GENTA INC DE/
Form 10-K
March 12, 2004

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, 2003

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 Rule 12b-2 of the Securities Exchange Act of 1934). 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 $508,349,195 as of June 30, 2003 (the last business day of the registrant s most recently completed second fiscal quarter). For purposes of determining this number, 36,307,738 shares of common stock held by affiliates as of June 30, 2003 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 11, 2004, the registrant had 77,722,489 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, 2004 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, 2004 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:

- U.S. Federal Drug Administration ("FDA") approval or failure to approve Genasense ;
- the Company's ability to develop, manufacture and sell its products;
- the safety and efficacy of the Company's products;
- the commencement and completion of pre-clinical and clinical trials;
- the Company's ability to obtain necessary regulatory approvals;
- the Company's contractual collaborative arrangements;
- the adequacy of the Company's capital resources;
- the ability to obtain sufficient financing to maintain the Company's planned operations;
- the possibility and effect of patent infringement claims;
- the impact of competitive products and market conditions;
- 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 are drugs based on chemical modifications of either deoxyribonucleic acid, or DNA, or ribonucleic acid, or RNA; and
- Small Molecules.

We began marketing our first commercial product, Ganite , which is part of our Small Molecule program in October 2003. Ganite has been approved by the U.S. Food and Drug Administration (FDA), for treatment of cancer-related hypercalcemia that is resistant to hydration. The drug is being marketed and sold exclusively by Genta in the United States by our dedicated sales force.

The Company s lead investigational antisense drug is called Genasense (oblimersen sodium), a molecule that 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 solely as a means of amplifying the effects of other anticancer therapy by pre-treating patients with Genasense .

In September 2003, Genta reported Phase 3 clinical data for Genasense in patients with advanced malignant melanoma. We included these data in our FDA New Drug Application (NDA), for Genasense , which we initiated on a rolling basis in August 2003 (i.e., we filed the NDA in several sections with each section being filed when completed). We completed the NDA filing for use of Genasense in combination with chemotherapy for patients with advanced malignant melanoma on December 8, 2003. The FDA accepted our NDA filing on February 5, 2004 and granted Priority Review status to the application, which targets 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 the FDA Oncology Drugs Advisory Committee.

We are pursuing further testing of both Ganite and Genasense in additional indications. Ganite is currently undergoing clinical testing for use as a cancer chemotherapy drug, especially in patients with non-Hodgkin s lymphoma, or NHL. Genasense is being tested as a drug that can increase the effectiveness of current types of cancer therapy. We have completed patient enrollment in two additional randomized Phase 3 trials that test the efficacy of Genasense in patients with multiple myeloma and chronic lymphocytic leukemia, or CLL. Genasense is also being tested in earlier clinical trials for treating more than 10 other cancer types, including non-small cell lung cancer, small cell lung cancer, NHL, acute and chronic leukemias, cancers of the prostate, colon and breast and other diseases. Genasense has received designations as Fast Track and Orphan Drug from the FDA in the advanced malignant melanoma, multiple myeloma and CLL indications.

We have a series of agreements with Aventis to develop and commercialize Genasense . Aventis and Genta will co-promote Genasense in the United States; Aventis is a major participant in the worldwide oncology market and possesses one of the largest oncology sales forces in the U.S. Under these agreements, Aventis has committed to provide up to $476.9 million in initial payments, milestone payments and for the purchase from us of equity and convertible notes. In addition, Aventis is responsible for 75% of development costs related to any U.S. NDA incurred by Genta or Aventis, and substantially all other development, marketing and sales costs incurred worldwide in connection with Genasense . Aventis has agreed to pay us royalties on its exclusive worldwide net sales of Genasense , and to reimburse a portion of our expense in building Genta s sales force to market Genasense in the United States.

Our pre-clinical pipeline of DNA/RNA Medicines includes technologies known as antisense, RNA inhibitor molecules, or RNAi, and decoys, as well as novel delivery system formulations that can increase the entry of these drugs into cells. In August 2003 we acquired a private company, Salus Therapeutics, Inc., or Salus, in order to strengthen our research and development activities in the DNA/RNA Medicines program. The acquisition of Salus provides a proprietary screening system that rapidly identifies hot spots or key target areas in messenger RNA, which can be targeted using both antisense oligonucleotides and RNAi; methods of using single-stranded small interfering RNA and micro-RNA molecules to knockdown gene expression in target cells; and a proprietary delivery platform designed to improve the pharmaceutical properties of oligonucleotides.

In addition to Ganite , current activities in the Small Molecule program include development of an oral formulation of a gallium-containing compound.

We carry out our strategy by identifying and licensing or acquiring from third parties early to mid-stage products and well-characterized targets. We design and manage the pre-clinical and clinical testing of promising products, which is carried out for us by contract research organizations. Generally we expect to scale up, validate, conduct late-stage clinical trials and commercialize our products either alone or in partnership with established businesses, such as Aventis and Avecia for Genasense . Our own product quality and regulatory staffs oversee FDA-regulated activities conducted by us or by our business partners.

In 2003, sales of Ganite accounted for $1.4 million, or 21%, of our consolidated revenues. License fees and development funding revenues received from Aventis pursuant to our collaborative agreement related to Genasense accounted for $1.0 million, or 15% and $4.2 million, or 63% of our consolidated revenues respectively. In 2002 license fees and development funding revenues received from Aventis accounted for $0.8 million, or 22% and $2.8 million, or 78% of our consolidated revenues respectively. In 2001 license fees and royalties derived from non-exclusive sub-license agreements involving antisense technology accounted for $0.1 million, or 100% of consolidated revenues.

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 and objectives in this regard are:

- *Build on our foundation in oligonucleotide therapeutics to establish a leadership position in the treatment of cancer.*

We believe that drugs based on DNA and RNA are an important next-generation development that Genta is well positioned to commercialize. We are committed to the discovery, clinical development and commercialization of these next-generation oncology drugs.

- *Establish Genasense as the preferred chemosensitizing drug for use in combination with other cancer therapies in a variety of human cancer types.*

We believe that Genasense will be more effective as a cancer drug used in conjunction with chemotherapy. We are testing Genasense in a variety of cancer types in order to establish its utility across many indications. The FDA accepted our filing on February 5, 2004 and granted Priority Review status to the application, which targets an agency action on or before June 8, 2004. Assuming FDA approval, we intend to launch Genasense in the United States via a co-promotion with Aventis. Aventis plans to file for regulatory approval for Genasense in advanced malignant melanoma in countries outside the United States. We are entitled to royalties on all sales of Genasense by Aventis. We have completed enrollment in Phase 3 clinical testing of Genasense in patients with multiple myeloma and CLL. We expect to complete data analysis and report our results from those clinical trials in 2004. If one or both of these trials proves positive, we believe we can submit a follow-on NDA for Genasense in at least one of those diseases in 2004. In addition, in collaboration with Aventis and the National Cancer Institute, or NCI, we plan to initiate both non-randomized and randomized trials for treating eligible patients, based on their disease state, suffering from some of the most prevalent cancers, including lung, breast, prostate and colon cancers and NHL.

- *Establish Ganite for the treatment of NHL and other diseases.*

In October 2003, we launched Ganite in the United States for the treatment of cancer-related hypercalcemia, and we intend to continue to commercialize the product for that indication. However, Ganite was originally developed as a chemotherapy agent, and published Phase 1 and Phase 2 studies have shown a high degree of clinical activity in several diseases, including NHL and bladder cancer. We are currently investigating the use of Ganite in Phase 2 clinical trials in patients with NHL, and we intend to pursue the clinical development of Ganite in this and other indications with the initiation of new clinical trials.

- *Continue to develop and strengthen our portfolio of R&D projects through internal development, licensing and acquisitions.*

We intend to continue to develop our other pipeline products for the treatment of patients with cancer, including DNA/RNA Medicines (antisense, siRNA and decoys) and Small Molecules (oral gallium). We intend to continue to evaluate licensing and acquisitions of complementary technologies.

- *Establish a strong presence in the U.S. oncology market.*

We plan to seek opportunities to license or acquire attractive new products, well-characterized targets, and technologies that could enable us to expand our internal applied research and pre-clinical capabilities. We will continue to strengthen our core competencies in clinical development and regulatory and quality assurance. We also are planning to build our U.S. sales and marketing capabilities.

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. 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 second generation phosphorothioate backbone, which is the nucleotide chain comprised of ribose and phosphate groups. However, we also have patents and technologies covering later third generation technologies that involve mixed phosphorothioate and methylphosphonate backbones, 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 of polymers that can be used to more efficiently increase the uptake of oligos into cells. Some of these advanced technologies may be incorporated into new DNA/RNA Medicines.

Programmed Cell Death

The programmed death of cells 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 programmed cell death process can result in diseases.

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). We believe that the ability to selectively halt the production of certain proteins may make the treatment of certain diseases more effective. The process of programmed cell death 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 programmed cell death also known as 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

The lead product from our DNA/RNA Medicines program is Genasense , an antisense oligonucleotide molecule that is designed to block the production of a protein known as 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 it is more effective as a means of amplifying the effectiveness of other cancer therapies, principally by pre-treatment of patients with Genasense . Accordingly, we are seeking FDA approval of Genasense in conjunction with chemotherapy.

Overview of Preclinical and Clinical studies of Genasense

Genasense Preclinical Studies

The Development of Genasense

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.

