genta acquired worldwide rights from Temple University to intellectual property and technology and a novel antisense compound (LR3001) that targets c-myb, a central gene that regulates the growth of cancer cells. LR3001 has been tested in two Phase 1 clinical trials at the University of Pennsylvania in patients with drug-resistant myeloid leukemia. To date, clinical investigations have been supported by grants from the NIH, including the Rapid Access to Investigational Drugs (RAID) program. Genta has submitted a request for designation of LR3001 as an Orphan Drug for the treatment of chronic myelocytic leukemia (CML) to the FDA, and notice of this designation was received in February 2005. The Company is currently working with the lead investigator to re-qualify a substantial inventory of LR3001, which if successful should be sufficient to complete the Phase 1 program. Following completion of Phase 1, the Company will then decide whether or not to take LR3001 into Phase 2 clinical trials. Based on the biology of c-myb, potential target diseases for LR3001 include CML, neuroblastoma and cancer of the breast and colon, among other conditions.

Antisense and RNAi Research and Discovery

We have had several other oligonucleotide-based discovery programs and collaborations devoted to the identification of both antisense- and RNAi-based inhibitors of oncology gene targets. However, spending on these research programs was sharply reduced due to financial constraints previously mentioned. The Company has no current agents that it considers lead compounds that would justify their being advanced into late-stage pre-clinical testing.

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

Patents and Proprietary Technology

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

We own or have licensed several patents and applications to numerous aspects of oligonucleotide technology, including novel compositions of matter, methods of large-scale synthesis, methods of controlling gene expression and methods of treating disease. Genta s patent portfolio includes approximately 90 granted patents and 105 pending applications in the U.S. and foreign countries. Genta endeavors to seek appropriate U.S. and foreign patent protection on its oligonucleotide technology.

Genta has licensed seven U.S. patents relating to Genasense® and its backbone chemistry that expire between 2008 and 2015 and three pending U.S. patent applications that relate to Genasense®. Corresponding patent applications have been filed in three foreign countries. Genta also owns three U.S. patent applications relating to methods of using Genasense® that expire in 2020, with approximately 45 corresponding foreign patent applications.

Included among Genta s property rights are certain rights licensed from the NIH covering phosphorothioate oligonucleotides. We also acquired from the University of Pennsylvania exclusive rights to antisense oligonucleotides directed against the Bcl-2 mRNA, as well as methods of their use for the treatment of cancer. In 1998, two U.S. patents were issued encompassing our licensed antisense oligonucleotide compounds targeted against the Bcl-2 mRNA and the use of these compounds outside of organisms. These claims cover our proprietary antisense oligonucleotide molecules, which target the Bcl-2 mRNA including Genasense®. Other related U.S. and corresponding foreign patent applications are still pending.

The patent covering the use of Ganite® for its approved indication will expire in April 2005. Genta has filed patent applications seeking additional patent protection for Ganite®.

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 prosecuting 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 issues, 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.

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

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

Research and Development

In addition to our current focus in the areas described above, we continually evaluate our programs in light of the latest market information and conditions, the availability of third-party funding, technological advances 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. In August 2004, Genta closed of its research facility in Salt Lake City, which had originated from the August 2003 acquisition of Salus Therapeutics, Inc. We recorded research and development expenses of $71.5 million, $83.1 million, and $87.2 million during the years ended December 31, 2004, 2003 and 2002, respectively.

Sales and Marketing

In May 2004, the Company initiated a series of steps that are designed to conserve cash in order to focus on Genasense®. The Company reduced its workforce by 85 employees, including the elimination of its sales force.

Either alone or in partnerships with other companies, we intend to be a direct marketer or co-marketer of our pharmaceutical products by rebuilding a sales and marketing infrastructure in the United States to launch and fully realize the commercial potential of our products if approved by the FDA. For international product sales, we intend to distribute our products through collaborations with third parties.

Manufacturing and Raw Materials

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

We currently rely on third parties to manufacture our products. In December 2002, we signed a five-year manufacturing and supply agreement with Avecia Biotechnology, Inc., or Avecia, a leading multinational manufacturer of pharmaceutical products, to supply quantities of Genasense®. This agreement is also renewable beyond the initial five-year period. We are not obligated to purchase further drug substance from Avecia prior to approval of Genasense®. We believe this agreement is sufficient for our production needs with respect to Genasense®.

We have a three-year manufacturing and supply agreement with Johnson Matthey Inc. expiring in December 2006, whereby Genta will purchase a minimum of 80% of our requirements for quantities of Ganite®. There are no minimum purchase requirements under the agreement.

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

Human Resources

In May 2004, as a part of the Company s reduction in workforce, the Company eliminated 85 employees, or approximately 45%, including 27 positions classified as research and development positions. In August 2004, Genta completed the closure of its research facility in Salt Lake City, which had originated from the August 2003 acquisition of Salus Therapeutics, Inc. As a result, the Company eliminated an additional 15 positions classified as research and development positions.

As of December 31, 2004, Genta had 73 employees, 15 of whom hold doctoral degrees. As of that date, there were 49 employees engaged in research, development and other technical activities, 2 employees in sales and marketing and 22 in administration. None of Genta s employees are represented by a union. Most of the management and professional employees of Genta have had prior experience and positions with pharmaceutical and biotechnology companies. Genta believes it maintains satisfactory relations with its employees and has not experienced interruptions of operations due to labor disagreements.

C. 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 pre-clinical 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 Genta, 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 pre-clinical testing. Pre-clinical 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 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 pre-clinical and clinical testing, together with chemistry, manufacturing and control information, are then submitted to the FDA for a pharmaceutical product in the form of an NDA. In responding to an NDA, biologics license application or premarket approval application, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not satisfy its regulatory approval criteria. There can be no assurance that the approvals that are being sought or may be sought by Genta 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 pre-clinical 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 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.

D. 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.

E. Certain Risks and Uncertainties Related to the Company s Business

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

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

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

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

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

We cannot assure you that Genasense® will receive FDA approval. Our financial condition and results of operations have been and will continue to be significantly affected by FDA action with respect to Genasense®. In late 2003, we filed our first NDA with the FDA for Genasense® as a treatment combined with chemotherapy for patients with malignant melanoma. On May 3, 2004 the FDA Oncology Drugs Advisory Committee voted not to recommend Genasense®. On May 13, 2004 the Company announced that it had withdrawn its NDA. Genta continues to track data from patients enrolled in this trial and to analyze its results. The Company expects to present updated information from this trial in 2005. The Company is currently reviewing the possibility for filing the updated data for marketing approval in Europe.

On November 8, 2004, we announced the results of our Phase 3 clinical trial of Genasense® in patients with relapsed or refractory CLL. The trial met its primary endpoint of significantly increasing the proportion of patients who achieved a complete or nodular partial remission, as determined by blinded expert review of clinical data and bone marrow biopsies. A significant increase in disease-free survival was also observed. No difference was observed in overall response rate, time-to-disease progression, or overall survival. The incidence of certain serious adverse reactions, including but not limited to nausea, fever and catheter-related complications, was increased in patients treated with Genasense®. Adverse events (irrespective of relation to study drugs) during treatment or within 30 days from last dose of treatment that resulted in death occurred in 9 patients treated with Genasense® plus chemotherapy compared with 5 patients treated with chemotherapy alone. The percentage of patients who experienced serious adverse events was increased in the Genasense® arm; however, the percentages of patients who discontinued treatment due to adverse events were equal in the treatment arms. We plan to discuss the feasibility of submitting a NDA based on these data in CLL with the FDA.

In November 2004, Genta reported that the Company's randomized Phase 3 clinical trial of Genasense® in patients with multiple myeloma did not meet its primary endpoint. The trial had been designed to evaluate whether the addition of Genasense® to standard therapy with high-dose dexamethasone could increase the time to development of progressive disease in patients who previously had received extensive therapy. Based on the results of the Phase 3 trial, the Company has no plans to submit an NDA in this indication at the current time. The Company has not yet determined what additional clinical trials, if any, may be undertaken in patients with multiple myeloma.

We cannot assure you that we will submit a NDA for Genasense® in CLL or submit regulatory filings in melanoma or other diseases to the FDA or outside the U.S. Even if submitted, we cannot provide assurance that these submissions will result in regulatory approval of Genasense® in any territory. Failure to obtain approval, or a substantial delay in approval of Genasense® for these or any other indications, would have a material adverse effect on our results of operations and financial condition.

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

We intend to be a direct marketer of some products in the United States. Currently we do not have a sales force. Our sales force was eliminated in 2004 following our decision to withdraw the NDA for Genasense® for the treatment of malignant melanoma. Our need to build a sales force capable of marketing our products may adversely affect our sales and limit the commercial success of our products.

On November 8, 2004, we received from Aventis a notice of termination of the agreements between Genta and Aventis regarding the development and commercialization of Genasense®. We will lose a significant source of funding as a result of this termination.

In April 2002, we entered into a series of agreements relating to the development and commercialization of Genasense®, to which we refer collectively as the Collaborative Agreement, with Aventis and its affiliates. On November 8, 2004, we received from Aventis a notice of termination of the Collaborative Agreement. The key financial aspects of the Collaborative Agreement were the following:

- Aventis committed to provide up to $476.9 million in initial payments, milestone payments and for the purchase from us of equity and convertible notes.
- If Genasense® received marketing approval from the FDA, we would have been entitled to royalties on Aventis exclusive worldwide net sales of Genasense®.
- Aventis agreed to pay 75% of the development costs related to any U.S. NDA incurred by either us or Aventis subsequent to the execution of our Collaborative Agreement, and substantially all other development, marketing, and sales costs incurred worldwide.
- Aventis agreed to reimburse a portion of our expenses in building our sales force to market in the United States.

As of December 31, 2004, we had received a total of $266.8 million in initial and near-term funding pursuant to the Collaborative Agreement, which included a $10.0 million licensing fee and $40.0 million in development funding, $10.0 million in convertible debt proceeds, $71.9 million pursuant to an at-market equity investment in our common stock, $127.6 million in expense reimbursements and $7.3 million in line of credit proceeds. As a result of the termination of the Collaborative Agreement, Aventis will continue to support the development of Genasense® for a six-month period lasting until May 8, 2005. After May 8, 2005, we will be responsible for all Genasense® costs. In addition, with the November 8, 2004 notice of termination by Aventis, Genta could no longer borrow additional funds under the line of credit and the remaining balance of the line of credit must be repaid no later than May 8, 2005. During the termination period, reimbursements due to Genta for ongoing development activities will continue to be applied against the line of credit balance. As a result of the termination of the Collaborative Agreement, Aventis has forgiven the $10.0 million of convertible debt and accrued interest issued to them in connection with the collaboration.

We are considering whether to seek a new partner for the development and commercialization of Genasense®. If we determine not to collaborate with a partner, or are unable to identify a partner, we will be solely responsible for the development and commercialization of Genasense®, including the costs associated therewith. We may not have sufficient resources to do so. Even if we are able to identify a partner, we may not be able to enter into an agreement on acceptable terms.

We 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 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. In this regard, we have received from Aventis a notice of termination of the Collaborative Agreement.

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 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. From the period since our inception to December 31, 2004, we have incurred a cumulative net loss of $356.0 million. We may never achieve revenue sufficient for us to attain profitability. Achieving profitability is unlikely before Genasense® receives approval from the FDA for commercial sale in one or more indications.

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

Our operations to date have required significant cash expenditures. As a result of Aventis termination of the Collaborative Agreement, after May 8, 2005, we will be responsible for all Genasense® costs. Our future capital requirements will depend on the results of our research and development activities, pre-clinical studies and clinical trials, competitive and technological advances, and regulatory activities of the FDA and other regulatory authorities. In order to commercialize our products, we will need to raise additional funds. On December 15, 2004, we sold 15 million shares of common stock at a price of $1.50 per share to two institutional investors, raising $21.6 million, net of fees and expenses. We will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing. We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. Future collaborations or similar arrangements may require us to license valuable intellectual property to, or to share substantial economic benefits with, our collaborators. If we raise additional capital by issuing additional equity or securities convertible into equity, our stockholders may experience dilution and our share price may decline. Any debt financing may result in restrictions on our spending.

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

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

Our business depends heavily on a small number of products.

We currently sell one product, Ganite®. We do not expect to expand our marketed product portfolio significantly in the short term unless Genasense® receives marketing approval. If Genasense® is not approved, if approval is significantly delayed, or if in the event of approval, the product is commercially unsuccessful, we do not expect significant sales of other products to offset this loss of potential revenue.