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, NHL and cancers of the prostate, colon, lung, breast and other tumor types. Since 2001, Genta and the NCI have jointly approved the initiation of approximately 20 new 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
Advanced Malignant Melanoma	Phase 3 fully enrolled; NDA filed and accepted for "Priority Review"; target FDA action date June 2004
Multiple Myeloma	Phase 3 (fully enrolled); Phase 1-2
Chronic Lymphocytic Leukemia (CLL)	Phase 3 (fully enrolled); Phase 2
Acute Myelocytic Leukemia	Phase 2
Non-Small-Cell Lung Cancer	Phase 2 (randomized)
Prostate Cancer	Phase 2
Small-Cell Lung Cancer	Phase 2 (randomized)
Breast Cancer	Phase 1-2
Colorectal Cancer	Phase 1-2
Non-Hodgkin's Lymphoma (NHL)	Phase 1-2; 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

To date, we have completed patient enrollment in three randomized Phase 3 trials, as follows:

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

On September 10, 2003, we and Aventis announced results from our Phase 3 clinical study of Genasense plus chemotherapy in patients with advanced malignant melanoma. The trial enrolled patients at 140 sites from 12 different countries. A total of 771 patients who had not been previously treated with chemotherapy were randomly assigned to receive dacarbazine, a standard chemotherapy drug, alone or in combination with Genasense . The primary endpoint of this trial was to compare the overall survival between the two treatment arms. Secondary endpoints included comparative analyses of progression-free survival and tumor response. The following results were obtained:

- Analysis of all patients on an intent-to-treat basis showed that the addition of Genasense to dacarbazine resulted in an estimated median survival of 9.1 months, compared with 7.9 months for patients treated with dacarbazine alone. The result was not statistically significant, as measured by a P-value of 0.184. Accordingly, we did not reach our primary endpoint. However, in part because both groups in the trial lived longer than we originally projected and because a substantial number of patients were accrued at a late stage into the trial, the analysis also revealed that a number of patients had not been followed for sufficiently long periods to establish the final median survival of this trial. For the 480 patients treated per-protocol who had completed a minimum follow-up of 12 months, the addition of Genasense resulted in a median survival of 10.1 months, compared with 8.1 months for dacarbazine alone. The P-value of this result was 0.035, which was statistically significant.

- For the 771 patients from the intent-to-treat analysis, patients treated with Genasense plus dacarbazine showed a significant increase in median progression-free survival to 78 days, compared with 49 days for patients treated with dacarbazine alone. The P-value of this result was 0.001, which was statistically significant.

- For the intent-to-treat population, 11.7% of the patients treated with Genasense plus dacarbazine experienced a 30% reduction in size of skin lesion (using RECIST criteria), compared with 6.8% for patients treated with dacarbazine alone. The P-value of this result was 0.019, which was statistically significant.

- The addition of Genasense to dacarbazine did not appear to be associated with serious, previously unreported adverse reactions compared with the use of dacarbazine alone.

Data from this trial comprised the basis of a rolling NDA for Genasense , a process that we initiated in August 2003 and completed in December 2003. The FDA accepted our NDA filing on February 5, 2004 and granted Priority Review status to the application, which targets 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 the FDA Oncology Drugs Advisory Committee.

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

We expect to report results in 2004 of a Phase 3 trial of Genasense plus chemotherapy in patients with multiple myeloma. This trial is directed at patients whose disease progressed despite chemotherapy. The primary goal of this trial is to increase the time to progression of disease in patients treated with Genasense plus high-dose dexamethasone compared with dexamethasone alone. This trial completed enrollment of 220 patients in December 2002, and follow-up of these patients is continuing.

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

We expect to report results in 2004 of a Phase 3 trial of Genasense plus chemotherapy in patients with CLL. This trial is directed at patients whose disease progressed despite chemotherapy. The primary goal of this trial is to increase the proportion of patients who achieve a complete (or nodular partial) response after treatment with Genasense plus fludarabine/cyclophosphamide compared with fludarabine/cyclophosphamide alone. This trial completed enrollment of 241 patients in the second quarter of 2003, and follow-up of these patients is continuing.

Current Phase 1 and Phase 2 Trials

In addition to the Phase 3 trials described above, Genasense is currently the subject of a number of other clinical trials, as indicated in the foregoing table, including randomized trials in patients with non-small cell lung cancer and small cell lung cancer, and non-randomized trials in patients with NHL, acute and chronic leukemias, various solid tumors and other disorders.

Regulatory Status

We completed the submission of our NDA for Genasense to the FDA in December 2003. The FDA accepted our NDA filing on February 5, 2004 and granted Priority Review status to the application, which targets 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 the FDA Oncology Drugs Advisory Committee. We believe we are well-positioned for FDA approval of Genasense in 2004 for use in advanced malignant melanoma patients. However, the approval is subject to a number of uncertainties, and we cannot assure you that Genasense will be approved in this time frame or at all. The FDA has granted several designations to Genasense that may expedite its regulatory review. These designations include:

- *Priority review for advanced malignant melanoma NDA*. Priority review is a designation granted by the FDA for a NDA after it has been submitted for review. Under the Food and Drug Administration Modernization Act, priority designation is intended for those products that address unmet medical needs. In general, the designation of priority review indicates that the FDA will render a decision on the approvability of a drug for marketing within six months from the date of filing.

- *Fast track status for advanced malignant melanoma, multiple myeloma and CLL.* The FDA fast track program is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The program allows sponsors to submit an NDA on a rolling basis, which means that portions of the application can be submitted separately as they are completed, rather than waiting to compile and submit the entire NDA as a whole.

- *Orphan drug designation for advanced malignant melanoma, multiple myeloma and CLL.* An orphan drug is a drug that is intended to treat conditions that affect fewer than 200,000 people in the United States. Designation as an orphan drug allows the sponsors of drugs for rare diseases to qualify for tax credits and certain marketing exclusivity incentives under the Orphan Drug Act.

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

We have applied for similar designations from regulatory agencies in Europe.

Commercialization Plan

In April 2002, we announced an exclusive agreement with Aventis to jointly develop and commercialize Genasense . We have agreed with Aventis that only Aventis may sell Genasense . Genta will supply Aventis with Genasense on a global basis. Aventis will pay us a royalty for all worldwide sales of Genasense . Genta retains sole ownership of and exclusive title to the intellectual property with respect to Genasense . We have jointly established an alliance management committee consisting of representatives from both Genta and Aventis to oversee the alliance. The agreement contains provisions that allow for assignment to a successor in the event of a merger of Aventis, such that the terms of the agreement remain unchanged.

In the United States, Genta and Aventis will jointly develop and co-promote Genasense . Joint teams have been created under our collaborative agreement, including a U.S. commercialization team that is responsible for coordinating the development and implementation of commercialization of Genasense in the United States. Genta is responsible for filing, prosecuting and maintaining all patent applications and patents in the United States. Aventis will reimburse Genta for the cost of an escalating number of Genta sales representatives throughout the United States.

In all countries outside of the United States, Aventis will have exclusive development and marketing rights and regulatory responsibilities. Genta retains responsibility for filing, prosecuting and maintaining all patent applications and patents outside of the United States.

Ganite

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 and our sales force is now promoting the product in the United States.

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.) We believe the development of methods to administer Ganite in the outpatient setting will improve the commercial prospects for Ganite as compared to when it was originally introduced.

The extension for an important patent covering the use of Ganite for its approved indication will expire in 2005. Genta has filed and continues to file patent applications seeking intellectual property protection for Ganite . In addition, Genta intends to seek orphan drug designation for the use of Ganite for the treatment of NHL.

Non-Hodgkin s Lymphoma and Other Cancer Types

Based on previously published data, we believe that Ganite may also be an effective treatment for patients with certain types of cancer, particularly NHL. 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. If our trials suggest that Ganite is safe and effective, we plan to seek expanded marketing approval for this indication. Approximately 54,000 new cases of NHL are diagnosed in the United States each year. We are also planning to evaluate Ganite in other indications, such as bladder cancer. Previous clinical trials of Ganite showed that it does not cause 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 readily incorporated into combination chemotherapy regimens that employ other drugs that cause myelosuppression.

Regulatory Status

In April 2000, we acquired assets, rights, licenses to patents, and technology relating to gallium-containing compounds for treatment of bone loss, and to Ganite (gallium nitrate injection), the liquid injectable product. The acquired assets included the ownership of an approved NDA relating to Ganite . Since this acquisition, we have worked with the FDA to address certain regulatory issues and to update certain aspects of drug manufacturing. In the first quarter of 2003, we filed a supplemental NDA for Ganite for the treatment of cancer-related hypercalcemia that has not responded to hydration. On September 18, 2003, we received approval from the FDA to market Ganite for the treatment of cancer-related hypercalcemia that is resistant to hydration.

Given the extensive published data on the anticancer activity of gallium nitrate, we filed a new IND request for Ganite with the Oncology Drug Products Division at the FDA for the treatment of patients with relapsed NHL. Under this IND, we initiated a clinical trial of Ganite in NHL patients in 2002.

Other Pipeline Products and Technology Platforms

Oral Gallium

We are currently planning to develop new formulations of gallium-containing compounds that can be taken orally. These formulations may be useful for diseases in which long-term low-dose therapy is deemed desirable. We believe that such formulations will be useful for the treatment of patients who have chronic bone loss diseases, such as bone metastases, Paget s disease and osteoporosis. Such patients are commonly afflicted by bone pain and susceptibility to fractures.

Decoys

In addition to the antisense program, we are developing compounds known as decoys, which are short strands of DNA or RNA that bind certain 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 cancer progression.

In December 2000, Genta licensed patents and technology relating to decoys from the NIH. Our current program is targeting 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. The CRE-BP decoy is currently undergoing additional pre-clinical testing.

Antisense and RNAi Research and Discovery

We have numerous oligonucleotide-based discovery programs and collaborations devoted to the identification of both antisense- and RNAi-based inhibitors of oncology gene targets. Several of these programs combine specific, clinically validated gene targets with our OptiSense technology to identify new therapeutic sequences. Other programs are longer-term projects that combine Optisense and oncology target validation assays to determine the therapeutic potential of newly discovered genes and identify new therapeutic agents simultaneously.

We continue to evaluate novel nucleic acid chemistries, through sponsored research and collaborative agreements, on an ongoing basis. These efforts will produce our next generation of antisense and RNAi molecules with enhanced biological activities.

Finally, our proprietary PolyBus delivery formulations, and formulations obtained through expert collaborations, are being used to enhance the pharmacokinetic properties of antisense and RNAi in preclinical efficacy studies.

Androgenics Technologies

Subsequent to a review of our preclinical research portolio of programs, we recently terminated our Androgenics program that was designed to develop inhibitors of androgen hormones for the treatment of patients with hormone-sensitive prostate cancer.

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 both U.S. and foreign applications and patents. To date, Genta has approximately 100 U.S. and foreign patent applications. Genta's portfolio of owned or licensed patents includes approximately 50 issued U.S. patents and approximately 13 pending U.S. patent applications. Genta endeavors to seek appropriate U.S. and foreign patent protection on its oligonucleotide technology.

In the United States, a patent filed on or before June 8, 1995 expires the later of 17 years from the issue date or 20 years from the date on which the application for patent was filed in the United States or the earliest claimed priority date. A patent filed after June 8, 1995 expires 20 years from the date on which the application for patent was filed in the United States or the earliest claimed priority date.

Genta has licensed six U.S. patents relating to Genasense that expire between 2008 and 2015, two pending U.S. patent applications that relate to Genasense , and approximately 45 foreign patent applications that are pending relating to Genasense . Genta also owns three U.S. patent applications relating to methods of using Genasense .

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 our lead clinical candidate, 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 2005. Genta has filed and continues to file patent applications seeking intellectual property protection for Ganite .

In May 2000, we entered into a licensing arrangement with Molecular Biosystems, Inc. for a broad portfolio of patents and technology that relates to antisense for therapeutic and diagnostic applications. The arrangement included a grant of both exclusive and non-exclusive rights from Molecular Biosystems, Inc. to Genta on a royalty-free basis in return for cash and shares of common stock.

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. We recorded research and development expenses of $82.9 million, $86.6 million, and $39.4 million during the years ended December 31, 2003, 2002 and 2001, respectively.

Sales and Marketing

On October 6, 2003 our oncology sales force began selling Ganite for use in the treatment of cancer-related hypercalcemia. We have been expanding our sales force to support the anticipated launch of Genasense ; currently, the U.S. sales force is comprised of 36 people. If Genasense is approved for marketing by the FDA, the sales force will be partially subsidized by Aventis, as described below. Overall, we presently have 46 employees dedicated to sales and marketing.

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. Under the terms of our collaborative agreement, Genta and Aventis will jointly develop and commercialize Genasense in the United States, and Aventis will have exclusive development and marketing rights to the compound in all countries outside of the United States. We retain responsibility for global manufacturing and for regulatory filings within the United States, while Aventis has assumed all regulatory responsibilities outside the United States. Joint management teams, including representatives from both Genta and Aventis, currently oversee the joint efforts of Genta and Aventis in developing and commercializing Genasense in the United States. Under our collaborative agreement, Aventis has committed to provide up to $476.9 million in initial payments, milestone payments and for the purchase from us of equity and convertible notes. In addition, we are entitled to royalties on Aventis exclusive worldwide net sales of Genasense , from which we are required to pay third-party pass-through royalties to the University of Pennsylvania and The National Institutes of Health, or NIH, based on net worldwide sales of Genasense . Furthermore, under our collaborative agreement, Aventis has agreed to pay 75% of development costs related to any U.S. NDA incurred by either Genta or Aventis subsequent to the execution of our collaborative agreement, and substantially all other development, marketing, and sales costs incurred worldwide. Aventis will also reimburse a portion of our expense in building our sales force to market Genasense in the United States. Genta has received a total of $235.7 million in initial and near-term funding, 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, $68.8 million in paid expense reimbursements and $35.0 million in line of credit proceeds. The commercialization agreement may be terminated by Aventis with six months notice. For additional discussion of the collaborative agreement (see Note 12 to our financial statements).

Either alone or in partnerships with other companies, we intend to be a direct marketer or co-marketer of our pharmaceutical products by continuing to build a sales and marketing infrastructure in the United States to launch and fully realize the commercial potential of our products. 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. In 2004, we are obligated to purchase $27.5 million in clinical drug substance from Avecia. Pursuant to our collaborative agreement with Aventis, we anticipate that we will be reimbursed for at least 75% of the drug purchases from Avecia once Genasense is shipped to the clinical sites or Aventis distribution sites. In addition, we have committed up to $5.0 million of advance financing to Avecia for facility expansion, which will be recovered with interest through future purchase payments to be made by us to Avecia. We believe these arrangements are sufficient for our medium-term production needs with respect to Genasense .

We have a three-year manufacturing and supply agreement with Johnson Matthey Inc. (JMI), whereby Genta will purchase a minimum of 80% of our requirements for quantities of Ganite .

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.

Genta Jago

Genta Jago Technologies B.V. (Genta Jago) is a joint venture formed by SkyePharma PLC and Genta. On March 4, 1999, SkyePharma PLC (on behalf of itself and its affiliates) entered into an interim agreement with Genta (the Interim JV Agreement) pursuant to which the parties to the joint venture released each other from all liability relating to unpaid development costs and funding obligations of Genta Jago. Under the terms of the Interim JV Agreement, SkyePharma PLC assumed responsibility for substantially all the obligations of the joint venture to third parties as well as further development of the product line. In addition, earnings of the joint venture are to be allocated equally between the two parties. Accordingly, Genta recognized $0.5 million as its equity in net income of the joint venture during the first quarter of 2000. Since the first quarter of 2000, there have been only $33 thousand in net earnings of the joint venture allocated to Genta and we plan to seek to terminate our involvement with the joint venture.

Human Resources

As of December 31, 2003, Genta had 155 employees, 36 of whom hold doctoral degrees. As of that date, there were 96 employees engaged in research, development and other technical activities, 30 employees in sales and marketing and 29 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. Phase 2a trials are pilot studies while Phase 2b trials typically incorporate more patients than Phase 2a trials in order to more precisely establish 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. Phase 3b trials are conducted after submission of a new drug application, 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.

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, for a biological product in the form of a biologics license application and for a particular medical device in the form of a premarket approval application in order to obtain approval to commence commercial sales. 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.

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.

For clinical investigation and marketing outside the United States, we are or may be subject to foreign regulatory requirements governing human clinical trials and marketing approval for drugs. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. Our approach is to design our European clinical trial studies to meet FDA, European Economic Community, or EEC, and other European countries standards. At present, the marketing authorizations are applied for at a national level, although certain EEC procedures are available to companies wishing to market a product in more than one EEC member state. If the competent authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a market authorization will be granted. The registration system proposed for medicines in the EEC after 1992 is a dual one in which products, such as biotechnology and high technology products and those containing new active substances, will have access to a central regulatory system that provides registration throughout the entire EEC. Other products will be registered by national authorities under the local laws of each EEC member state. With regulatory harmonization finalized in the EEC, our clinical trials will be designed to develop a regulatory package sufficient for multi-country approval in our European target markets without the need to duplicate studies for individual country approvals. This approach also takes advantage of regulatory requirements in some countries, such as in the United Kingdom, which allow Phase 1 studies to commence after appropriate toxicology and pre-clinical pharmacology studies, prior to formal regulatory approval.

Prior to the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Waxman/Hatch Act, the FDA, by regulation, permitted certain pre-1962 drugs to be approved under an abbreviated procedure which waived submission of the extensive animal and human studies of safety and effectiveness normally required to be in a new drug application. Instead, the manufacturer only needed to provide an abbreviated new drug application containing labeling, information on chemistry and manufacturing procedures and data establishing that the original pioneer product and the proposed generic product are bioequivalent when administered to humans.

Originally, the FDA s regulations permitted this abbreviated procedure only for copies of a drug that was approved by the FDA as safe before 1962 and which was subsequently determined by the FDA to be effective for its intended use. In 1984, the Waxman/Hatch Act extended permission to use the abbreviated procedure established by the FDA to copies of post-1962 drugs subject to the submission of the required data and information, including data establishing bioequivalence. However, approval of such abbreviated new drug applications was dependent upon there being no outstanding patent or non-patent exclusivity.

Additionally, the FDA allows, under section 505(b)(2) of the Food Drug and Cosmetic Act, for the submission and approval of a hybrid application for certain changes in drugs which, but for the changes, would be eligible for an effective abbreviated new drug application approval. Under these procedures the applicant is required to submit the clinical efficacy and/or safety data necessary to support the changes from the abbreviated new drug application-eligible drug (without submitting the basic underlying safety and efficacy data for the chemical entity involved) plus manufacturing and chemistry data and information. Approval of a 505(b)(2) application is dependent upon the abbreviated new drug application being subject to no outstanding patent or non-patent exclusivity. As compared to a new drug application, an abbreviated new drug application or a 505(b)(2) application typically involves reduced research and development costs. However, there can be no assurance that any such applications will be approved. Furthermore, the supply of raw materials must also be approved by the FDA.

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 Uncertanties 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 in the time frame we expect or at all. We have filed our first new drug application, or NDA, with the FDA for Genasense as a treatment combined with chemotherapy for patients with advanced malignant melanoma. We filed and received priority designation , which increased the probability that the review by the FDA will be concluded within six months from the date of the completed application. The FDA may not complete its review within the time it has targeted. In addition, the action it takes may be to request further data or to disapprove the application. If Genasense is not approved by the FDA for melanoma, if the review time is substantially prolonged or if the FDA requires further clinical studies prior to approval, we have no short-term alternative for generating substantial revenue or income. Genasense may not be approved because the FDA may find our efficacy and safety data deficient or for other reasons. While we have completed enrollment in Phase 3 trials for other indications (including multiple myeloma and chronic lymphocytic leukemia), we do not yet know whether the results of these clinical trials will warrant submission of a NDA. Moreover, preparation of NDAs for either or both of these indications would entail significant delay relative to the melanoma application, and there can be no assurance that either or both of these applications would suffice for Genasense approval. Failure to obtain approval or a substantial delay in approval of Genasense 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 have a limited number of sales personnel. Our inability to build a sales force capable of marketing our pharmaceutical products will adversely affect our sales and limit the commercial success of our products.

We anticipate that we will incur additional losses and we may never be profitable.

We have not been profitable. We have incurred substantial operating losses associated with ongoing research and development activities, pre-clinical testing, clinical trials, regulatory submissions and manufacturing activities. From the period since our inception to December 31, 2003, we have incurred a cumulative net loss of $323.3 million. We may never achieve revenue sufficient for us to attain profitability. Achieving profitability is unlikely before Genasense becomes an approved drug and we receive at least a full year of royalties from Aventis Pharmaceuticals Inc., or Aventis, on worldwide sales pursuant to the development and commercialization agreements which we have entered into with Aventis. For a further description of our agreements with Aventis, see B. Summary of Business and Research and Development Programs Sales and Marketing .