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

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

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

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

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

We hold numerous U.S., foreign and international patents covering various aspects of our technology, which include novel compositions of matter, use, methods of large-scale synthesis and methods of controlling gene expression. 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 sufficiently broad 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 any 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 expensive, and we may not be able to enter into any required licensing arrangement on terms acceptable to us.

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

We also may be required to participate in interference proceedings declared by the U.S. Patent and Trademark Office 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.

The patent covering the use of Ganite® for its approved indication will expire in April 2005. Genta has filed and continues to file patent applications seeking intellectual property protection for Ganite®.

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

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

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

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

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

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

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

The FDA and comparable regulatory agencies in foreign countries impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve lengthy and detailed pre-clinical and clinical testing and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more depending upon the type, complexity and novelty of the product. We cannot apply for FDA approval to market any of our products under development until pre-clinical and clinical trials on the product are successfully completed. Several factors could prevent successful completion or cause significant delays of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that the product is safe and effective for use in humans. If safety concerns develop, the FDA could stop our trials before completion. We may not market or sell any product for which we have not obtained regulatory approval. On May 3, 2004, the FDA Oncology Drugs Advisory Committee voted not to recommend Genasense® for marketing approval for the treatment of malignant melanoma. As a result, on May 13, 2004 we announced that we withdrew our NDA. We cannot assure you that the FDA or other regulatory agencies will ever approve the use of our products that are under development. If the patient populations for which our products are approved are not sufficiently broad, or if approval is accompanied by unanticipated labeling restrictions, the commercial success of our products could be limited and our business, results of operations and financial condition could consequently be materially adversely affected.

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

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

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

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

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

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

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

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

The raw materials that we require to manufacture our drugs, particularly oligonucleotides, are available from only a few suppliers. If these suppliers cease to provide us with the necessary raw materials or fail to provide us with 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.

The outcome of and costs relating to pending shareholder class action and shareholder derivative actions are uncertain.

In 2004, numerous complaints were filed in the United States District Court for the District of New Jersey against Genta and certain of our principal officers on behalf of purported classes of our shareholders who purchased our securities during several class periods. The complaints have been consolidated into a single action and allege that we and certain of our principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action complaint in the various actions seeks monetary damages in an unspecified amount and recovery of plaintiffs costs and attorneys fees. In addition, three shareholder derivative actions have been filed against the directors and certain officers of Genta in New Jersey State and Federal courts. Based on facts substantially similar to those asserted in the shareholder class actions, the derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and other violations of New Jersey law. The Company believes these litigations are without merit and will vigorously defend against these suits.

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 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 Genta.

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

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

Our stock price is volatile.

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

- the results of pre-clinical 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.

As of December 31, 2004, we had 95.4 million shares of common stock outstanding and options, warrants and convertible preferred stock outstanding exercisable for or convertible into 11.5 million additional shares. Future sales of shares of common stock by existing stockholders, holders of preferred stock who might convert such preferred stock 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 the common stock. Moreover, the perception that sales of substantial amounts of our common stock might occur could adversely affect prevailing market prices.

Item 2. ***Properties***

We lease approximately 93 thousand square feet of office space in Berkeley Heights, New Jersey. Our annual rental costs for this space are approximately $2.4 million. Our lease on this space terminates in 2010.

Item 3. ***Legal Proceedings***

In 2004, numerous complaints were filed in the United States District Court for the District of New Jersey against Genta and certain of our principal officers on behalf of purported classes of our shareholders who purchased our securities during several class periods. The complaints have been consolidated into a single action and allege that we and certain of our principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action complaint in the various actions seeks monetary damages in an unspecified amount and recovery of plaintiffs costs and attorneys fees. In addition, three shareholder derivative actions have been filed against the directors and certain officers of Genta in New Jersey State and Federal courts. Based on facts substantially similar to those asserted in the shareholder class actions, the derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and other violations of New Jersey law. The Company believes these litigations are without merit and will vigorously defend against these suits.

Management does not believe that this litigation will have a material adverse impact on the Company s financial results or liquidity.

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

No matters were submitted to a vote of security holders in the quarter ended December 31, 2004.

Item 5. ***Market For Registrant s Common Equity and Related Stockholder Matters***

(a) Market Information

The Company s common stock is traded on the Nasdaq National Market under the symbol GNTA. The following table sets forth, for the periods indicated, the high and low sales prices for the common stock as reported by Nasdaq.

	High	Low
2004		
First Quarter	$ 14.25	$ 9.25
Second Quarter	16.65	2.06
Third Quarter	3.20	1.35
Fourth Quarter	3.03	1.18
2003		
First Quarter	$ 8.80	$ 5.50
Second Quarter	14.69	6.52
Third Quarter	17.65	11.10
Fourth Quarter	12.90	8.59

(b) Holders

There were 605 holders of record of the Company s common stock as of March 9, 2005.

(c) Dividends

The Company has never paid cash dividends on its common stock and does not anticipate paying any such dividends in the foreseeable future. The Company currently intends to retain its earnings, if any, for the development of its business.

(f) Use of Proceeds

In December 2004, the Company raised $21.6 million, net of issuance costs, from the issuance of common stock pursuant to our shelf registration statement. The net proceeds from the sale of the common stock will be used for general corporate purposes.

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

(In thousands, except share data)	Years Ended December 31, 2004	2003	2002	2001	2000
Consolidated Statements of Operations Data:					
Revenues:					
License fees and royalties	$ 3,022	$ 1,045	$ 756	$ 146	$ 22
Development funding	12,105	4,194	2,803		
Product sales - net	(512)	1,420			
Total revenues	14,615	6,659	3,559	146	22
Cost of goods sold	170	404			
Provision for excess inventory	1,350				
Total cost of goods sold	1,520	404			
Gross margin	13,095	6,255	3,559	146	22
Costs and expenses:					
Research and development	71,494	83,084	87,162	39,925	8,311
Selling, general and administrative	28,576	29,831	20,551	8,719	10,447
Promega settlement				1,000	
Loss on disposition of property and equipment	1,254	3	13	19	
Total cost and expenses - gross	101,324	112,918	107,726	49,663	18,758
Aventis reimbursement	(43,292)	(55,891)	(28,451)		
Total cost and expenses - net	58,032	57,027	79,275	49,663	18,758
Gain on extinguishment of debt	11,495				
Other (expense)/income	(147)	669	1,372	2,804	6,285
Loss before income taxes	(33,589)	(50,103)	(74,344)	(46,713)	(12,451)
Income tax benefit/(expense)	904	(6)	(184)		
Net loss	(32,685)	(50,109)	(74,528)	(46,713)	(12,451)
Preferred stock dividends					(3,443)
Net loss applicable to common shares	$ (32,685)	$ (50,109)	$ (74,528)	$ (46,713)	$ (15,894)
Net loss per basic and diluted share	$ (0.41)	$ (0.67)	$ (1.05)	$ (0.84)	$ (0.41)
Shares used in computing net loss per basic and diluted share	79,798	75,093	70,656	55,829	38,659

	As of December 31,				
	2004	2003	2002	2001	2000
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 42,247	$ 82,929	$ 113,716	$ 54,086	$ 50,199
Working capital	(4,269)	81,252	91,586	42,709	48,321
Total assets	50,532	114,675	136,419	60,630	57,208
Total stockholders equity	1,752	12,254	46,703	48,310	53,567

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

Overview

Since its inception in February 1988, Genta has devoted its principal efforts toward drug discovery and research and development. Genta s strategy is to build a product and technology portfolio primarily focused on its cancer-related products. Genta has been unprofitable to date and expects 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, 2004, we have incurred a cumulative net loss of $356.0 million. We have experienced significant quarterly fluctuations in operating results and we expect that these fluctuations in revenues, expenses and losses will continue.

Our financial results in 2004 have been and will continue to be significantly affected by FDA action with respect to Genasense®. In late 2003 we filed a NDA for Genasense® to be used in combination with dacarbazine for the treatment of patients with melanoma who have not previously received chemotherapy. In the absence of increased survival, the FDA Oncology Drugs Advisory Committee voted that the evidence presented did not provide substantial evidence of effectiveness, as measured by response rate and progression-free survival, to outweigh the increased toxicity of administering Genasense® for the treatment of patients with metastatic melanoma who have not received prior chemotherapy. On May 13, 2004 the Company announced that it had withdrawn its NDA. On the same day, the Company initiated a series of steps that were designed to conserve cash in order to focus on Genasense®. The Company reduced its workforce by 85 employees, or approximately 45%, including its field sales employees. The Company also significantly reduced its marketing support of Ganite®, its only marketed product. In August 2004, Genta closed its research facility in Salt Lake City, Utah, with a further reduction of 15 employees.

In November 2004, the Company reported results from a randomized Phase 3 clinical trial of Genasense® in patients with relapsed or refractory chronic lymphocytic leukemia (CLL). Two hundred forty one patients were randomized to receive standard chemotherapy with fludarabine and cyclophosphamide with or without Genasense®. The primary objective of the study was to evaluate whether the addition of Genasense® would increase the proportion of patients who attained major objective responses (defined as complete remission or a nodular partial remission), as determined by review of clinical data and bone marrow biopsies using experts who were blinded as to treatment assignment. Analysis of study results has shown that the addition of Genasense® to chemotherapy was associated with a statistically significant increase in the major objective response rate compared with the rate observed in patients who were treated with chemotherapy alone. A significant increase in disease-free survival was also observed. No difference was observed in overall response rate, time-to-disease progression, or overall survival. The incidence of certain serious adverse reactions, including but not limited to nausea, fever and catheter-related complications, was increased in patients treated with Genasense®. Adverse events (irrespective of relation to study drugs) during treatment or within 30 days from last dose of treatment that resulted in death occurred in 9 patients treated with Genasense® plus chemotherapy compared with 5 patients treated with chemotherapy alone. The percentage of patients who experienced serious adverse events was increased in the Genasense arm; however, the percentages of patients who discontinued treatment due to adverse events were equal in the treatment arms.

In November 2004, Genta reported that the Company's randomized Phase 3 clinical trial of Genasense® in patients with multiple myeloma did not meet its primary endpoint. The trial had been designed to evaluate whether the addition of Genasense® to standard therapy with high-dose dexamethasone could increase the time to development of progressive disease in patients who previously had received extensive therapy. As a result of the outcome of the Phase 3 trial, the Company has virtually eliminated activities on this indication.

A significant source of funds during the last several years has been provided by the Company s collaboration with Aventis, regarding the development and commercialization of Genasense®. The key financial aspects of the Collaborative Agreement were the following:

- Aventis committed to provide up to $476.9 million in initial payments, milestone payments and for the purchase from us of equity and convertible notes.
- If Genasense® received marketing approval from the FDA, we would have been entitled to royalties on Aventis exclusive worldwide net sales of Genasense®.
- Aventis agreed to pay 75% of the development costs related to any U.S. NDA incurred by either us or Aventis subsequent to the execution of our Collaborative Agreement, and substantially all other development, marketing, and sales costs incurred worldwide.
- Aventis agreed to reimburse a portion of our expenses in building our sales force to market in the United States.

On November 8, 2004 the Company received from Aventis notice of termination of the agreements between Genta and Aventis. Pursuant to those agreements, Aventis will continue to support the development of Genasense® for a six-month period lasting until May 8, 2005.