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

Our operations to date have required significant cash expenditures. Our future capital requirements will depend on the results of our research and development activities, pre-clinical studies and clinical trials, competitive and technological advances, and regulatory activities of the FDA and other regulatory authorities. Our credit line with Aventis terminates with respect to new borrowings upon the earlier of December 31, 2004 or the first FDA approval of Genasense (which triggers a milestone payment from Aventis), and amounts borrowed under the credit line are due six months after termination. In order to commercialize our products, we will need to raise additional funds. We may obtain those funds through public and private offerings of our securities, including debt or equity financing, or through collaborations or other arrangements with research institutions and corporate partners. 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 are currently marketing one product, Ganite , and we are actively seeking FDA approval of Genasense for advanced malignant melanoma. We do not expect to expand our marketed product portfolio significantly in the short term. If Genasense is not approved, or 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 2005. Genta has filed and continues to file patent applications seeking intellectual property protection for Ganite . If these applications are unsuccessful, competition from generic drugs may adversely affect the profitability of Ganite .

Many 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, among our products, 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. While limited trials of some of our products have produced favorable results, 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. 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.

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. The loss of any of these collaborative relationships could have a material adverse effect on our business. In addition, 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, Genta Jago Technologies B.V., a joint venture we entered into with SkyePharma PLC to develop oral controlled-release drugs, has not resulted in any commercial products, and we plan to seek to terminate our involvement in this joint venture. Moreover, we may be unable to negotiate advantageous strategic alliances in the future. Our failure to enter into strategic alliances, or the failure of a current or future strategic alliance to achieve its goals, could harm our efforts to develop and commercialize our drugs.

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.

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 are dependent on our collaborators and cannot be sure that our collaborators will perform as expected. Moreover, collaborations might produce conflicts that could delay or prevent the development or commercialization of our potential product candidates and negatively impact our business and financial condition.

We have agreed to commercialize Genasense , if and when it is approved by the FDA, jointly with Aventis. Aventis will sell the product and pay us a royalty, and we and Aventis will cooperate on various aspects of commercialization. We have entered into an agreement under which Avecia Biotechnology, Inc., or Avecia, will manufacture Genasense if and when it is approved. We cannot control the resources that Aventis, Avecia or any future 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.

Our commercialization agreement with Aventis may be terminated by Aventis with six months prior notice. Recently Aventis has been the subject of acquisition proposals. If Aventis is acquired, it may undergo strategic or managerial changes that could reduce its commitment to Genasense or lead it to terminate our collaborative agreement. The agreement contains provisions that allow for assignment to a successor in the event of a merger of Aventis, such that the terms of the agreement remain unchanged. 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 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.

The nature of the business activities or positions of our principal stockholders and present and future officers and directors may involve conflicts of interest.

One of our principal stockholders is Paramount Capital Asset Management, Inc. The sole stockholder and chairman of Paramount Capital Asset Management, Inc. is also the chairman of Paramount Capital Inc. and of Paramount Capital Investment LLC. These three companies, together with their affiliates, are collectively referred to as the Paramount Companies. The Paramount Companies beneficially own approximately 22% of our common stock, including beneficial ownership by Aries Select I, LLC, Aries Select II, LLC, and Aries Select, Ltd., of which Paramount Capital Asset Management, Inc. is the investment manager. The Paramount Companies have been distributing shares of Genta Incorporated to their fundholders and these distributions have lowered Paramount Companies beneficial ownership from approximately 41% as of May 1, 2003 to approximately 22% as of February 29, 2004. In the regular course of business, the Paramount Companies evaluate and pursue

investment opportunities in biomedical and pharmaceutical products, technologies and companies. We cannot assure you that these other companies will not have interests in conflict with ours. In addition, some of our current or future officers and directors may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies in which Paramount has an investment.

Risks Related to Our Common Stock

Concentration of ownership of our stock could delay or prevent a change of control.

Our directors, executive officers and principal stockholders the Paramount Companies and the Aries Funds and Garliston Limited, a subsidiary of Aventis, beneficially own approximately 38% of our outstanding common stock. As a result, these stockholders, if acting together, have the ability to significantly influence the outcome of corporate actions requiring stockholder approval. This concentration of ownership may have the effect of delaying or preventing a change in control of Genta.

In addition, Garliston Limited has agreed not to participate in hostile takeover attempts and to vote its shares in ways that may have anti-takeover effects.

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 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.

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. We currently have an open search for a Senior Vice President, Research. If we are unable to fill this position or others that open, our business may be harmed.

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

As of December 31, 2003, we had 75,927,033 shares of common stock outstanding and options, warrants, convertible preferred stock and convertible debt outstanding exercisable for or convertible into 19,047,612 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 93,000 square feet of office space in Berkeley Heights, New Jersey. Our annual rental costs for this space are approximately $2.5 million. Our lease on this space terminates in 2010.

Our facilities in Utah currently consist of 11,178 square feet of laboratory and office space at an annual rental cost of $0.2 million. Our lease on this space terminates in 2009.

Item 3. ***Legal Proceedings***

JBL Scientifics, Inc.

During May 2000, Promega notified Genta of two claims against Genta and Genta s subsidiary, Genko Scientific, Inc. (formerly known as JBL Scientifics, Inc.), for indemnifiable damages in the aggregate amount of $2.82 million under the purchase agreement pursuant to which Promega acquired the assets of JBL. Promega s letter stated that it intended to reduce to zero the principal amount of the $1.2 million promissory note it issued as partial payment for the assets of Genko Scientific, Inc. and that therefore Genta owed Promega approximately $1.6 million. On October 16, 2000 Genta filed suit in a U.S. District Court in California against Promega for the non-payment of the $1.2 million note plus accrued interest. On November 6, 2000, Promega filed a counterclaim alleging indemnifiable damages in the aggregate amount of $2.8 million. During the first quarter of 2001, we agreed to resolve the matter with Promega, and, in connection therewith, agreed to restructure its $1.2 million promissory note receivable to provide for a $0.2 million non-interest bearing note due to be repaid by Promega upon final resolution of certain environmental issues related to JBL and forgave all accrued interest. While we have resolved one of these environmental issues, we are awaiting final acceptance by the EPA of our settlement offer on the other environmental issue before the restructured note will be repaid by Promega. We are uncertain as to whether and when the EPA will issue such final acceptance.

Genta Pharmaceutical Europe S.A.

During 1995, Genta Pharmaceutical Europe S.A., or Genta Europe, a wholly-owned subsidiary of Genta, received funding in the form of a loan from ANVAR, a French government agency, of which the proceeds were intended to fund research and development activities. In October 1996, in connection with a restructuring of Genta s operations, Genta terminated all scientific personnel of Genta Europe. In 1998, ANVAR asserted that Genta Europe was not in compliance with the ANVAR Agreement, notified Genta Europe of its demand for accelerated repayment of the loan and notified Genta that it was liable as a guarantor on the note. Based on the advice of French counsel, Genta does not believe that ANVAR is entitled to payment under the terms of the ANVAR Agreement and that Genta will likely not incur any liability in this matter, although there can be no assurances thereof. During the quarter ended September 30, 2003, we reversed the accrued net liability of $0.2 million related to this matter, as management believes that a loss is not probable.

University of Pennsylvania

In October 2002, a licensing officer from the University of Pennsylvania asserted a claim to a portion of the initial $40.0 million development funding we received from Aventis pursuant to the collaborative agreement between Genta and Aventis. In October 2003, we reached a settlement with the University of Pennsylvania with respect to this claim. Under the terms of the settlement, in exchange for an agreement by the University of Pennsylvania to forego any and all claims in the future to any portion of any milestone and other payments (other than royalty payments on sales) made to Genta pursuant to the collaborative agreement, Genta has agreed to make the following payments to the University of Pennsylvania: (i) $750,000 on November 5, 2003, (ii) $250,000 on February 2, 2004, (iii) $1.5 million upon the first new drug application or foreign equivalent approval of Genasense and (iv) provided that the first new drug application or foreign equivalent approval of Genasense has been received by Genta, $750,000 on the earlier of (a) the second new drug application or foreign equivalent approval of Genasense or (b) December 30, 2004.

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, 2003.

PART II

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
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
2002		
First Quarter	$ 18.25	$ 10.88
Second Quarter	17.74	6.29
Third Quarter	8.70	6.15
Fourth Quarter	11.50	6.14

(b) Holders

There were 704 holders of record of the Company s common stock as of March 11, 2004.

(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.

(d) Recent Sale of Unregistered Securities

In August 2003, Genta issued 1.03 million shares of common stock with a fair value of approximately $13.0 million to Salus stockholders in exchange for all of the outstanding shares of Salus common stock, including those issued pursuant to the conversion of Salus preferred stock. The shares were issued in a transaction not involving a public offering and were issued in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act of 1933.

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

(In thousands, except share data)	Years Ended December 31, 2003	2002	2001	2000	1999
Consolidated Statements of Operations Data (1):					
Revenues:					
Product sales - net	$ 1,420	$ --	$ --	$ --	$ --
License fees and royalties	1,045	756	146	22	
Development funding	4,194	2,803	--	--	--
Total revenues - net:	6,659	3,559	146	22	--
Cost of goods sold	404	--	--	--	--
Gross margin	6,255	3,559	146	22	--
Costs and expenses:					
Research and development	82,875 *	86,645	39,355	6,830	4,205
Selling, general and administrative	29,604	20,052	8,215	3,323	4,054
Compensation expenses	436	1,016	1,074	8,605	3,074
Promega settlement	--	--	1,000	--	--
Total cost and expenses - gross	112,915	107,713	49,644	18,758	11,333
Aventis reimbursement	(55,891)	(28,451)	--	--	--
Total cost and expenses - net	57,024	79,262	49,644	18,758	11,333
Loss before other income and income taxes	(50,769)	(75,703)	(49,498)	(18,736)	(11,333)
Other income	666	1,359	2,785	6,285	2,471
Income taxes	(6)	(184)	--	--	--
Loss from continuing operations	(50,109)	(74,528)	(46,713)	(12,451)	(8,862)
Loss from discontinued operations	--	--	--	--	(189)
Gain on sale of discontinued operations	--	--	--	--	1,607
Net loss	(50,109)	(74,528)	(46,713)	(12,451)	(7,444)
Preferred stock dividends	--	--	--	(3,443)	(10,085)
Net loss applicable to common shares	$ (50,109)	$ (74,528)	$ (46,713)	$ (15,894)	$ (17,529)
Continuing operations	$ (0.67)	$ (1.05)	$ (0.84)	$ (0.41)	$ (1.07)
Discontinued operations	--	--	--	--	0.08
Net loss per basic and diluted share	$ (0.67)	$ (1.05)	$ (0.84)	$ (0.41)	$ (0.99)
Average shares used in computing net loss per basic and diluted share	75,093	70,656	55,829	38,659	17,784

* includes $13,465 write-off of acquired In-Process R&D related to the acquisition of Salus Therapeutics, Inc. in August 2003 (see Note 5 to our financial statements).