Results of Operations

	Summary Operating Results For the years ended December 31,				
($ thousands)	**2004**	**Increase (Decrease)**	**2003**	**Increase (Decrease)**	**2002**
Revenues:					
License fees and royalties	$ 3,022	$ 1,977	$ 1,045	$ 289	$ 756
Development funding	12,105	7,911	4,194	1,391	2,803
Product sales - net	(512)	(1,932)	1,420	1,420	
Total revenues	14,615	7,956	6,659	3,100	3,559
Cost of goods sold	170	(234)	404	404	
Provision for excess inventory	1,350	1,350			
Total cost of goods sold	1,520	1,116	404	404	
Gross margin	13,095	6,840	6,255	2,696	3,559
Costs and expenses:					
Research and development (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of $158, $209 and $517 for the twelve months ended December 31, 2004, 2003 and 2002, respectively)	71,494	(11,590)	83,084	(4,078)	87,162
Selling, general and administrative (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of $62, $227 and $499 for the twelve months ended December 31, 2004, 2003 and 2002, respectively)	28,576	(1,255)	29,831	9,280	20,551
Loss on disposition of equipment	1,254	1,251	3	(10)	13
Total costs and expenses - gross	101,324	(11,594)	112,918	5,192	107,726
Less: Aventis reimbursement	(43,292)	12,599	(55,891)	(27,440)	(28,451)
Total costs and expenses - net	58,032	1,005	57,027	(22,248)	79,275

Gain on extinguishment of debt	11,495	11,495			
Other (expense)/income	(147)	(816)	669	(703)	1,372
Loss before income taxes	(33,589)	16,514	(50,103)	(24,241)	(74,344)
Income tax benefit/(expense)	904	910	(6)	178	(184)
Net loss	$ (32,685)	$ 17,424	$ (50,109)	$ 24,419	$ (74,528)

Total Revenues

Total revenues, consisting of license fees, development funding and product sales were $14.6 million in 2004 compared to $6.7 million in 2003 and $3.6 million in 2002. License fees and development funding revenues are generated by the initial $10.0 million licensing fee and $40.0 million development funding received from Aventis in 2002 under the Collaborative Agreement (see Note 4 to our financial statements), along with non-exclusive sub-license agreements involving antisense technology. On November 8, 2004 Aventis gave notice to Genta that it was terminating its Collaborative Agreement with the Company regarding the development and commercialization of Genasense®. Under the terms of the Collaborative Agreement, Aventis will continue to fund ongoing development activities through May 8, 2005. The Company had previously determined that, due to the nature of the ongoing development work related to the Collaborative Agreement, the end of the development phase and the fair-value of the undelivered elements were not determinable. Accordingly, we deferred recognition of the initial licensing fee and up-front development funding received from Aventis and recognized these payments on a straight-line basis over the original estimated useful life of the related first-to-expire patent of 115 months. As a result of the notice of termination of the Collaborative Agreement, the Company has determined that the period over which the remaining deferred revenue should be recognized will be through May 8, 2005. On November 9, 2004 we began to recognize the remaining deferred revenue over a six-month period, resulting in increased revenue of $9.9 million for 2004.

In October 2003, the Company launched the commercial product Ganite® for the treatment of cancer-related hypercalcemia that is resistant to hydration, generating $1.4 million in product sales in 2003. In May 2004, the Company eliminated its sales force and significantly reduced its marketing support for Ganite®. After evaluating various options, we decided during the third quarter of 2004 to continue selective marketing support of the product. In December 2004, a wholesaler contacted the Company to return a significant portion of its inventory of Ganite®. The Company agreed to the return of this product and recorded a provision for sales returns, as well as provided for potential returns from other wholesalers. Our provision for sales returns increased by $1.2 million in 2004, resulting in net sales of ($.5) million for 2004.

Total revenues for 2003 of $6.7 million increased $3.1 million from the prior-year period. As we entered into the Collaborative Agreement in April 2002, 2002 annual results included the recognition of eight months of license fee and development funding revenue received from Aventis, while 2003 annual results included the recognition of twelve months of revenue. In October 2003, the Company launched Ganite®, generating $1.4 million in product sales.

Cost of goods sold

During 2004 we recorded provisions for excess Ganite® inventory of $1.4 million.

Research and Development Expenses

Research and development expenses before reimbursement were $71.5 million in 2004 compared to $83.1 million in 2003 and $87.2 million in 2002.

Approximately $66.8 million or 93% of research and development expenses before reimbursement were incurred on the Genasense® project for the twelve months ended December 31, 2004. Research and development expenses in 2004 include $33.0 million related to the expensing of vialed Genasense® product and Genasense® bulk drug substance, much of which had been originally produced and acquired to be commercial inventory and other expenses related to the manufacturing and purchase of Genasense® bulk drug substance. Research and development expenses in 2003 include a $13.5 million write-off of acquired in-process research and development resulting from the August 2003 acquisition of Salus Therapeutics, Inc. In August 2004, Genta completed the closure of its research facility in Salt Lake City, which had originated from the acquisition of Salus Therapeutics, Inc. Excluding these items, research and development expenses declined $31.1 million in 2004, primarily resulting from our decision in May 2004 to reduce staff and reduce most non-Genasense® related programs, as well as from the comparison to a prior-year period where expenses were significantly higher resulting from Genasense® Phase 3 clinical trials and NDA preparation activities.

Research and development expenses incurred on the Genasense® project in 2003 were approximately $63.5 million, representing 91% of research and development expenses after excluding the write-off of acquired in-process research and development expenses.

During 2002, we purchased substantial amounts of drug substance to be used in Genasense® Phase 3 clinical trials, leading to higher research and development expenses.

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are not reasonably estimable. 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 reviewing 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 $28.6 million in 2004 compared to $29.8 million in 2003 and $20.6 million in 2002. In 2004, a higher rate of spending in the first half of the year, in anticipation of approval and launch of Genasense®, was more than offset by the impact of the May 2004 elimination of the sales force, reduction of other administrative positions and substantial reduction of marketing support for Ganite®. This net decrease was partially offset by the recognition of $1.0 million of legal expenses related to a shareholder class action suit and three shareholder derivative suits (see Note 19 to our financial statements).

During 2003, expenses substantially increased from 2002 due to the creation of a sales force, Ganite® launch activities, a larger administrative staff and higher general corporate expenses driven by business growth.

Loss on disposition of property and equipment

In August 2004, we completed the closure of our research facility in Salt Lake City, sold all related equipment and assigned our lease on the facility to another company. Additionally, we disposed of excess equipment at corporate headquarters. As a result of these actions, we recorded a loss on disposition of property and equipment of approximately $1.3 million.

Aventis Reimbursement

Under the Collaborative Agreement with Aventis, Aventis paid 75% of U.S. NDA-directed development costs incurred by either Genta or Aventis and 100% of all other development, marketing and sales costs incurred within the U.S. and elsewhere as subject to the Collaborative Agreement. A breakdown of the various third-party, drug supply costs and internal costs of scientific and technical personnel (Full-Time Equivalents or FTE s) that Aventis is required to reimburse under our Collaborative Agreement with Aventis, follows ($ thousands):

Reimbursement to Genta	2004	2003	2002
Third-party costs	$ 19,284	$ 34,073	$ 18,168
Drug supply costs	20,061	16,326	6,879
FTE s	5,833	7,228	3,404
Amount due to Genta	$ 45,178	$ 57,627	$ 28,451
Reimbursement to Aventis	1,886	1,736	
Net reimbursement to Genta	$ 43,292	$ 55,891	$ 28,451

Net expense reimbursement from Aventis of $43.3 million for 2004 decreased from $55.9 million for 2003 primarily due to the greater activity and expenses in 2003 resulting from the NDA filing for Genasense®. Purchases of drug material are expensed as incurred and are not reimbursable pursuant to our Collaborative Agreement with Aventis until they are used in clinical trials.

In September 2004, the Company transferred $15.5 million of vialed Genasense® drug product and Genasense® bulk drug substance to Aventis; this material had been expensed in May 2004. This amount is included in Drug supply costs in the above table. The companies agreed to offset amounts owed under the line of credit extended by Aventis under the Collaborative Agreement (Line of Credit) by $14.8 million and accrued interest on the Line of Credit by $.7 million (see Note 13 to our financial statements).

Once Aventis provided notice of termination of the Collaborative Agreement, all payments otherwise due from Aventis have been and will continue to be applied against any balance on the Line of Credit until the Line of Credit is repaid. In 2004, $12.9 million of reimbursement due to Genta was applied to the balance of the Line of Credit.

Net expense reimbursement from Aventis of $55.9 million for the year ended December 31, 2003 increased from $28.5 million for the year ended December 31, 2002 due to the following factors: the comparison of twelve months of activity in 2003 compared to eight months in 2002, greater activity and expenses resulting from the NDA filing for Genasense® and reimbursement for 2002 and 2003 drug substance purchases used in Phase 3 clinical trials.

Reimbursement to Aventis consists of our 25% share of third party costs incurred by Aventis and internal costs of Aventis scientific and technical personnel.

Gain on extinguishment of debt

On November 8, 2004, Aventis gave notice to Genta that it was terminating its Collaborative Agreement with the Company. Under the terms of the Collaborative Agreement, Aventis has forgiven the $10.0 million of convertible debt issued to them in connection with the collaboration, along with $1.5 million in accrued interest, resulting in a gain on extinguishment of debt of $11.5 million.

Other (expense)/income

Net other expense of $.1 million for 2004 unfavorably compared to net other income of $.7 million for the prior year, primarily due to lower average investment balances throughout 2004 as compared to 2003. Net other income of $.7 million for 2003 declined $.7 million, or 50%, from 2002, principally due to lower investment balances and higher borrowings from Aventis.

Income tax benefit/(expense)

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits. During 2004, New Jersey allowed the Company to sell $11.6 million of its net operating loss carryforwards and we received $0.9 million from the sale, which we recognized as income tax benefit.

If still available under New Jersey law, the Company will attempt to sell its tax loss carryforwards in 2005. 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, or if the Company will be able to find a buyer for its tax benefits.

Net Loss

Genta incurred a net loss of $32.7 million, or $0.41 per share, for 2004, $50.1 million, or $0.67 per share, for 2003 and a net loss of $74.5 million, or $1.05 per share, for 2002. In 2004, the improvement in net loss and per share net loss to common shareholders was primarily due to accelerated recognition of the initial licensing fee and up-front development funding previously received from Aventis and the gain on extinguishment of debt as described above. In 2003, the improvement in net loss and per share net loss to common shareholders was primarily due to lower clinical drug substance purchases and higher reimbursement by Aventis as described above.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement (SFAS) No. 123(R), *Share-Based Payment* that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. With limited exceptions, the amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. In addition, liability awards will be remeasured each reporting period. Compensation cost will be recognized over the period that an employee provides service in exchange for the award. SFAS No. 123(R) replaces SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*. The Company will adopt the provisions of SFAS No. 123R in 2005. We are evaluating the impact that the adoption of this standard will have on the Company s results of operations, financial position or cash flows.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Non-monetary Assets*, an amendment of APB Opinion No. 29. We do not expect that the adoption of this statement will have any impact on the Company s results of operations, financial position or cash flows.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material. As the Company uses third-party manufacturers and does not manufacture its own products, we do not expect that the adoption of this statement will have a material impact on the Company s results of operations, financial position or cash flows.

Critical Accounting Policies

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. The Company believes that the following represent its critical accounting policies:

- *Revenue recognition*. Our policy is to recognize revenues under license arrangements when delivery has occurred or services have been rendered, persuasive evidence of an arrangement exists, the fee is fixed and determinable and collectibility is reasonably assured. Royalties are recognized when earned. Consistent with Staff Accounting Bulletin No. 104 *Revenue Recognition*, initial funding of ongoing development received from Aventis, after the achievement of certain research and development milestones were being recognized on a straight-line basis over the original estimated useful life of the related first-to-expire patent of 115 months. On November 8, 2004 we received from Aventis notice of termination of the agreements between Genta and Aventis, with an effective termination date of May 8, 2005. Accordingly, we are recognizing the remaining balance of the initial funding on a straight-line basis over the time period from November 9, 2004 through May 8, 2005 (see Note 12 to our financial statements).

  Genta recognizes revenue from product sales when title to product and associated risk of loss has passed to the customer and we are reasonably assured of collecting payment for the sale. All revenue from product sales are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances. We allow return of our product for up to twelve months after product expiration. In May 2004 the Company eliminated its sales force and significantly reduced its marketing support for Ganite®. After evaluating various options, we decided during the third quarter of 2004 to continue selective marketing support of the product. In December 2004, a wholesaler contacted the Company to return a significant portion of its inventory of Ganite®. The Company agreed to the return of this product and recorded a provision for sales returns, as well as provided for potential returns from other wholesalers. Our provision for sales returns increased by $1.2 million in 2004.

- *Research and development costs*. All such costs are expensed as incurred, including raw material costs required to manufacture drugs for clinical trials. Reimbursements for applicable Genasense® related costs under the Collaborative Agreement, will continue to be recorded as a reduction to expense (see Note 4 to our financial statements).

Liquidity and Capital Resources

At December 31, 2004, we had cash, cash equivalents and marketable securities totaling $42.2 million, a decline of $40.7 million from $82.9 million at December 31, 2003. During 2004 cash flow used in operating activities was $61.2 million, primarily resulting from a net loss of $32.7 million and non-cash reimbursements of research and development expenses of $27.3 million. Partially offsetting this outflow, in December we raised $21.6 million, net of issuance costs, from the issuance of common stock. Although no assurances can be expressed, management believes that at the current rate of spending, the Company should have sufficient cash funds to maintain its present operations through 2005.