	As of December 31,

	2003	2002	2001	2000	1999
Consolidated Balance Sheet Data (1):					
Cash, cash equivalents and marketable securities	$ 82,929	$ 113,716	$ 54,086	$ 50,199	$ 10,101
Working capital	82,281	91,586	42,709	48,321	9,434
Total assets	114,675	136,419	60,630	57,208	12,228
Total stockholders' equity	12,254	46,703	48,310	53,567	10,206

(1) The above selected financial data reflects discontinued operations and balance sheet data of JBL as of May 10, 1999.

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, 2003, we have incurred a cumulative net loss of $323.3 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 may be significantly affected by FDA action with respect to Genasense . We have filed a New Drug Application (NDA) for Genasense to be used in combination with dacarbazine for the treatment of patients with advanced melanoma who have not previously received chemotherapy. The FDA accepted our NDA filing on February 5, 2004 and granted Priority Review status to the application, which targets 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 the FDA Oncology Drugs Advisory Committee. If the FDA approves the NDA and qualifies Avecia, our contract manufacturer, then Aventis, Genta s collaborative partner, will begin to market the product in the United States, Avecia will begin to manufacture the product and Genta will sell the product to Aventis. Genta will also earn a royalty from Aventis on all sales of Genasense .

Results of Operations

	Summary Operating Results For the years ended December 31,				
($ thousands)	**2003**	**Increase (Decrease)**	**2002**	**Increase (Decrease)**	**2001**
Revenues:					
Product sales - net	$ 1,420	$ 1,420	$ --	$ --	$ --
License fees and royalties ..	1,045	289	756	610	146
Development funding	4,194	1,391	2,803	2,803	--
Net revenues	6,659	3,100	3,559	3,413	146
Cost of goods sold	404	404	--	--	--
Gross margin	6,255	2,696	3,559	3,413	146
Costs and expenses:					
Research and development	82,875*	(3,770)	86,645	47,290	39,355
Selling, general and administrative	29,604	9,552	20,052	11,837	8,215
Promega settlement	--	--	--	(1,000)	1,000
Compensation expense related to stock options	436	(580)	1,016	(58)	1,074
Total costs and expenses - gross ..	112,915	5,202	107,713	58,069	49,644
Less: Aventis reimbursement	(55,891)	(27,440)	(28,451)	(28,451)	--
Total costs and expenses - net	57,024	(22,238)	79,262	29,618	49,644
Loss before other income and taxes	(50,769)	24,934	(75,703)	(26,205)	(49,498)
Other income, principally net interest income	666	(693)	1,359	(1,426)	2,785
Income taxes	(6)	178	(184)	(184)	--

Net loss	$ (50,109)	$ 24,419	$ (74,528)	$ 27,815	$ (46,713)

* includes $13,465 write-off of acquired In-Process R&D related to the acquisition of Salus Therapeutics, Inc. in August 2003 (see Note 5 to our financial statements).

Net Revenues

Net revenues, consisting of license fees, development funding and product sales were $6.7 million in 2003 compared to $3.6 million in 2002 and $0.1 million in 2001. 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 12 to our financial statements), along with non-exclusive sub-license agreements involving antisense technology. The initial payments received from Aventis are being recognized over the original estimated useful life of the related first-to-expire patent of 115 months.

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.

Research and Development Expenses

Research and development expenses before reimbursement were $82.9 million in 2003 compared to $86.6 million in 2002 and $39.4 million in 2001. Research and development expenses in 2003 include a $13.5 million write-off of acquired in-process research and development resulting from the acquisition of Salus Therapeutics, Inc. (see Note 5 to our financial statements).

During 2002 Genta purchased substantial amounts of drug substance to be used in Genasense Phase 3 clinical trials, leading to higher research and development expenses in 2002 than in 2001. During 2003, total research and development expenses declined, primarily due to significantly lower purchases of clinical drug substance. Of the $82.9 million in research and development expenses for the twelve months ended December 31, 2003, $13.5 million is related to acquired in-process research and development and $55.9 million is reimbursable pursuant to our collaborative agreement with Aventis, $15.5 million of which related to the three months ended December 31, 2003, is expected to be reimbursed by Aventis in the first quarter of 2004 (see Note 4 to our financial statements).

Services and capabilities that have not been retained within the Company are out-sourced through short-term contracts or from consultants. Substantially, all pre-clinical biology and clinical trial work are now conducted through such collaborations with external scientists and clinicians. The Company anticipates that, if sufficient collaborative revenues and other funding are available, research and development expenses may increase in future years due to requirements for pre-clinical studies, clinical trials and increased regulatory costs. The Company will continue to assess the potential cost benefit ratio of developing its own antisense oligonucleotide manufacturing, if and as such products are successfully developed and approved for marketing.

It is anticipated that research and development expenses will continue to increase in the future, as Genta expands its other product development programs. Furthermore, the Company is also pursuing other opportunities for new product development candidates, which, if successful, will require additional research and development expenses.

In an effort to focus its research and development on areas that provide the most significant commercial opportunities, the Company continually evaluates its ongoing programs in light of the latest market information and conditions, availability of third party funding, technological advances, and other factors. As a result of such evaluation, the Company s product development plans have changed from time to time, and the Company anticipates that they will continue to do so in the future.

Corporate Acquisitions

In August 2003, Genta acquired Salus Therapeutics, Inc., (Salus), a privately held company that specializes in the identification and development of DNA and RNA-based drugs including antisense, RNA interference, and delivery systems for DNA/RNA-based drugs. The acquisition provided enhanced laboratory capabilities that complement the Company s oncology drug discovery programs in DNA and RNA Medicines.

Under the terms of the merger agreement, Genta issued 1.03 million shares of common stock with a fair value of approximately $13.0 million to Salus stockholders in exchange for all of the outstanding shares of Salus common stock, including those issued pursuant to the conversion of Salus preferred stock. Contingent upon the achievement of certain preclinical and clinical milestones, an additional $17.0 million may be paid in stock or cash at Genta s option.

The purchase price was allocated to the assets purchased and liabilities assumed based upon their respective fair values, which was determined by an independent valuation. Acquired in-process research and development expense represents that portion of the purchase price of an acquisition related to the research and development activities that are yet to demonstrate their technological feasibility and have no alternative future use. Accordingly, in-process research and development of $13.5 million was charged to operations in the fourth quarter of 2003.

Selling, general and administrative expenses

Selling, general and administrative expenses were $29.6 million in 2003 compared to $20.1 million in 2002 and $8.2 million in 2001. Expenses have substantially increased due to the creation of a sales force, Ganite launch activities, a larger administrative staff and higher general corporate expenses driven by business growth. There were no sales and marketing related expenses reimbursable at 100% pursuant to our collaborative agreement with Aventis for the twelve months ended December 31, 2003, as sales and marketing related expenses related to Genasense are incurred by, billed to and paid by Aventis. In 2002, selling, general and administrative expenses include $.7 million of expense reimbursement from Aventis.

Aventis Reimbursement

Under the Collaborative Agreement with Aventis, (see Note 12 to our financial statements), Aventis will pay 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. Expense reimbursement from Aventis of $55.9 million for the year ended December 31, 2003 increased from $28.5 million for the year ended December 31, 2002 due to the following factors: the comparison of twelve months of activity in 2003 compared to eight months in 2002, greater activity resulting from the NDA filing for Genasense and reimbursement for 2002 and 2003 drug substance purchases used in Phase 3 clinical trials. A breakdown of the various third-party, drug supply costs and internal costs of scientific and technical personnel, (Full-Time Equivalents or FTE s) that Aventis is required to reimburse under our collaborative agreement with Aventis, follows ($ thousands) (see Note 12 to our financial statements):

Reimbursement to Genta	2003	2002
Third-party costs	$ 34,073	$ 18,168
Drug supply costs	16,326	6,879
FTE's	7,228	3,404
Amount due to Genta	$ 57,627	$ 28,451
Reimbursement to Aventis	1,736	--
Net reimbursement to Genta	$ 55,891	$ 28,451

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

Other Income

Net other income for the year ended December 31, 2003 declined $.7 million, or 50% from the comparable period in 2002, principally as a result of lower investment balances and higher borrowings from Aventis (see Note 15 to our financial statements). Net other income for the year ended December 31, 2002 declined $1.4 million, or 50% from the comparable period in 2001, principally as a result of lower investment balances and lower yields on investments. The proceeds received from Aventis in 2002 were not placed into any investment instruments until October 2002.

Net Loss

Genta incurred a net loss of $50.1 million, or $0.67 per share, for the year ended December 31, 2003, compared to a net loss of $74.5 million, or $1.05 per share, for the year ended December 31, 2002 and $46.7 million, or $.84 per share in 2001. 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 described above. In 2002, the increases in net loss and per share net loss to common shareholders were attributable to increased research and development and selling, general and administrative expenses described above.