At December 31, 2004, the Company had $7.3 million outstanding (compared to $35.0 million as of December 31, 2003) on the Line of Credit from Aventis. Prior to June 30, 2004 the Line of Credit was classified as long term debt and beginning June 30, 2004, it was classified as short term debt. During 2004, as a result of certain non-cash transactions, the Company reduced amounts owed under the Line of Credit by $27.7 million. As a result of Aventis purchase commitments to Genta, in September we supplied $15.5 million of vialed Genasense® drug product and Genasense® bulk drug substance to Aventis. This amount is included in the Company s Consolidated Statement of Operations as Aventis reimbursement. The companies agreed to offset amounts owed under the Line of Credit by $14.8 million and accrued interest on the Line of Credit by $0.7 million. With the Aventis notice of termination, Genta cannot borrow additional funds and the Line of Credit must be repaid no later than May 8, 2005. All payments otherwise due to Genta are applied against any balance on the Line of Credit until the Line of Credit is repaid. In 2004, $12.9 million of reimbursement due to Genta was applied to the balance of the Line of Credit. Under the terms of the Collaborative Agreement, Aventis will continue to reimburse Genta for ongoing Genasense® clinical trials and development activities during the six-month notice period. We expect that a substantial portion of the $7.3 million outstanding on the Line of Credit will be repaid through the application of reimbursements. After May 8, 2005, all Genasense® costs will be the responsibility of Genta.

The terms of the Line of Credit provide for a favorable interest rate, which is set two days prior to the first day of each calendar quarter. As security for the repayment of the Line of Credit, Genta has granted Aventis a security interest in all of its rights to payments under the Collaborative Agreement, as well as all inventory related to Genasense®.

At December 31, 2003 cash, cash equivalents and marketable securities totaling $82.9 million declined $30.8 million from $113.7 million at December 31, 2002. During 2003, cash flow used in operating activities was $64.4 million, primarily resulting from a net loss of $50.1 million and lower accounts payable and accrued expenses of $17.4 million. Partially offsetting this outflow were borrowings under the Line of Credit from Aventis of $35.0 million.

At December 31, 2002 cash, cash equivalents and marketable securities totaling $113.7 million increased $59.6 million from $54.1 million at December 31, 2001. During 2002, cash flow used in operating activities was $20.4 million, primarily resulting from a net loss of $74.5 million offset by the initial $10.0 million licensing fee and $40.0 million development funding received from Aventis under our collaborative agreement in 2002. The Company had proceeds of $71.0 million from a private placement of common stock and $10.0 million from the sale of convertible debt to Aventis.

Our principal expenditures relate to our research and development activities, primarily focused on Genasense®, which include our ongoing and future clinical trials. We expect these expenditures to continue. The Company currently anticipates total company average monthly cash outflows to be in the $3.0 million to $4.0 million range. Although no assurances can be expressed, management believes that at the current rate of spending, the Company should have sufficient cash funds to maintain its present operations through 2005. The Company may also seek collaborative agreements 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 on favorable terms, if at all. The Company will need substantial additional funds before it can expect to realize significant product revenue.

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

Contractual Obligations

Future contractual obligations at December 31, 2004 are as follows ($ thousands):

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Short term debt obligation (1)	$ 7,312	$ 7,312	$	$	$
Operating lease obligations	13,498	2,568	5,330	5,171	429
Total	$ 20,810	$ 9,880	$ 5,330	$ 5,171	$ 429

(1) Consists of amounts under our line of credit with Aventis which are due on May 8, 2005.

Not included in the above table are any Genasense® bulk drug purchase obligations to Avecia per the terms of the Manufacturing and Supply Agreement entered into between Avecia and Genta in December 2002. The agreement calls for Genta to purchase a percentage of our global Genasense® bulk drug requirements from Avecia during the term of the agreement. Due to the uncertainties regarding the timing of any Genasense® approval and sales/volume projections, specific obligation amounts cannot be estimated at this time. Due to past purchases of Genasense® bulk drug substance, the Company has access to sufficient drug for its current needs.

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

Our carrying values of cash, marketable securities, accounts payable, accrued expenses and debt are a reasonable approximation of their fair value. The estimated fair values of financial instruments have been determined by us using available market information and appropriate valuation methodologies (see Note 2 to our 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.

Genta s 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, 2004. Therefore there will be no ongoing exposure to material adverse effect on our business, financial condition or results of operation for sensitivity to changes in interest rates or to changes in currency exchange rates.

Item 8. Financial Statements and Supplemental Data

Genta Incorporated
Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Genta Incorporated:

We have audited the accompanying consolidated balance sheets of Genta Incorporated and subsidiaries (the Company) as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Genta Incorporated and subsidiaries as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note (1) to the consolidated financial statements of Genta Incorporated, the Company received from Aventis notice of termination of the agreements between Aventis and the Company in November 2004. The implications of such termination to the Company are discussed in Note (1) to the consolidated financial statements.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company s internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2005 expressed an unqualified opinion on management s assessment of the effectiveness of the Company s internal control over financial reporting and an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey
March 14, 2005

GENTA INCORPORATED
CONSOLIDATED BALANCE SHEETS

(In thousands, except par value data)

ASSETS	December 31, 2004	December 31, 2003
Current assets:		
Cash and cash equivalents	$ 36,489	$ 25,153
Marketable securities (Note 3)	5,758	57,776
Accounts receivable- net (Note 5)		16,675
Inventory (Note 6)	354	518
Prepaid expenses and other current assets	1,910	2,484
Total current assets	44,511	102,606
Property and equipment, net (Note 7)	2,847	4,917
Notes receivable (Note 8)		3,542
Intangibles, net (Note 9)	286	863
Prepaid royalties (Note 10)	1,268	1,268
Other assets	1,620	1,479
Total assets	$ 50,532	$ 114,675
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses (Note 11)	$ 14,424	$ 15,319
Deferred revenues, current portion (Note 12)	26,228	5,287
Notes payable	816	748
Short term debt (Note 13)	7,312	
Total current liabilities	48,780	21,354
Deferred revenues (Note 12)		36,067
Convertible debt (Note 14)		10,000
Long term debt (Note 13)		35,000
Total liabilities	48,780	102,421
Commitments and contingencies (Note 19)		
Stockholders equity (Note 17):		
Series A convertible preferred stock, $.001 par value; 5,000 shares authorized, 10 and 261 shares issued and outstanding, liquidation value of $485 and $13,025 at December 31, 2004 and December 31, 2003, respectively		
Common stock, $.001 par value; 150,000 and 120,000 shares authorized, 95,358 and 75,927 shares issued and outstanding at December 31, 2004 and December 31, 2003, respectively	95	76
Additional paid-in capital	357,714	335,713
Accumulated deficit	(355,984)	(323,299)
Deferred compensation	(41)	(261)
Accumulated other comprehensive (loss) income	(32)	25

Total stockholders equity	1,752	12,254
Total liabilities and stockholders equity	$ 50,532	$ 114,675

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)	Years Ended December 31, 2004	2003	2002
Revenues:			
License fees and royalties (Note 12)	$ 3,022	$ 1,045	$ 756
Development funding (Note 12)	12,105	4,194	2,803
Product sales - net	(512)	1,420	
Total revenues	14,615	6,659	3,559
Cost of goods sold	170	404	
Provision for excess inventory (Note 6)	1,350		
Total cost of goods sold	1,520	404	
Gross margin	13,095	6,255	3,559
Costs and expenses:			
Research and development (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of $158, $209 and $517 for the years ended December 31, 2004, 2003 and 2002, respectively)	71,494	83,084	87,162
Selling, general and administrative (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of $62, $227 and $499 for the years ended December 31, 2004, 2003 and 2002, respectively)	28,576	29,831	20,551
Loss on disposition of property and equipment (Note 7)	1,254	3	13
Total costs and expenses - gross	101,324	112,918	107,726
Aventis reimbursement (Note 4)	(43,292)	(55,891)	(28,451)
Total costs and expenses - net	58,032	57,027	79,275
Gain on extinguishment of debt (Note 14)	11,495		
Other (expense)/income	(147)	669	1,372
Loss before income taxes	(33,589)	(50,103)	(74,344)
Income tax benefit/(expense) (Note 15)	904	(6)	(184)
Net loss	$ (32,685)	$ (50,109)	$ (74,528)
Net loss per basic and diluted share	$ (0.41)	$ (0.67)	$ (1.05)
Shares used in computing net loss per basic and diluted share	79,798	75,093	70,656

See accompanying notes to consolidated financial statements.

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GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
For the Years Ended December 31, 2004, 2003 and 2002

(In thousands)	Convertible Preferred Stock Shares	Convertible Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Treasury Stock Shares	Treasury Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
Balance at January 1, 2002	261	$	66,000	$ 66		$	$ 248,685	$ (198,662)	$ (1,713)	$ (66)	$ 48,310
Comprehensive loss:											
Net loss								(74,528)			(74,528)
Unrealized investment loss										91	91
Total comprehensive loss											(74,437)
Issuance of common stock in connection with private placement, net of issuance costs of $899			6,665	7			71,028				71,035
Issuance of common stock in connection with exercise of warrants and stock options			1,503	1			3,284				3,285
Purchase of treasury stock					(393)	(2,506)					(2,506)
Compensation expense related to certain stock options issued in 1999 and 2000									1,016		1,016
Balance at December 31, 2002	261		74,168	74	(393)	(2,506)	322,997	(273,190)	(697)	25	46,703
Comprehensive loss:											
Net Loss								(50,109)			(50,109)
Unrealized investment loss											
Total comprehensive loss											(50,109)
Issuance of common stock in connection with exercise of warrants and stock options			1,172	1			2,542				2,543
Purchase of treasury stock					(51)	(303)					(303)
Retirement of treasury stock			(444)		444	2,809	(2,809)				
Issuance of common stock in connection with acquisition of Salus Therapeutics, Inc.			1,031	1			12,983				12,984
Compensation expense related to certain stock options issued in 1999 and 2000									436		436

Balance at December 31, 2003	261	$	75,927	$	76	$	$ 335,713	$ (323,299)	$ (261)	$ 25	$ 12,254

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GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
For the Years Ended December 31, 2004, 2003 and 2002

(In thousands)	Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
	Shares	Amount	Shares	Amount	Shares	Amount					
Comprehensive loss:											
Net Loss								(32,685)			(32,685)
Unrealized investment loss										(57)	(57)
Total comprehensive loss											(32,742)
Issuance of common stock in connection with Series A conversion	(251)		1,855	2			(2)				
Issuance of common stock in connection with exercise of warrants and stock options			2,576	2			478				480
Issuance of common stock in connection with direct placement, net of issuance costs of $960			15,000	15			21,525				21,540
Compensation expense related to certain stock options issued in 1999 and 2000									220		220
Balance at December 31, 2004	10	$	95,358	$ 95		$	$ 357,714	$ (355,984)	$ (41)	$ (32)	$ 1,752

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Years Ended December 31, 2004	2003	2002
Operating activities:			
Net loss	$ (32,685)	$ (50,109)	$ (74,528)
Items reflected in net loss not requiring cash:			
Depreciation and amortization	3,003	2,383	1,646
Loss on disposition of property and equipment (Note 7)	1,254	3	13
Non-cash reimbursement of research & development expense (Note 5 & 13)	(27,328)		
Amortization of deferred revenues (Note 12)	(15,127)	(5,237)	(3,499)
Provision for sales returns	1,291	30	
Provision for excess inventory (Note 6)	1,350		
Gain on extinguishment of debt (Note 14)	(11,495)		
Write-off of acquired in-process research and development (Note 2)		13,465	
Compensation expense related to certain stock options issued in 1999 and 2000 (Note 18)	220	436	1,016
Changes in operating assets and liabilities, net of effects of acquisition of Salus Therapeutics, Inc. in 2003:			
Accounts receivable (Note 5)	15,509	(2,131)	(14,538)
Inventory (Note 6)	(1,185)	(518)	
Notes receivable (Note 8)	3,542	(3,542)	
Prepaid expenses and other current assets	574	(817)	(751)
Accounts payable and accrued expenses	58	(17,404)	20,405
Deferred revenues (Note 12)			50,000
Other assets	(141)	(972)	(142)
Net cash used in operating activities	(61,160)	(64,413)	(20,378)
Investing activities:			
Purchase of marketable securities (Note 3)	(7,281)	(107,350)	(88,317)
Maturities and sales of marketable securities (Note 3)	59,241	130,590	23,380
Purchase of property and equipment	(1,767)	(3,293)	(2,387)
Proceeds from sale of equipment	157		
Cash paid for acquisition of Salus, net of cash acquired (Note 2)		(579)	
Net cash provided by (used in) investing activities	50,350	19,368	(67,324)
Financing activities:			
Issuance of common stock, net (Note 17)	21,598		71,035
Borrowings under long term debt (Note 13)		35,000	
Issuance of convertible debt (Note 14)			10,000
Borrowings under note payable	1,431	998	868
Repayments of note payable	(1,363)	(740)	(378)
Purchase of treasury stock		(303)	(2,506)
Issuance of common stock upon exercise of warrants and options (Note 17 & 18)	480	2,543	3,285
Net cash provided by financing activities	22,146	37,498	82,304
Increase (decrease) in cash and cash equivalents	11,336	(7,547)	(5,398)
Cash and cash equivalents at beginning of year	25,153	32,700	38,098
Cash and cash equivalents at end of year	$ 36,489	$ 25,153	$ 32,700

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended December 31, 2004, 2003 and 2002

1. Organization and Business

Genta Incorporated (Genta or the Company) is a biopharmaceutical company engaged in pharmaceutical (drug) research and development, its sole reportable segment. The Company is dedicated to developing innovative drugs to treat cancer. In the past, the Company s research efforts have focused primarily on the development of antisense drugs, which are designed to selectively prevent the production of specific proteins that contribute to the cause or progression of disease. More recently, the Company has broadened its research portfolio into other DNA medicines , which, in addition to antisense drugs, consist of decoy aptamers and small molecules, which include the Company s gallium products.

The Company has had recurring operating losses since its inception. Management expects that such losses will continue at least until its lead product, Genasense®, receives approval from the U.S. Food and Drug Administration (FDA) for commercial sale in one or more indications. Achievement of profitability for the Company is dependent on the timing of Genasense® regulatory approvals in the U.S. and outside the U.S. A significant source of funds during the last several years has been from the Company s collaboration with Aventis, a member of the sanofi-aventis Group (Aventis), regarding the development and commercialization of Genasense®. On November 8, 2004 the Company received from Aventis notice of termination of the agreements between Genta and Aventis. Pursuant to those agreements, Aventis will continue to support the development of Genasense® for a six-month period lasting until May 8, 2005. Although no assurances can be expressed, management believes that at the current rate of spending, the Company should have sufficient cash funds to maintain its present operations through 2005. There are a number of alternatives available to the Company to sustain its operations beyond 2005 should there be a delay in approval of Genasense®.

The Company may also seek collaborative agreements, equity financing 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 on favorable terms, if at all. The Company will need substantial additional funds before it can expect to realize significant product revenue.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements are presented on the basis of accounting principles generally accepted in the United States. All professional accounting standards that are effective as of December 31, 2004 have been considered in preparing the consolidated financial statements. Such financial statements include the accounts of the Company and all majority-owned subsidiaries. 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. Certain reclassifications have been made to prior-year amounts to conform to current-year presentation.

Revenue Recognition

In April 2002, the Company entered into a development and commercialization agreement (Collaborative Agreement) with Aventis. Under the terms of the Collaborative Agreement, the Company and Aventis would jointly develop and commercialize Genasense® in the U.S., and Aventis would have exclusive development and marketing rights to the compound in all countries outside of the U.S. Under the Collaborative Agreement, Aventis would pay 75% of U.S. New Drug Application (NDA)-directed development costs incurred by either Genta or Aventis, subsequent to the execution of the Collaborative Agreement, and 100% of all other development, marketing, and sales costs incurred within the U.S. and elsewhere as subject to the Collaborative Agreement. On November 8, 2004 Aventis gave notice to Genta that it was terminating its Collaborative Agreement with the Company. Under the terms of the agreement, Aventis will continue to fund ongoing development activities through May 8, 2005.

The Company follows the provisions of the Securities and Exchange Commission s Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition and Emerging Issues Task Force (EITF) No. 00-21 , *Accounting for Revenue Arrangements with Multiple Deliverables*.

In accordance with EITF No. 00-21 the Company analyzes its multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. The Company recognizes license payments as revenue if the license has stand-alone value and the fair value of the undelivered items can be determined. If the license is considered to have stand-alone value but the fair value on any of the undelivered items cannot be determined, the license payments are recognized as revenue over the period of performance for such undelivered items or services. The Company s estimate of the period of performance involves management judgment. Amounts received for milestones are recognized upon achievement of the milestone, as long as the milestone is deemed to be substantive and the Company has no other performance obligations.

The Company determined that, due to the nature of the ongoing development work related to our Collaborative Agreement with Aventis, the end of the development phase and the fair value of the undelivered elements were not determinable. Accordingly, the Company deferred recognition of the initial licensing fee and up-front development funding received from Aventis and recognized these payments on a straight-line basis over the original estimated useful life of the related first-to-expire patent of 115 months. As a result of the notice of termination of the agreement with Aventis, the Company determined that the period over which the remaining deferred revenue should be recognized will be through May 8, 2005. In accordance with EITF No. 00-21 and SAB No. 104, the Company has reclassified the remaining deferred revenue as current and will recognize such revenue through May 8, 2005.

Genta recognizes revenue from product sales when title to product and associated risk of loss has passed to the customer and the Company is reasonably assured of collecting payment for the sale. All revenue from product sales are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances. The Company allows return of its product for up to twelve months after product expiration. In May 2004 the Company eliminated its sales force and significantly reduced its marketing support for Ganite®. After evaluating various options, the Company decided during the third quarter of 2004 to continue selective marketing support of the product. In December 2004, a wholesaler contacted the Company to return a significant portion of its inventory of Ganite®. The Company agreed to the return of this product and recorded a provision for sales returns, as well as provided for potential returns from other wholesalers. The Company s provision for sales returns increased by $1.2 million in 2004.

Research and Development

Research and development costs are expensed as incurred, including raw material costs required to manufacture products for clinical trials. Reimbursements for applicable Genasense®-related costs, under the Collaborative Agreement, have been recorded as a reduction to expenses in the Consolidated Statement of Operations. Research and development expenses in 2003 include $13.5 million from the write-off of acquired in-process research and development related to the acquisition of Salus Therapeutics, Inc. in August 2003.

Cash, Cash Equivalents and Marketable Securities

The carrying amounts of cash, cash equivalents and marketable securities approximate fair value due to the short-term nature of these instruments. Marketable securities primarily consist of government securities, all of which are classified as available-for-sale marketable securities. Management determines the appropriate classification of securities at the time of purchase and reassesses the classification at each reporting date.

Property and Equipment

Property and equipment is stated at cost and depreciated on the straight-line method over the estimated useful lives of the assets, ranging from three to five years. Leasehold improvements incurred in the renovation of the Company s current offices are being amortized over the remaining life of the leases. The Company s policy is to evaluate the appropriateness of the carrying value of the undepreciated value of long-lived assets. If such evaluation were to indicate an impairment of assets, such impairment would be recognized by a write-down of the applicable assets. Based on the valuation, no impairment was indicated in accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*.

Intangible Assets

Intangible assets, consisting of capitalized patent costs, are amortized using the straight-line method over their estimated useful lives of five years. The Company s policy is to evaluate the appropriateness of the carrying values of the unamortized balances of intangible assets. If such evaluation were to indicate an impairment of these assets, such impairment would be recognized by a write-down of the applicable assets. Based on the valuation, no impairment was indicated in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*.

Inventories

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

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, 2004 and December 31, 2003, used a valuation allowance to reduce these assets to zero to reflect that, more likely than not, they will not be realized.

Stock Options

The Company has two stock-based compensation plans (Note 18). The Company accounts for stock-based compensation arrangements in accordance with provisions of Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* and complies with the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*. Under APB Opinion No. 25, compensation expense is based on the difference, if any, on the date of grant, between the fair value of the Company's stock and the exercise price. The Company accounts for stock options issued to non-employees in accordance with the provisions of SFAS No. 123, and EITF Consensus on Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. The Company is amortizing deferred stock compensation using the graded vesting method, in accordance with Financial Accounting Standards Board Interpretation (FIN) No. 28, over the vesting period of each respective option, which is generally four years.

In December 2004, the FASB issued SFAS No. 123(R) *Share-Based Payment* that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. With limited exceptions, the amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. In addition, liability awards will be remeasured each reporting period. Compensation cost will be recognized over the period that an employee provides service in exchange for the award. SFAS No. 123(R) replaces SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*. The Company will adopt the provisions of SFAS No. 123R in 2005. The Company is evaluating the impact that the adoption of this standard will have on its results of operations, financial position or cash flows.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure* - Amendment of FASB SFAS No. 123, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation and amends the disclosure requirements of SFAS No. 123. The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

	Years Ended December 31,		
($ thousands, except per share data)	**2004**	**2003**	**2002**
Net loss applicable to common shares, as reported	$ (32,685)	$ (50,109)	$ (74,528)
Add: Equity related employee compensation expense related to certain stock options issued in 1999 and 2000 included in reported net income, net of related tax effects	220	436	1,016
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(7,236)	(7,644)	(6,840)
Pro forma net loss	$ (39,701)	$ (57,317)	$ (80,352)
Net loss per share attributable to common shareholders:			
As reported: Basic and diluted	$ (0.41)	$ (0.67)	$ (1.05)
Pro forma: Basic and diluted	$ (0.50)	$ (0.76)	$ (1.14)

The pro-forma disclosure shown above was calculated for all options using the Black-Scholes option-pricing model with the following assumptions:

	Years Ended December 31,		
	2004	**2003**	**2002**
Risk-free interest rate	3.5%	3.3%	2.8%
Dividend yield			
Expected life (years)	4.0	4.0	4.0
Volatility	98%	58%	65%

Net Loss Per Common Share

Net loss per common share for the twelve months ended December 31, 2004, 2003 and 2002, respectively, are based on the weighted average number of shares of common stock outstanding during the periods. Basic and diluted loss per share are identical for all periods presented as potentially dilutive securities, including options, warrants and convertible preferred stock, aggregating 11.4 million, 18.0 million and 16.7 million in 2004, 2003 and 2002, respectively, have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would be antidilutive.

Recently Issued Accounting Standards

In December 2004, the FASB issued SFAS No. 123(R), *Share-Based Payment*, which will require compensation costs related to share-based payment transactions to be recognized in the financial statements. With limited exceptions, the amount of compensation cost will be measured based on the grant-date fair value of the equity or liability instruments issued. In addition, liability awards will be remeasured each reporting period. Compensation cost will be recognized over the period that an employee provides service in exchange for the award. SFAS No. 123(R) replaces FASB SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*. The Company will adopt the provisions of FAS No. 123R in 2005. The Company is evaluating the impact that the adoption of this standard will have on its results of operations, financial position or cash flows.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Non-monetary Assets*, an amendment of APB Opinion No. 29. The Company does not expect that the adoption of this statement will have any impact on the Company s results of operations, financial position or cash flows.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material. As the Company uses third-party manufacturers and does not manufacture its own products, the Company does not expect that the adoption of this statement will have a material impact on its results of operations, financial position or cash flows.

3. Marketable Securities

The carrying amounts of the company s marketable securities, which primarily consist of government securities, approximate fair value due to the short-term nature of these instruments. The fair value of marketable securities is as follows ($ thousands):

	Amortized costs	Unrealized gains	Unrealized losses	Fair value
December 31, 2004	$ 5,790	$ 10	$ (42)	$ 5,758
December 31, 2003	$ 57,751	$ 29	$ (4)	$ 57,776

The fair value of marketable securities by contractual maturity, is as follows ($ thousands):

	December 31,	
	2004	2003
Due within one year	$ 5,758	$ 20,950
Due after one year		36,826
	$ 5,758	$ 57,776

The fair value of each marketable security has been compared to its cost and therefore, an unrealized loss of approximately $32 thousand has been recognized in accumulated other comprehensive loss at December 31, 2004.