Recent Accounting Pronouncements

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Liabilities, Equity, or Both*. This limited scope statement prescribes changes to the classification of mandatorily redeemable preferred stock, preferred securities of subsidiary trusts and the accounting for forward purchase contracts issued by a company in its own stock among other issues. SFAS No. 150 does not apply to features that are embedded in a financial instrument that is not a derivative in its entirety and requires all preferred securities of subsidiary trusts to be classified as debt on the consolidated balance sheet and the related dividends as interest expense. The Company adopted the provisions of SFAS No. 150, including the deferral of certain effective dates as a result of the provisions of FASB Staff Position 150-3, *Effective Date, Disclosures, and Transition for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests Under FASB Statement No. 150 Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. The adoption of this statement did not have any impact on the Company s results of operations, financial position or cash flows.

In April 2003, the FASB issued SFAS No. 149*, Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. In particular, SFAS No. 149 (1) clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative discussed in paragraph 6(b) of SFAS No. 133, (2) clarifies when a derivative contains a financing component, (3) amends the definition of an underlying to conform it to language used in FIN 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, and (4) amends certain other existing pronouncements. SFAS No. 149 is to be applied prospectively to contracts entered into or modified after June 30, 2003, with certain exceptions, and for hedging relationships designated after June 30, 2003. The adoption of this statement did not have any impact on the Company s results of operations, financial position or cash flows.

In January 2003, the FASB issued Interpretation No. 46 *Consolidation of Variable Interest Entities*. This interpretation defines when a business must consolidate a variable interest entity. This interpretation applies immediately to variable interest entities created after January 31, 2003 and became effective for all other transactions as of July 1, 2003. However, in October 2003 the FASB permitted companies to defer the July 1, 2003 effective date to December 31, 2003. Again in December 2003, the FASB permitted companies to defer the December 31, 2003 effective date, in certain circumstances, to the first interim or annual period ending after March 15, 2004. The Company has determined that it is not reasonably probable that it will be required to consolidate or disclose information about a variable interest entity.

In November 2002, FASB Interpretation (FIN) 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. This interpretation requires a guarantor to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. It also enhances a guarantor s disclosure requirements to be made in its interim and annual financial statements about its obligations under certain guarantees it has issued. The initial recognition and initial measurement provisions of this interpretation are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements or interim or annual periods ending after December 15, 2002. In the normal course of business, the Company does not issue guarantees to third parties; accordingly, this interpretation does not have an effect on the Company s financial position or results of operations.

Critical Accounting Policies

Our significant accounting policies are more fully described in Note 2 to the consolidated financial statements for the fiscal year ended December 31, 2003. 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. 101 *Revenue Recognition*, initial funding of ongoing development received from Aventis, after the achievement of certain research and development milestones are being recognized on a straight-line basis over the original estimated useful life of the related first-to-expire patent of 115 months (See Note 12 to our financial statements). Any subsequent milestone payments that may be received from Aventis will also be recognized over the then-remaining estimated useful life of the related first-to-expire patent.

  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.

- *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 between Genta and Aventis, will continue to be recorded as a reduction to expense (See Note 12 to our financial statements).

- *Intangible assets*. Our intangible assets consist primarily of licensed technology and capitalized patent costs, and are amortized using the straight-line method over their estimated useful lives. Our policy is to evaluate the appropriateness of the carrying values of the unamortized balances of intangible assets on the basis of estimated future cash flows (undiscounted) and other factors. If such evaluation were to indicate an impairment of these intangible assets, such impairment would be recognized by a corresponding write-down of the applicable assets. We evaluate the continuing value of patents and patent applications each financial reporting period. As a result of this evaluation, we may elect to continue to maintain, seek to out-license, or abandon these patents.

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

- *Acquired in-process research and development.* Costs to acquire in-process research and development projects and technologies which have no alternative future use and which have not reached technological feasibility at the date of acquisition are expensed as incurred (see Note 5 to our financial statements). Acquired in-process research and development is considered as part of total research and development expense.

Liquidity and Capital Resources

Since inception, we have financed our operations primarily through private placements and public offerings of our equity securities. Cash provided from these offerings totaled approximately $278.8 million through December 31, 2003, including net proceeds of $71.0 million received in 2002 and $32.2 million received in 2001.

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. Total debt increased $35.0 million, resulting from borrowings under the line of credit from Aventis (see Note 15 to our financial statements). Total cash and cash equivalents declined $7.5 million in 2003. At December 31, 2003, we had cash, cash equivalents and marketable securities totaling $82.9 million compared to $113.7 million at December 31, 2002 and $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 2003 (see Note 12 to our financial statements). 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. Total cash and cash equivalents declined $5.4 million in 2002 from $38.1 million to $32.7 million.

In March 2003, Genta and Aventis negotiated a line of credit for an amount up to $40.0 million which terminates with respect to additional borrowings on the earlier to occur of FDA approval of Genasense or December 31, 2004. Loans under this line of credit are subject to repayment six months after termination. As of December 31, 2003, approximately $4.7 million remained available under this line of credit. FDA approval of Genasense would trigger a milestone payment from Aventis of $75.0 million and an obligation by Aventis to purchase at our option $20.0 million of convertible notes from Genta. Management believes that at the current rate of spending, primarily in support of ongoing and anticipated clinical trials, and after considering expense reimbursement and the line of credit provided by Aventis, we should have sufficient cash funds to maintain our present operations through 2004.

Our principal expenditures relate to our research and development activities, which include our on-going and future clinical trials. We expect these expenditures to continue. We expect increased total expenditures, prior to expense reimbursement, for clinical trials and drug supply related to Genasense as a result of our collaboration agreement with Aventis. In addition, expenditures associated with other products under development by us may increase as research and development activities become more focused and as other clinical trials are initiated.

If we successfully secure sufficient levels of collaborative revenues and other sources of financing, we expect to use such financing to continue to expand our ongoing research and development activities, pre-clinical testing and clinical trials, costs associated with the market introduction of potential products and expansion of our administrative activities.

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

Contractual Obligations

Future contractual obligations at December 31, 2003 are as follows ($ thousands):

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Long term debt obligations (1)	$ 35,000	$ --	$ 35,000	$ --	$ --
Convertible debt	10,000	--	--	--	10,000
Operating lease obligations	16,067	2,571	5,235	5,256	3,005
Drug purchase obligations to Avecia (2)	137,500	27,500	110,000	--	--
Drug purchase obligations to JMI (3)	252	46	206	--	--
Total	$ 198,819	$ 30,117	$ 150,441	$ 5,256	$ 13,005

(1) Consists of amounts under our line of credit with Aventis, which are due six months after termination, which will occur on the earlier of FDA approval of Genasense or December 31, 2004. FDA approval of Genasense would trigger a milestone payment from Aventis of $75 million and an obligation by Aventis to purchase at our option $20 million of convertible notes from us (see Note 15 to our financial statements).

(2) Consists of drug purchase obligations to Avecia which are subject to FDA approval of Genasense and qualification and validation of Avecia s production facilities expansion. The amounts actually purchased will be dependent upon the aforementioned conditions, as well as the volume purchased in any given year. Pursuant to the collaborative agreement with Aventis, (see Note 12 to our financial statements), the Company anticipates that it will be reimbursed from 75% to 100% of these purchase commitments after the drug is shipped to Aventis for clinical use or commercial sales. For a further description of our agreement with Avecia, see Part I, Item 1, B. Summary of Business and Research and Development Manufacturing. If Genasense is not approved or Avecia s production facility expansion is not validated, our total drug purchase obligations will be $27.5 million. We may terminate our Avecia contract if we determine that Genasense will not be approved by the FDA. In addition, we have committed up to $5.0 million of advance financing to the drug substance manufacturer, for facility expansion, which would be recovered with interest through future payments determined as a function of drug substance purchases to be made by Genta in the future.

(3) Consists of drug purchase obligations to Johnson Matthey Inc. (JMI). Genta is obligated to purchase 80% of drug substance requirements for Ganite from JMI. The sales projections for Ganite are very dependent on the Company s ability to obtain compendial listings and/or approvals for the use of Ganite as a chemotherapy drug. The sales projections reflected in the contractual obligations reflect the current approved hypercalcemia indication and limited sales as a chemotherapy drug. Depending on the Company s ability to obtain additional compendial listings and/or approvals, the sales projections and resulting contractual obligations could be higher.

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).

However, considerable judgment is required in interpreting market data to develop the estimates of fair value. Accordingly, the estimates utilized in the consolidated financial statements are not necessarily indicative of the amounts that we could realize in a current market exchange. 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, 2003. 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

INDEPENDENT AUDITORS REPORT

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, 2003 and 2002, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2003. 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 auditing standards generally accepted in the United States of America. 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 as of December 31, 2003 and 2002, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey
March 10, 2004

GENTA INCORPORATED
CONSOLIDATED BALANCE SHEETS

(In thousands, except par value data)

ASSETS	December 31, 2003	December 31, 2002
Current assets:		
Cash and cash equivalents (Note 2)	$ 25,153	$ 32,700
Marketable securities (Note 3)	57,776	81,016
Accounts receivable - net(Note 4)	16,675	14,574
Notes receivable	200	200
Inventory (Note 7)	518	--
Prepaid expenses and other current assets	3,313	1,458
Total current assets	103,635	129,948
Property and equipment, net (Note 8)	4,917	3,256
Notes receivable (Note 6)	3,542	--
Intangibles, net (Note 9)	863	1,440
Prepaid royalties (Note 10)	1,268	1,268
Other assets	450	507
Total assets	$ 114,675	$ 136,419
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses (Note 11)	$ 15,319	$ 32,423
Notes payable	748	490
Deferred revenues, current portion (Note 13)	5,287	5,237
Other current liabilities	--	212
Total current liabilities	21,354	38,362
Deferred revenues (Note 13)	36,067	41,354
Convertible debt (Note 14)	10,000	10,000
Long term debt (Note 15)	35,000	--
Total liabilities	102,421	89,716
Commitments and contingencies (Note 21)		
Stockholders' equity (Note 19):		
Series A convertible preferred stock, $.001 par value; 5,000 shares authorized, 261 shares issued and outstanding, liquidation value of $13,025 at December 31, 2003 and December 31, 2002 respectively	--	--
Common stock, $.001 par value; 120,000 shares authorized, 75,927 and 74,168 shares issued and outstanding at December 31, 2003 and December 31, 2002, respectively	76	74
Additional paid-in capital	335,713	322,997
Accumulated deficit	(323,299)	(273,190)
Deferred compensation	(261)	(697)
Accumulated other comprehensive income	25	25
	12,254	49,209
Less cost of treasury stock: 393 shares at December 31, 2002	--	(2,506)
Total stockholders' equity	12,254	46,703

Total liabilities and stockholders' equity	$ 114,675	$ 136,419

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)	Years Ended December 31, 2003	2002	2001
Revenues:			
Product sales - net	$ 1,420	$ --	$ --
License fees and royalties	1,045	756	146
Development funding (Note 13)	4,194	2,803	--
	6,659	3,559	146
Cost of goods sold	404	--	--
Gross margin	6,255	3,559	146
Costs and expenses:			
Research and development (Note 12)	82,875*	86,645	39,355
Selling, general and administrative (Note 12)	29,604	20,052	8,215
Compensation expense related to stock options (Note 20)	436	1,016	1,074
Promega settlement	--	--	1,000
Total costs and expenses - gross	112,915	107,713	49,644
Aventis reimbursement (Note 12)	(55,891)	(28,451)	--
Total costs and expenses - net	57,024	79,262	49,644
Loss before other income and income taxes	(50,769)	(75,703)	(49,498)
Other income	666	1,359	2,785
Income taxes (Note 16)	(6)	(184)	--
Net loss	$ (50,109)	$ (74,528)	$ (46,713)
Net loss per basic and diluted share	$ (0.67)	$ (1.05)	$ (0.84)
Shares used in computing net loss per basic and diluted share	75,093	70,656	55,829

* includes $13,465 write-off of acquired In-Process R&D related to the acquisiton of Salus Therapeutics, Inc. in August 2003 (Note 5).

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2003, 2002 and 2001

(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					
Balance at January 1, 2001	261	$ --	51,085	$ 51	--	$ --	$ 206,451	$ (151,949)	$ (1,081)	$ 95	$ 53,567
Comprehensive loss:											
Net loss	--	--	--	--	--	--	--	(46,713)	--	--	(46,713)
Unrealized investment loss	--	--	--	--	--	--	--	--	--	(161)	(161)
Total comprehensive loss											(46,874)
Issuance of common stock upon conversion of convertible preferred stock	--	--	2	--	--	--	--	--	--	--	--
Issuance of common stock in connection with private placement, net of issuance costs of $502	--	--	2,500	3	--	--	32,220	--	--	--	32,223
Issuance of common stock in connection with exercise of warrants and stock options ..	--	--	12,245	12	--	--	8,309	--	--	--	8,321
Issuance of common stock as hiring bonus	--	--	6	--	--	--	--	--	--	--	--
Issuance of common stock related to license agreement	--	--	162	--	--	--	--	--	--	--	--
Equity related compensation	--	--	--	--	--	--	1,705	--	(632)	--	1,073
Balance at December 31, 2001	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 (Note 20)	--	--	--	--	(393)	(2,506)	--	--	--	--	(2,506)
Equity related compensation	--	--	--	--	--	--	--	--	1,016	--	1,016
Balance at December 31, 2002	261	--	74,168	74	(393)	(2,506)	322,997	(273,190)	(697)	25	46,703

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2003, 2002 and 2001

(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	--	--	--	--	--	--	--	(50,109)	--	--	(50,109)
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 (Note 19)	--	--	--	--	(51)	(303)	--	--	--	--	(303)
Retirement of treasury stock	--	--	(444)	--	444	2,809	(2,809)	--	--	--	--
Issuance of common stock in connection with Salus asset purchase (Note 5)	--	--	1,031	1	--	--	12,983	--	--	--	12,984
Equity related compensation	--	--	--	--	--	--	--	--	436	--	436
Balance at December 31, 2003	261	$ --	75,927	$ 76	--	$ --	$ 335,713	$ (323,299)	$ (261)	$ 25	$ 12,254

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Years Ended December 31, 2003	2002	2001
Operating activities:			
Net loss	$ (50,109)	$ (74,528)	$ (46,713)
Items reflected in net loss not requiring cash:			
Depreciation and amortization	2,383	1,646	1,131
Loss on disposition of equipment	3	13	19
Promega settlement	--	--	1,000
Write-off of acquired in-process R&D (Note 5)	13,465	--	--
Compensation expense related to stock options (Note 20) ..	436	1,016	1,074
Changes in operating assets and liabilities, net of effects of acquisition of Salus Therapeutics, Inc.:			
Accounts, notes and loan receivable (Note 4)	(2,101)	(14,538)	102
Notes receivable (Note 6)	(3,542)	--	--
Inventory (Note 7)	(518)	--	--
Prepaids and other assets	(1,846)	(751)	(282)
Accounts payable and accrued expenses	(17,404)	20,405	8,679
Deferred revenue (Note 13)	(5,237)	46,501	--
Other assets	57	(142)	(68)
Net cash used in operating activities	(64,413)	(20,378)	(35,058)
Investing activities:			
Purchase of available-for-sale short-term investments (Note 3)	(107,350)	(88,317)	(14,521)
Maturities and sales of available-for-sale short-term investments (Note 3)	130,590	23,380	29,546
Purchase of property and equipment	(3,293)	(2,387)	(1,438)
Cash paid for acquisition of Salus, net of cash acquired .	(579)	--	--
Net cash (used in) provided by investing activities	19,368	(67,324)	13,587
Financing activities:			
Issuance of common stock from private placement, net (Note 19)	--	71,035	32,223
Borrowings under long term debt (Note 15)	35,000	--	--
Issuance of convertible debt	--	10,000	--
Borrowings under note payable	998	868	--
Repayments of note payable	(740)	(378)	--
Purchase of treasury stock (Note 19)	(303)	(2,506)	--
Issuance of common stock upon exercise of warrants and options (Note 19 & 20)	2,543	3,285	8,321
Net cash provided by financing activities	37,498	82,304	40,544
(Decrease) increase in cash and cash equivalents	(7,547)	(5,398)	19,073
Cash and cash equivalents at beginning of year	32,700	38,098	19,025
Cash and cash equivalents at end of year	$ 25,153	$ 32,700	$ 38,098

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended December 31, 2003, 2002 and 2001

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 and Androgenics compounds.

The Company has had recurring operating losses since inception and management expects that such losses will continue until Genasense receives approval from the FDA for commercial sales and we receive a full year of royalties from Aventis on worldwide sales. Although no assurances can be expressed, management believes that at the current rate of spending, coupled with the amounts to be reimbursed by and the available line of credit from Aventis, the Company should have sufficient cash funds to maintain its present operations to the end of 2004. Additional Aventis milestone payments and other funding available to the Company upon the anticipated NDA approval of Genasense should provide sufficient capital resources for beyond 2004.

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, 2003 have been considered in preparing the consolidated financial statements. Such financial statements include the accounts of the Company and all majority-owned subsidiaries. All material intercompany transactions and balances have been eliminated in consolidation. 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 with current-year presentation.

Revenue Recognition

In April 2002, the Company entered into a development and commercialization agreement (Collaborative Agreement) with Aventis Pharmaceuticals Inc. (Aventis). Under the terms of the Collaborative Agreement, the Company and Aventis will jointly develop and commercialize Genasense in the U.S. (the Alliance), and Aventis will have exclusive development and marketing rights to the compound in all countries outside of the U.S. Under the Collaborative Agreement, Aventis will pay 75% of U.S. 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 (Note 12). Reimbursements are to be made pursuant to a single net payment from one party to the other. Such payments are due and payable 60 days following the end of the quarter in which such expenses are incurred.

In December 2003, the SEC published Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*. This SAB updates portions of the SEC staff s interpretive guidance provided in SAB 101 and codifies its guidance in applying generally accepted accounting principles with regard to revenue recognition. Consistent with both SAB 101 and SAB 104, initial funding of ongoing development received from Aventis after the achievement of certain research and development milestones (Note 12) are being recognized on a straight-line basis over the original estimated useful life of the related first-to-expire patent of 115 months. Any subsequent milestone payments that may be received from Aventis will also be recognized over the then remaining estimated useful life of the first-to-expire patent.

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.

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 (Note 12), have been recorded as a reduction to expenses in the consolidated statement of operations.

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents consisted entirely of money market funds. The carrying amounts of cash, cash equivalents and marketable securities approximate fair value due to the short-term nature of these instruments. Marketable securities consisted primarily of corporate notes and government securities, all of which are classified as available-for-sale marketable securities. Management determines the appropriate classification of debt and equity securities at the time of purchase and reassesses the classification at each reporting date. The Company invests its excess cash primarily in debt instruments of domestic corporations and government-backed securities. The Company has established guidelines relative to diversification and maturities that attempt to maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

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 on the basis of estimated future cash flows (undiscounted) and other factors. If such evaluation were to indicate an impairment of these intangible assets, such impairment would be recognized by a write-down of the applicable assets. There was no impairment incurred 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 primarily of licensed technology and 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 on the basis of estimated future cash flows (undiscounted) and other factors. If such evaluation were to indicate an impairment of these assets, such impairment would be recognized by a write-down of the applicable assets. The Company evaluates, each financial reporting period, the continuing value of patents and patent applications. Through this evaluation, the Company may elect to continue to maintain these patents, seek to out-license them, or abandon them. There was no impairment incurred 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.

The Company may record 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. At December 31, 2003, the Company has reviewed its deferred tax assets and believes that the valuation allowance reduces such assets to an amount that is more likely than not to be realized.

Stock Options

The Company has two stock-based compensation plans (Note 20). 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 Emerging Issues Task Force 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 No. 28, over the vesting period of each respective option, which is generally four years.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* Amendment of FASB Statement 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 Statement 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)	**2003**	**2002**	**2001**
Net loss applicable to common shares, as reported	$ (50,109)	$ (74,528)	$ (46,713)
Add: Equity related employee compensation expense included in reported net income, net of related tax effects	436	1,016	1,074
Deduct: Total stock-based employee compensation expense determined under fair values based method for all awards, net of related tax effects	(7,644)	(6,840)	(5,477)
Pro forma net loss	$ (57,317)	$ (80,352)	$ (51,116)
Net loss per share attributable to common shareholders:			
As reported: Basic and diluted	$ (0.67)	$ (1.05)	$ (0.84)
Pro forma: Basic and diluted	$ (0.76)	$ (1.14)	$ (0.92)

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

	Years Ended December 31,		
	2003	2002	2001
Risk-free interest rate	3.3%	2.8%	4.0%
Dividend yield	--	--	--
Expected life (years)	4.0	4.0	4.5
Volatility	58%	65%	69%

Net Loss Per Common Share

Basic earnings per share are based upon the weighted-average number of shares outstanding during the period. Diluted earnings per share includes the weighted average number of all potentially dilutive common shares such as shares outstanding, options, warrants and convertible preferred stock outstanding.