4. Collaborative Agreement

In April 2002, the Company entered into a development and commercialization agreement (Collaborative Agreement) with Aventis. Under the terms of the Collaborative Agreement, Genta and Aventis would jointly develop and commercialize Genasense® in the U.S, and Aventis would have exclusive development and marketing rights to the compound in all countries outside the U.S. Under the Collaborative Agreement Aventis paid 75% of the U.S. NDA-directed development costs incurred by either Genta or Aventis and 100% of all other development, marketing, and sales costs incurred within the U.S. and elsewhere as subject to the Collaborative Agreement. An analysis of expenses reimbursed under the Collaborative Agreement follows ($ thousands):

	Twelve Months Ended December 31,		
	2004	2003	2002
Research and development expenses, gross	$ 71,494	$ 83,084	$ 87,162
Less expense reimbursement	(43,292)	(55,891)	(27,746)
Research and development expenses, net	$ 28,202	$ 27,193	$ 59,416
Selling, general and administrative expenses, gross	28,576	$ 29,831	$ 20,551
Less expense reimbursement			(705)
Selling, general and administrative expenses, net	$ 28,576	$ 29,831	$ 19,846

5. Accounts Receivable-Net

Once Aventis provided notice of termination of the Collaborative Agreement, all payments otherwise due from Aventis are applied against any balance on the Line of Credit until the Line of Credit is repaid. Accordingly, the Accounts receivable-net balance at December 31, 2004 does not include any reimbursement from Aventis, as reimbursement due from Aventis has been applied to the Line of Credit.

At December 31, 2003, the balance of Accounts receivable-net of $16.7 million was comprised of $15.5 million in net expense reimbursements due from Aventis for various third-party costs, internal costs of scientific and technical personnel and Genasense® drug supply costs and $1.2 million related to the sale of Ganite®, net of allowances of $0.1 million.

6. Inventory

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

	December 31	
	2004	2003
Raw materials	$ 21	$ 189
Work in process		318
Finished goods	333	11
	$ 354	$ 518

In May 2004, the Company eliminated its sales force and significantly reduced its marketing support for Ganite®. After evaluating various options, the Company decided during the third quarter to continue selective marketing support of the product. During 2004, the Company recorded provisions for excess Ganite® inventory of $1.4 million.

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7. Property and Equipment, Net

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

	Estimated Useful Lives	December 31, 2004	2003
Computer equipment	3	$ 2,860	$ 3,337
Software	3	3,349	2,632
Furniture and fixtures	5	936	1,009
Leasehold improvements	Life of lease	443	767
Equipment	5	166	299
		7,754	8,044
Less accumulated depreciation and amortization		(4,907)	(3,127)
		$ 2,847	$ 4,917

In August 2004, the Company completed the closure of its research facility in Salt Lake City, Utah, sold all related equipment and assigned its lease on this facility to another company. Additionally, the Company disposed of excess equipment at corporate headquarters. As a result of these actions, the Company recorded a loss of approximately $1.3 million.

8. Notes Receivable

At December 31, 2003, the Company had a note receivable of $3.5 million relating to advance financing provided to Avecia Biotechnology, Inc. (Avecia) for facility expansion, which was to be repaid with interest through future payments determined as a function of future drug substance purchases by Genta. Based on negotiations between the two companies, amounts owed to the Company under this note were offset against amounts payable to Avecia, resulting in a non-cash reduction to Note receivable and Accounts payable and accrued expenses of approximately $4.2 million.

9. Intangibles

Intangible assets consist of the following ($ thousands):

	December 31, 2004	2003
Patent and patent applications	$ 3,992	$ 3,992
Less accumulated amortization	(3,706)	(3,129)
	$ 286	$ 863

The remaining intangible asset amount will be fully amortized in 2005.

10. Prepaid Royalties

In December 2000, the Company recorded $1.3 million as the fair value for its commitment to issue 162,338 shares of common stock to a major university as consideration for an amendment to a license agreement initially executed on August 1, 1991 related to antisense technology licensed from the university. The amendment provided for a reduction in the royalty percentage rate to be paid to the university based on the volume of sales of the Company s products containing the antisense technology licensed from such university. These shares were issued in the first quarter of 2001. The Company will amortize the prepaid royalties upon the commercialization of Genasense® through the term of the arrangement, which expires twelve years from the date of first commercial sale.

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11. Accounts Payable and Accrued Expenses

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

	December 31, 2004	December 31, 2003
Accounts payable	$ 5,683	$ 6,462
Accrued compensation	1,957	2,516
Accrued interest		1,235
Reserve for sales returns	1,261	
Other accrued expenses	5,523	5,106
	$ 14,424	$ 15,319

12. Deferred Revenues

As of December 31, 2004, the Company had recorded $26.2 million, net of amortization in current deferred revenues relating to the initial $10.0 million licensing fee and $40.0 million development funding received from Aventis under the Collaborative Agreement. On November 8, 2004, Aventis gave notice to Genta that it was terminating the Collaborative Agreement. Under the terms of the agreement, Aventis will continue to fund ongoing development activities through May 8, 2005. As a result of the notice of termination of the agreements with Aventis, the Company has determined that the period over which the remaining deferred revenue should be recognized will be through May 8, 2005. In accordance with EITF No. 00-21 and SAB No. 104, the Company has reclassified the remaining deferred revenue as current and will recognize such revenue through May 8, 2005.

13. Short Term Debt

This revolving debt was issued in connection with an amendment, dated March 14, 2003, to the Collaborative Agreement that established a line of credit related to the development, manufacturing and commercialization of Genasense® (Line of Credit). The debt was considered an advance against both past and future costs and the borrowing base was adjusted on a monthly basis. Prior to June 30, 2004 the Line of Credit was classified as long-term debt and beginning June 30, 2004, it was classified as short-term debt. During 2004, as a result of certain non-cash transactions, the Company reduced amounts owed under the Line of Credit by $27.7 million. As a result of Aventis purchase commitments to Genta, in September the Company supplied $15.5 million of vialed Genasense® drug product and Genasense® bulk drug substance to Aventis. This amount is included in the Company s Consolidated Statement of Operations as Aventis reimbursement. The companies agreed to offset amounts owed under the Line of Credit by $14.8 million and accrued interest on the Line of Credit by $0.7 million. With the Aventis notice of termination, Genta cannot borrow additional funds and the Line of Credit must be repaid no later than May 8, 2005. All payments otherwise due to Genta are applied against any balance on the Line of Credit until the Line of Credit is repaid. The Company expects that a substantial portion of the $7.3 million outstanding on the Line of Credit will be repaid through the application of reimbursements. In 2004, $12.9 million of reimbursement due from Aventis was applied to the balance of the Line of Credit.

The terms of the Line of Credit provide for a favorable interest rate of the three-month London Interbank Offered Rate plus .35% per annum, compounded quarterly, which is set two days prior to the first day of each calendar quarter. As security for the repayment of the Line of Credit, Genta has granted Aventis a security interest in all of its rights to payments under the Collaborative Agreement, as well as all inventory related to Genasense®.

14. Convertible Debt

On November 8, 2004, Aventis gave notice to Genta that it was terminating its Collaborative Agreement with the Company. Under the terms of the Agreement, Aventis has forgiven the $10.0 million of convertible debt, along with its accrued interest, issued to them in connection with the collaboration, resulting in a gain on extinguishment of debt of $11.5 million.

15. Income Taxes

Significant components of the Company s deferred tax assets as of December 31, 2004 and 2003 and related valuation reserves are presented below ($ thousands):

	December 31,	
	2004	**2003**
Deferred tax assets:		
Deferred compensation	$ 754	$ 658
Net operating loss carryforwards	74,138	90,861
Research and development credit carryforwards	96,009	75,028
Purchased technology and license fees	4,850	4,850
Deferred revenue - current	11,540	2,326
Deferred revenue - non-current		15,869
New Jersey Alternative Minimum Assessment (AMA) Tax	182	182
New Jersey research and development credits	7,558	4,093
Provision for excess inventory	2,656	
Reserve for product returns	568	
Other, net	266	241
	198,521	194,108
Valuation allowance for deferred tax assets	(198,505)	(193,491)
Net deferred tax assets	16	617
Deferred tax liabilities:		
Depreciation, net	(16)	(617)
Net deferred tax assets (liabilities)	$	$

A full valuation allowance has been provided at December 31, 2004 and 2003, respectively, to reserve for deferred tax assets, as it appears more likely than not that net deferred tax assets will not be realized.

New Jersey has enacted legislation permitting certain corporations located in New Jersey to sell state tax loss carryforwards and state research and development credits. During 2004, New Jersey allowed the Company to sell $11.6 million of its net operating loss carryforwards and the Company received $0.9 million from the sale, which was recognized as Income tax benefit.

If still available under New Jersey law, the Company will attempt to sell its tax loss carryforwards in 2005. The Company can not be assured that the New Jersey program will continue next year, nor can the Company estimate what percentage of its 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.

At December 31, 2004, the Company has federal and state net operating loss carryforwards of approximately $169.8 million and $171.9 million, respectively. The federal tax loss carryforwards began expiring in 2003. The Company also has federal research and development credit carryforwards of $96.0 million, which began expiring in 2003.

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16. Operating Leases

At December 31, 2004 and December 31, 2003, the Company maintained $1.6 million and $1.5 million, respectively, in restricted cash balances with financial institutions related to lease obligations on its corporate facilities and leased fleet vehicles. Such restricted cash balances collateralize letters of credit issued by the financial institutions in favor of the Company s landlord with respect to corporate facilities and to a financial institution with respect to leased fleet vehicles.

Future minimum obligations under operating leases at December 31, 2004 are as follows ($ thousands):

	Operating Leases
2005	$ 2,568
2006	2,669
2007	2,661
2008	2,595
2009	2,576
Thereafter	429
	$ 13,498

Annual rent expense incurred by the Company in 2004 and 2003 was $2.5 million and $2.2 million, respectively.

17. Stockholders Equity

Common Stock

In August 2003, the Company issued 1.03 million shares of its common stock, with a fair value of $13.0 million, to Salus stockholders, in connection with its purchase of Salus Therapeutics in exchange for all of the outstanding shares of Salus preferred stock.

In March 2004, the Board of Directors approved an amendment to increase the authorized common stock to 150.0 million shares from 120.0 million. In June 2004, shareholders approved this amendment at the Annual Meeting of Stockholders.

In December 2004, the Company issued 15.0 million shares of its common stock through a direct placement with two institutions and received net proceeds of approximately $21.6 million.

Preferred Stock

The Company has authorized 5.0 million shares of preferred stock and has issued and outstanding 9,700 shares of Series A Convertible Preferred Stock as of December 31, 2004.

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, 2004 and 2003, each share of Series A Preferred Stock was convertible into 8.4274 and 7.3967 shares of common stock, respectively.

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 $0.5 million at December 31, 2004.

In February 2004, substantially all of the Series A Preferred Stock was converted into shares of the Company s Common Stock.

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Warrants

Summary information with respect to outstanding common stock warrants at December 31, 2004 is presented below:

Outstanding Warrants	Exercise Price	Potential Warrant Exercise Proceeds	Common Equivalents	Expiration Date
June 1997	$ 0.86	$ 22,320	25,954	December 2007
August 1999 Androgenics	$ 1.25	100,000	80,000	August 2006
December 1999				
	$ 3.02	372,091	123,209	June 2007
	$ 4.71	316,027	67,097	June 2007
	$ 4.25	187,591	44,139	May 2005
September 2000	$ 6.75	76,214	11,291	September 2005
		$ 1,074,243	351,690	

In June 1997, in connection with a private equity placement, a series of warrants were issued. The remaining outstanding warrants are exercisable and can be converted into approximately 26 thousand common shares; they expire in December 2007.

In August 1999, the Company acquired Androgenics Technologies, Inc. (Androgenics) and as part of that acquisition, issued a series of warrants. The outstanding warrants that are exercisable can be converted into 80 thousand common shares; they expire in August 2006.

In December 1999, in connection with a private equity placement, a series of warrants were issued. The remaining outstanding warrants are exercisable and can be converted into a total of approximately 234 thousand common shares. These warrants expire in May 2005 or in June 2007.

In September 2000, in connection with a private equity placement, a series of warrants were issued. The remaining outstanding warrants are exercisable and can be converted into approximately 11 thousand common shares; they expire in September 2005.

Common Stock Reserved

At December 31, 2004, an aggregate of 11.5 million shares of common stock were reserved for the conversion of preferred stock and the exercise of outstanding options and warrants.

18. Employee Benefit Plans

1998 Plan

Pursuant to the Company s 1998 Stock Incentive Plan as amended (the 1998 Plan), 18.5 million shares have been provided for the grant of stock options to employees, directors, consultants and advisors of the Company. In March 2004, the Board of Directors approved an amendment to increase the total number of shares of common stock authorized for issuance under the 1998 Plan to 18.5 million shares from 17.0 million. In June 2004, the stockholders approved this amendment at the Annual Meeting of Stockholders. Options may be designated as incentive stock options or non-statutory stock options; however, incentive stock options may be granted only to employees of the Company. Options under the 1998 Plan have a term of up to ten years and must be granted at not less than the fair market value, or 85% of fair market value for non-statutory options, on the date of the grant. Common stock sold and options granted pursuant to the 1998 Plan generally vest over a period of four years.

During 1999 and 2000, the Company granted to certain key employees, 6,188,250 and 325,000 options, respectively. Such options were granted with exercise prices below the market value of the Company s common stock on the date of the grant. Accordingly, the Company recorded deferred compensation of $2.0 million and $0.1 million in 1999 and 2000 attributable to the intrinsic value of these options and amortized $0.2 million, $0.2 million and $0.7 million as non-cash equity related compensation expense in 2004, 2003 and 2002, respectively.

In 2001, the Company granted options to purchase common stock to members of Genta s Scientific Advisory Board, for which the Company recorded a total of $0.7 million in deferred compensation, of which $0.2 million and $0.3 million was amortized as non-cash equity related compensation expense in 2003 and 2002, respectively.

The Company s employees were granted 1,442,000, 2,468,300 and 1,274,400 stock options with exercise prices equal to the fair value on the date of grant in 2004, 2003 and 2002, respectively. Summary information with respect to the Company s 1998 Stock Plan is as follows:

1998 Plan	Shares Under Option	Weighted Average Exercise Price Per Share
Balance at December 31, 2001	8,295,244	$ 3.71
Granted	1,274,400	11.88
Exercised	(871,632)	2.12
Canceled	(198,400)	11.88
Balance at December 31, 2002	8,499,612	$ 4.89
Granted	2,468,300	9.85
Exercised	(834,400)	1.87
Canceled	(262,425)	10.75
Balance at December 31, 2003	9,871,087	$ 6.23
Granted	1,442,000	7.56
Exercised	(79,775)	2.76
Canceled	(1,239,492)	9.97
Balance at December 31, 2004	9,993,820	$ 5.99

At December 31, 2004, options to purchase 5,570,729 shares of common stock were exercisable at a weighted average exercise price of approximately $4.51 per share and 3,851,323 shares of common stock were available for grant or sale under the Plan.

1998 Non-Employee Directors Plan

Pursuant to the Company s Non-Employee Directors 1998 Stock Plan as amended, (the Directors Plan) 3.3 million shares have been provided for the grant of stock options to non-employee members of the Board of Directors. Options under the Directors Plan have a term of up to ten years and must be granted at not less than the fair market value on the date of grant. As amended and approved, each director shall be granted 24,000 options upon election to the Board of Directors. Each option granted shall become exercisable over a three-year period. In addition, annually, each director receives 20,000 options at the first Board of Directors meeting they attend. Each option granted shall become exercisable in full on the date of grant.

In June 2004, the stockholders approved an amendment to the 1998 Directors Plan at the Annual Meeting of Stockholders, whereby the Lead Director and Non-Employee Chairperson of a Committee of the Board of Directors are granted an annual option to purchase 5,000 shares of common stock. Each option granted shall become exercisable in full on the date of grant.

The Company s directors were granted stock options to purchase a total of 160,000, 184,000 and 174,667 shares of common stock in 2004, 2003 and 2002, respectively, with an exercise price equal to the fair market value of the common stock on the date of grant.

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Summary information with respect to the Company s 1998 Directors Plan is as follows:

1998 Directors Plan	Shares Under Option	Weighted Average Exercise Price Per Share
Balance at December 31, 2001	1,289,669	$ 5.01
Granted	174,667	11.29
Exercised	(475,000)	1.96
Canceled	(125,000)	8.77
Balance at December 31, 2002	864,336	$ 7.41
Granted	184,000	7.98
Exercised	(100,000)	8.66
Canceled	(20,000)	13.66
Balance at December 31, 2003	928,336	$ 7.26
Granted	160,000	8.16
Exercised	(4,500)	6.86
Canceled	(59,500)	10.33
Balance at December 31, 2004	1,024,336	$ 7.17

At December 31, 2004, options granted under the Directors Plan to purchase 992,335 shares of common stock were exercisable at a weighted average exercise price of approximately $7.04 per share and 322,877 shares of common stock were available for grant or sale under the Directors Plan.

In 2002, a combined total of 1,449,067 options were granted pursuant to the 1998 Plan and 1998 Directors Plan at fair market value with a weighted average grant date fair value of $11.81 per share. In 2003, a combined total of 2,656,300 options were granted pursuant to the 1998 Plan and 1998 Directors Plan at fair market value with a weighted average grant date fair value of $9.72 per share. In 2004, a total of 1,602,000 options were granted pursuant to the 1998 Plan and the 1998 Directors Plan at fair market value with a weighted average grant date fair value of $7.62 per share. No options were granted below fair market value in 2004, 2003 or 2002.

An analysis of all options outstanding as of December 31, 2004 is presented below:

Range of Prices	Options Outstanding	Weighted Average Remaining Life in Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price of Options Exercisable
$0.94 - $3.25	5,550,462	5.2	$ 2.61	4,259,385	$ 2.61
$5.63 - $6.89	927,033	6.4	$ 6.31	727,658	$ 6.39
$7.08 - $8.97	1,427,771	7.1	$ 7.90	802,882	$ 7.95
$9.02 - $10.99	1,815,000	8.6	$ 10.04	208,025	$ 10.09
$11.04 -$18.25	1,297,889	7.6	$ 13.38	565,114	$ 13.95
	11,018,155	6.4	$ 6.10	6,563,064	$ 4.89

Employee Savings Plan

In January 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 $0.7 million, $0.6 million and $0.3 million for 2004, 2003 and 2002, respectively.

19. Commitments and Contingencies

Litigation and Potential Claims

In 2004, numerous complaints were filed in the United States District Court for the District of New Jersey against Genta and certain of our principal officers on behalf of purported classes of our shareholders who purchased our securities during several class periods. The complaints have been consolidated into a single action and allege that the Company and certain of its principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action complaint in the various actions seeks monetary damages in an unspecified amount and recovery of plaintiffs costs and attorneys fees. In addition, three shareholder derivative actions have been filed against the directors and certain officers of Genta in New Jersey State and Federal courts. Based on facts substantially similar to those asserted in the shareholder class actions, the derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and other violations of New Jersey law. The Company believes these litigations are without merit and will vigorously defend against these suits.

Under Genta s directors and officers liability insurance coverage, the Company is liable for the first $1.0 million of legal expenses. As it is reasonably certain that the Company will incur these expenses, $1.0 million was recorded in June 2004.

Management does not believe that this litigation will have a material adverse impact on the Company s financial results or liquidity.

Contractual Obligations

Future contractual obligations at December 31, 2004 are as follows ($ thousands):

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Short term debt obligations (1)	$ 7,312	$ 7,312	$	$	$
Operating lease obligations	13,498	2,568	5,330	5,171	429
Total	$ 20,810	$ 9,880	$ 5,330	$ 5,171	$ 429

(1) Consists of amounts outstanding on the line of credit with Aventis, which are due on May 8, 2005.

Not included in the above table are any Genasense® bulk drug purchase obligations to Avecia per the terms of the Manufacturing and Supply Agreement entered into between Avecia and Genta in December 2002. The agreement calls for Genta to purchase a percentage of our global Genasense® bulk drug requirements from Avecia during the term of the agreement. Due to the uncertainties regarding the timing of any Genasense® approval and sales/volume projections, specific obligation amounts cannot be estimated at this time. Due to past purchases of Genasense® bulk drug substance, the Company has access to sufficient drug for its current needs.

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

During 2004, as a result of certain non-cash transactions, the Company reduced amounts owed under the Line of Credit by $27.7 million. In September the Company supplied $15.5 million of vialed Genasense® drug product and Genasense® bulk drug substance to Aventis. This amount is included in the Company s Consolidated Statement of Operations as Aventis reimbursement. The companies agreed to offset amounts owed under the Line of Credit by $14.8 million and accrued interest on the Line of Credit by $0.7 million. With the Aventis notice of termination, Genta cannot borrow additional funds and the Line of Credit must be repaid no later than May 8, 2005. All payments otherwise due to Genta are applied against any balance on the Line of Credit until the Line of Credit is repaid. In 2004, $12.9 million of reimbursement due to Genta was applied to the balance of the Line of Credit.

Based on negotiations between the Company and Avecia, amounts owed to Genta under a note receivable from Avecia were offset against amounts payable to Avecia, resulting in a non-cash reduction to Note receivable and Accounts payable and accrued expenses of approximately $4.2 million.

No interest was paid for the twelve months ended December 31, 2004, 2003, and 2002, respectively.

21. Selected Quarterly Financial Data (Unaudited)

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

	Quarter Ended			
2004 ($ thousands, except per share data)	**Mar. 31**	**Jun. 30**	**Sep. 30**	**Dec. 31**
Revenues	$ 1,682	$ 1,561	$ 1,397	$ 9,975
Gross Margin	1,589	1,509	685	9,313
Operating expenses-net	14,144	30,698	6,129	7,063
Net (loss) income	(12,532)	(29,155)	(5,580)	14,582
Net (loss) income per common share:				
Basic and diluted *	$ (0.16)	$ (0.37)	$ (0.07)	$ 0.18

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

For the quarter ended December 31, 2004 the Company reported income of $14.6 million or $.18 per share. With the Aventis notice of termination, Aventis has forgiven the $10.0 million of convertible debt issued to them in connection with the collaboration, resulting in a gain on extinguishment of debt of $11.5 million. In addition, the Aventis notice of termination resulted in the acceleration of the recognition of previously deferred revenue over a six-month period beginning November 9, 2004. As a result, revenue recognized in the quarter ended December 31, 2004 increased $9.9 million.

2003 ($ thousands, except per share data)	**Mar. 31**	**Jun. 30**	**Sep. 30**	**Dec. 31**
Revenues	$ 1,309	$ 1,320	$ 1,296	$ 2,734
Gross Margin	1,309	1,320	1,296	2,330
Operating expenses-net	11,224	4,953	18,612	22,238
Net loss	(9,603)	(3,418)	(17,165)	(19,923)
Net loss per common share:				
Basic and diluted	$ (0.13)	$ (0.05)	$ (0.23)	$ (0.26)

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 Chief Financial Officer conducted an evaluation as of the end of the period covered by this report of the effectiveness of the Company s disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)). Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company s disclosure controls and procedures were operating effectively as of the end of the period covered by this report.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2004. Our management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included herein.

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.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Genta Incorporated:

We have audited management s assessment, included in Item 9A Controls and Procedures Management s Report on Internal Control Over Financial Reporting, that Genta Incorporated and subsidiaries (the Company) maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that the Company maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2004 of the Company and our report dated March 14, 2005 expressed an unqualified opinion on those financial statements and included an explanatory paragraph regarding the termination of the Collaborative Agreement between Aventis and the Company.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey
March 14, 2005

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

The information required in this item is incorporated by reference from the Company s definitive proxy statement to be filed not later than April 30, 2005 pursuant to Regulation 14A of the General Rules and Regulations under the Securities Exchange Act of 1934, as amended (Regulation 14A).

Item 11. ***Executive Compensation***

The information required in this item is incorporated by reference from the Company s definitive proxy statement to be filed not later than April 30, 2005 pursuant to Regulation 14A.

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

The information required in this item is incorporated by reference from the Company s definitive proxy statement to be filed not later than April 30, 2005 pursuant to Regulation 14A.

Item 13. ***Certain Relationships and Related Transactions***

The information required in this item is incorporated by reference from the Company s definitive proxy statement to be filed not later than April 30, 2005 pursuant to Regulation 14A.

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

The information required in this item is incorporated by reference from the Company s definitive proxy statement to be filed not later than April 30, 2005 pursuant to Regulation 14A.

PART IV

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

Exhibit Number	Description of Document
3.1.a	Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).1 to the Company s Annual Report on Form 10-K for the year ended December 31, 1995, Commission File No. 0-19635)
3.1.b	Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i) to the Company s Current Report on Form 8-K filed on February 28, 1997, Commission File No. 0-19635)
3.1.c	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.d	Amended Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).4 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.e	Certificate of Increase of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).5 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.f	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).4 to the Company s Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)
3.1.g	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company s Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)
3.1.h	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).8 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
3.1.i	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.i to the Company s Registration Statement on Form S-1, Commission File No. 333-110238)
3.1.j	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.j to the Company s Registration Statement on Form S-1, Commission File No. 333-110238)
3.1.k	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.k to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, Commission File No. 0-19635
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, Commission File No. 0-19635)
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company s Registration Statement on Form S-1, Commission File No. 333-110238)
10.1	Amended and Restated 1991 Stock Plan of Genta Incorporated (incorporated by reference to Exhibit 10.1 to the Company s Registration Statement on Form S-8, Reg. No. 333-101022)
10.2	Non-Employee Directors 1998 Stock Option Plan, as amended and restated (incorporated by reference to Exhibit 99.B to the Company s Definitive Proxy Statement on Schedule 14A filed on April 30, 2004, Commission File No. 0-19635)
10.3	1998 Stock Incentive Plan, as amended and restated, effective March 19, 2004 (incorporated by reference to Exhibit 99.A to the Company s Definitive Proxy Statement on Schedule 14A filed on April 30, 2004, Commission File No. 0-19635)
10.4	Form of Indemnification Agreement entered into between the Company and its directors and officers (incorporated by reference to Exhibit 10.7 to the Company s Registration Statement on Form S-1, Commission File No. 0-19635)

Exhibit Number	Description of Document
10.5*	Development, License and Supply Agreement dated February 2, 1989 between the Company and Gen-Probe Incorporated (incorporated by reference to Exhibit 10.10 to the Company s Registration Statement on Form S-1, Commission File No. 0-19635)
10.6	Asset Purchase Agreement, dated as of March 19, 1999, among JBL Acquisition Corp., JBL Scientific Incorporated and the Company (incorporated by reference to Exhibit 10.2 to the Company s Quarterly Report filed on Form 10-Q for the quarter ended March 31, 1999, Commission File No. 0-19635)
10.7	Warrant Agreement, dated as of December 23, 1999, among the Company, ChaseMellon Shareholder Services, L.L.C., as warrant agent, and Paramount Capital, Inc. (incorporated by reference to Exhibit 10.67 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
10.8	Employment Letter Agreement, dated as of October 28, 1999, from the Company to Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.70 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
10.9	Stock Option Agreement, dated as of October 28, 1999, between the Company and Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.71 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
10.10	Letter Agreement, dated March 4, 1999, from SkyePharma Plc to the Company (incorporated by reference to Exhibit 10.72 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)
10.11	Subscription Agreement executed in connection with the November 26, 2001 sale of common stock to Franklin Small-Mid Cap Growth Fund, Franklin Biotechnology Discovery Fund, and SF Capital Partners Ltd., and the November 30, 2001 sale of common stock to SF Capital Partners Ltd. (incorporated by reference to Exhibit 10.73 to the Company s Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)
10.12	Employment Letter Agreement, dated as of March 27, 2001, from the Company to Loretta M. Itri, M.D. (incorporated by reference to Exhibit 10.74 to the Company s Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)
10.13	Agreement of Lease dated June 28, 2000 between The Connell Company and the Company (incorporated by reference to Exhibit 10.76 to the Company s Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)
10.13A	Amendment of Lease, dated June 19, 2002 between The Connell Company and the Company (incorporated by reference to Exhibit 10.10 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.14	Agreement of Sublease dated August 13, 2001 between Expanets, Inc. and the Company (incorporated by reference to Exhibit 10.77 to the Company s Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)
10.15*	U.S. Commercialization Agreement dated April 26, 2002, by and between Genta Incorporated and Aventis Pharmaceuticals Inc.
10.15A*	Amendment No. 1 dated March 14, 2003 to the U.S. Commercialization Agreement between Genta Incorporated and Aventis Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2003).
10.16*	Ex-U.S. Commercialization Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited
10.17*	Global Supply Agreement, dated April 26, 2002, by and among Genta Incorporated, Aventis Pharmaceuticals Inc. and Garliston Limited (incorporated by reference to Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.18*	Securities Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.4 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)

Exhibit Number	Description of Document
10.19	Standstill and Voting Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.20	Registration Rights Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.6 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.21	Convertible Note Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.7 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.22*	5.63% Convertible Promissory Note, due April 26, 2009 (incorporated by reference to Exhibit 10.8 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.23*	Subordination Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.9 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)
10.24*	Manufacture and Supply Agreement, dated December 20, 2002, between Genta Incorporated and Avecia Biotechnology Inc. (incorporated by reference to Exhibit 10.88 to the Company s Annual Report on Form 10-K for the year ended December 31, 2002, Commission File No. 0-19635)
10.25	Employment Agreement, dated as of December 1, 2002, between the Company and Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.89 to the Company s Annual Report on Form 10-K/A for the year ended December 31, 2001, Commission File No. 0-19635)
10.26	Employment Agreement, dated as of August 5, 2003, between the Company and Loretta M. Itri, M.D. (incorporated by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, Commission File No. 0-19635)
10.27*	License Agreement dated August 1, 1991, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.1 to the Company s Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)
10.27A*	Amendment to License Agreement, dated December 19, 2000, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.2 to the Company s Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)
10.27AA*	Second Amendment to License Agreement, dated October 22, 2003, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.3 to the Company s Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)
10.28*	Settlement Agreement and Release, dated October 22, 2003, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.4 to the Company s Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)
21	Subsidiaries of the Registrant
23.1	Consent of Deloitte & Touche LLP
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 14th day of March 2005.

GENTA INCORPORATED

/s/ RAYMOND P. WARRELL, JR., M.D.
Raymond P. Warrell, Jr., M.D.
Chairman and Chief Executive Officer

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

Signature	Capacity	Date
/s/ RAYMOND P. WARRELL, JR., M.D. Raymond P. Warrell, Jr., M.D.	Chairman and Chief Executive Officer	March 14, 2005
/s/ WILLIAM P. KEANE William P. Keane	Vice President, Chief Financial Officer and Corporate Secretary (Principal Accounting Officer)	March 14, 2005
/s/ JEROME E. GROOPMAN, M.D. Jerome E. Groopman, M.D.	Director	March 14, 2005
/s/ BETSY MCCAUGHEY Betsy McCaughey, Ph.D.	Director	March 14, 2005
/s/ PETER TATTLE Peter T. Tattle	Director	March 14, 2005
/s/ DANIEL D. VON HOFF, M.D. Daniel D. Von Hoff, M.D.	Director	March 14, 2005
/s/ HARLAN J. WAKOFF Harlan J. Wakoff	Director	March 14, 2005
/s/ DOUGLAS G. WATSON Douglas G. Watson	Director	March 14, 2005
/s/ MICHAEL S. WEISS Michael S. Weiss	Director	March 14, 2004

Exhibit Number	Description of Document	Sequentially Numbered Pages
3.1.a	Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).1 to the Company s Annual Report on Form 10-K for the year ended December 31, 1995, Commission File No. 0-19635)	
3.1.b	Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i) to the Company s Current Report on Form 8-K filed on February 28, 1997, Commission File No. 0-19635)	
3.1.c	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
3.1.d	Amended Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).4 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
3.1.e	Certificate of Increase of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).5 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
3.1.f	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).4 to the Company s Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)	
3.1.g	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company s Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)	
3.1.h	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).8 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
3.1.i	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.i to the Company s Registration Statement on Form S-1, Commission File No. 333-110238)	
3.1.j	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.j to the Company s Registration Statement on Form S-1, Commission File No. 333-110238)	
3.1.k	Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.k to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, Commission File No. 0-19635	
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, Commission File No. 0-19635)	
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company s Registration Statement on Form S-1, Commission File No. 333-110238)	
10.1	Amended and Restated 1991 Stock Plan of Genta Incorporated (incorporated by reference to Exhibit 10.1 to the Company s Registration Statement on Form S-8, Reg. No. 333-101022)	
10.2	Non-Employee Directors 1998 Stock Option Plan, as amended and restated (incorporated by reference to Exhibit 99.B to the Company s Definitive Proxy Statement on Schedule 14A filed on April 30, 2004, Commission File No. 0-19635)	

Exhibit Number	Description of Document	Sequentially Numbered Pages
10.3	1998 Stock Incentive Plan, as amended and restated, effective March 19, 2004 (incorporated by reference to Exhibit 99.A to the Company s Definitive Proxy Statement on Schedule 14A filed on April 30, 2004, Commission File No. 0-19635)	
10.4	Form of Indemnification Agreement entered into between the Company and its directors and officers (incorporated by reference to Exhibit 10.7 to the Company s Registration Statement on Form S-1, Commission File No. 0-19635)	
10.5*	Development, License and Supply Agreement dated February 2, 1989 between the Company and Gen-Probe Incorporated (incorporated by reference to Exhibit 10.10 to the Company s Registration Statement on Form S-1, Commission File No. 0-19635)	
10.6	Asset Purchase Agreement, dated as of March 19, 1999, among JBL Acquisition Corp., JBL Scientific Incorporated and the Company (incorporated by reference to Exhibit 10.2 to the Company s Quarterly Report filed on Form 10-Q for the quarter ended March 31, 1999, Commission File No. 0-19635)	
10.7	Warrant Agreement, dated as of December 23, 1999, among the Company, ChaseMellon Shareholder Services, L.L.C., as warrant agent, and Paramount Capital, Inc. (incorporated by reference to Exhibit 10.67 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
10.8	Employment Letter Agreement, dated as of October 28, 1999, from the Company to Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.70 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
10.9	Stock Option Agreement, dated as of October 28, 1999, between the Company and Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.71 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
10.10	Letter Agreement, dated March 4, 1999, from SkyePharma Plc to the Company (incorporated by reference to Exhibit 10.72 to the Company s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)	
10.11	Subscription Agreement executed in connection with the November 26, 2001 sale of common stock to Franklin Small-Mid Cap Growth Fund, Franklin Biotechnology Discovery Fund, and SF Capital Partners Ltd., and the November 30, 2001 sale of common stock to SF Capital Partners Ltd. (incorporated by reference to Exhibit 10.73 to the Company s Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)	
10.12	Employment Letter Agreement, dated as of March 27, 2001, from the Company to Loretta M. Itri, M.D. (incorporated by reference to Exhibit 10.74 to the Company s Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)	
10.13	Agreement of Lease dated June 28, 2000 between The Connell Company and the Company (incorporated by reference to Exhibit 10.76 to the Company s Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)	

Exhibit Number	Description of Document	Sequentially Numbered Pages
10.13A	Amendment of Lease, dated June 19, 2002 between The Connell Company and the Company (incorporated by reference to Exhibit 10.10 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.14	Agreement of Sublease dated August 13, 2001 between Expanets, Inc. and the Company (incorporated by reference to Exhibit 10.77 to the Company s Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)	
10.15*	U.S. Commercialization Agreement dated April 26, 2002, by and between Genta Incorporated and Aventis Pharmaceuticals Inc.	
10.15A*	Amendment No. 1 dated March 14, 2003 to the U.S. Commercialization Agreement between Genta Incorporated and Aventis Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2003).	
10.16*	Ex-U.S. Commercialization Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.2 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.17*	Global Supply Agreement, dated April 26, 2002, by and among Genta Incorporated, Aventis Pharmaceuticals Inc. and Garliston Limited (incorporated by reference to Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.18*	Securities Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.4 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.19	Standstill and Voting Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.20	Registration Rights Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.6 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.21	Convertible Note Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.7 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.22*	5.63% Convertible Promissory Note, due April 26, 2009 (incorporated by reference to Exhibit 10.8 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.23*	Subordination Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.9 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)	
10.24*	Manufacture and Supply Agreement, dated December 20, 2002, between Genta Incorporated and Avecia Biotechnology Inc. (incorporated by reference to Exhibit 10.88 to the Company s Annual Report on Form 10-K for the year ended December 31, 2002, Commission File No. 0-19635)	
10.25	Employment Agreement, dated as of December 1, 2002, between the Company and Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.89 to the Company s Annual Report on Form 10-K/A for the year ended December 31, 2001, Commission File No. 0-19635)	

Exhibit Number	Description of Document	Sequentially Numbered Pages
10.26	Employment Agreement, dated as of August 5, 2003, between the Company and Loretta M. Itri, M.D. (incorporated by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, Commission File No. 0-19635)	
10.27*	License Agreement dated August 1, 1991, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.1 to the Company s Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)	
10.27A*	Amendment to License Agreement, dated December 19, 2000, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.2 to the Company s Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)	
10.27AA*	Second Amendment to License Agreement, dated October 22, 2003, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.3 to the Company s Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)	
10.28	Settlement Agreement and Release, dated October 22, 2003, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.4 to the Company s Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)	
21	Subsidiaries of the Registrant	
23.1	Consent of Deloitte & Touche LLP	
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	
31.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	
32.1	Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	
32.2	Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	