Net loss per common share for the three years ended December 31, 2003 is 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 18.0 million, 16.7 million and 17.2 million in 2003, 2002 and 2001, respectively, have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would be antidilutive. Net loss per common share is based on net loss adjusted for imputed and accrued dividends on preferred stock.

Recently Issued Accounting Standards

In May 2003, the FASB issued SFAS No. 150*, Accounting for Certain Financial Instruments with Characteristics of Liabilities, Equity, or Both*. This limited scope statement prescribes changes to the classification of mandatorily redeemable preferred stock, preferred securities of subsidiary trusts and the accounting for forward purchase contracts issued by a company in its own stock among other issues. SFAS No. 150 does not apply to features that are embedded in a financial instrument that is not a derivative in its entirety and requires all preferred securities of subsidiary trusts to be classified as debt on the consolidated balance sheet and the related dividends as interest expense. The Company adopted the provisions of SFAS No. 150, including the deferral of certain effective dates as a result of the provisions of FASB Staff Position 150-3, *Effective Date, Disclosures, and Transition for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests Under FASB Statement No. 150 Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. The adoption of this statement did not have any impact on the Company s results of operations, financial position or cash flows.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. In particular, SFAS No. 149 (1) clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative discussed in paragraph 6(b) of SFAS No. 133, (2) clarifies when a derivative contains a financing component, (3) amends the definition of an underlying to conform it to language used in FIN 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, and (4) amends certain other existing pronouncements. SFAS No. 149 is to be applied prospectively to contracts entered into or modified after June 30, 2003, with certain exceptions, and for hedging relationships designated after June 30, 2003. The adoption of this statement did not have any impact on the Company s results of operations, financial position or cash flows.

In January 2003, the FASB issued Interpretation No. 46 *Consolidation of Variable Interest Entities*. This interpretation defines when a business must consolidate a variable interest entity. This interpretation applies immediately to variable interest entities created after January 31, 2003 and became effective for all other transactions as of July 1, 2003. However, in October 2003 the FASB permitted companies to defer the July 1, 2003 effective date to December 31, 2003. Again in December 2003, the FASB permitted companies to defer the December 31, 2003 effective date, in certain circumstances, to the first interim or annual period ending after March 15, 2004. The Company has determined that it is not reasonably probable that it will be required to consolidate or disclose information about a variable interest entity.

In November 2002, FASB Interpretation (FIN) 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. This interpretation requires a guarantor to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. It also enhances guarantor s disclosure requirements to be made in its interim and annual financial statements about its obligations under certain guarantees it has issued. The initial recognition and initial measurement provisions of this interpretation are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statement or interim or annual periods ending after December 15, 2002. In the normal course of business, the Company does not issue guarantees to third parties; accordingly, this interpretation does not have an effect on the Company s financial position or results of operations.

3. Marketable Securities

The carrying amounts of the company s marketable securities, which are solely corporate debt securities, approximate fair value due to the short-term nature of these instruments. The fair value of available-for-sale marketable securities is as follows ($ thousands):

	Amortized costs	Unrealized gains	Unrealized losses	Estimated fair value
December 31, 2003	$ 57,751	$ 29	$ (4)	$ 57,776
December 31, 2002	$ 80,991	$ 42	$ (17)	$ 81,016

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

	December 31,	
	2003	2002
Due within one year	$ 20,950	$ 55,979
Due after one year	36,826	25,037
	$ 57,776	$ 81,016

The estimated fair value of each marketable security has been compared to its cost, and therefore, an unrealized gain of approximately $25 thousand has been recognized in accumulated other comprehensive income at December 31, 2003.

4. Accounts Receivable-Net

Included in accounts receivable and netted against operating expenses in the consolidated statement of operations at December 31, 2003, is $15.5 million in net expense reimbursements due from Aventis for various third-party costs, internal costs of scientific and technical personnel (Full-time Equivalents or FTE s) and Genasense drug supply costs for the three month period ended December 31, 2003. Net expense reimbursement consists of the appropriate reimbursement rate (75% or 100%) for costs incurred by Genta and internal costs of Genta scientific and technical personnel net of our 25% share of expenses incurred by Aventis and internal costs of Aventis scientific and technical personnel. Also included in accounts receivable-net are receivables of $1.2 million related to the sale of Ganite , which are net of allowances of $0.1 million. At December 31, 2002, $14.6 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 for the three month period ended December 31, 2002 was included in accounts receivable and netted against operating expenses in the consolidated statement of operations.

5. Salus Therapeutics, Inc. Acquisition

In August 2003, the Company acquired Salus Therapeutics, Inc. (Salus), a privately held company located in Salt Lake City, Utah. Salus specializes in the identification and development of drugs that are based on DNA or RNA, including antisense, small interfering RNAs (siRNA), and delivery systems for DNA/RNA-based drugs. Under the terms of the merger agreement, Genta issued 1.03 million shares of common stock with a fair value of approximately $13.0 million to Salus stockholders in exchange for all of the outstanding shares of Salus common stock, including those issued pursuant to the conversion of Salus preferred stock. Approximately thirty-five percent of the initial payment (0.36 million shares) is held in escrow and will be released on the first anniversary of the acquisition, assuming no event of default occurs as described in the merger agreement. Contingent upon the achievement of certain preclinical and clinical milestones, an additional $17.0 million may be paid in stock or cash at Genta s option.

The following unaudited condensed consolidated pro forma financial information has been prepared to give effect to Genta s acquisition of Salus. The pro forma adjustments are based upon available information and assumptions that Genta believes are reasonable. The unaudited condensed consolidated pro forma financial information do not purport to represent what the consolidated results of operations or financial position of Genta would actually have been if the acquisition had occurred on the dates referred to below, nor do they purport to project the results of operations or financial position of Genta for any future period.

The unaudited condensed consolidated pro forma statement of operations data was prepared by combining Genta s statement of operations for the years ended December 31, 2003 and December 31, 2002 with Salus statement of operations for the years ended December 31, 2003 and December 31, 2002, giving effect to the acquisition as though it occurred on the first day of the respective fiscal year.

The unaudited condensed consolidated pro forma statement of operations data do not give effect to any restructuring costs or any potential cost savings or other operating efficiencies that could result from the acquisition, or any non-recurring charges or credits resulting from the transaction such as in-process research and development charges.

	For the year ended December 31, 2003				
	Genta	Salus	Adjustments	F/N	Pro Forma
Revenues	$ 6,659	$ 194	$ --		$ 6,853
Net loss	$ (50,109)	$ (1,828)	$ 587	(1)	$ (51,350)
Net loss per basic and diluted shares	$ (0.67)				$ (0.68)

	For the year ended December 31, 2002				
	Genta	Salus	Adjustments	F/N	Pro Forma
Revenues	$ 3,559	$ 386	$ --		$ 3,945
Net loss	$ (74,528)	$ (1,193)	$ --		$ (75,721)
Net loss per basic and diluted shares	$ (1.05)				$ (1.06)

(1) An adjustment was made to eliminate the revenues and net losses recorded twice in the table above during the period from August 21, 2003, the date Genta purchased Salus, through December 31, 2003 (Consolidation Period). During that period, Salus financial information was consolidated into Genta; however, to accurately depict the financial results of both entities for the twelve months ended

December 31, 2003, both revenues and net loss were shown on a stand alone basis, and properly adjusted for by backing out the amounts during the Consolidation Period to determine the pro forma information.

The effects of the acquisition have been presented using the purchase method of accounting. The total purchase price of the transaction has been allocated to assets and liabilities based on management s estimate of their fair values. The following represents the allocation of the purchase price over the estimated fair values of the acquired assets and assumed liabilities of Salus:

Current assets	$ 66
Property, plant and equipment	177
Acquired in-process research and development	13,465
Other assets	6
Total assets acquired	$ 13,714
Current liabilities	75
Long term liabilities	13
Total liabilities assumed	88
Purchase price	$ 13,626

The value of $13.5 million assigned to acquired in-process research and development was charged to earnings in the fourth quarter of 2003.

6. Notes Receivable

At December 31, 2003, the Company had recorded $3.5 million as a note receivable relating to advance financing provided to Avecia Biotechnology, Inc. (Avecia) for facility expansion, which will be repaid with interest through future payments determined as a function of drug substance purchases to be made by the Company in the future.

Advance funding for facility expansion	$ 3,552
Interest recorded	95
Payments received	(105)
	$ 3,542

7. Inventories

Inventories, comprised of Ganite , 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 (in thousands):

	December 31, 2003
Raw materials	$ 189
Work in process	318
Finished goods	11
	$ 518

8. Property and Equipment

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

	Estimated Useful Lives	December 31, 2003	December 31, 2002
Computer equipment	3	$ 3,337	$ 1,734
Software	3	2,632	1,237
Furniture and fixtures	5	1,009	920
Leasehold improvements	6	767	613
Equipment	Life of lease	299	80
		8,044	4,584
Less accumulated depreciation and amortization		(3,127)	(1,328)
		$ 4,917	$ 3,256

9. Intangibles

Intangible assets consist of the following ($ thousands):

	December 31, 2003	December 31, 2002
Patent and patent applications	3,992	3,992
Less accumulated amortization	(3,129)	(2,552)
	$ 863	$ 1,440

Future amortization expense related to intangibles at December 31, 2003 are as follows ($ thousands):

	Amortization Expense
2004	577
2005	286
Thereafter	--
Total	$ 863

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 , the Company s leading antisense drug, through the term of the arrangement which expires twelve years from the date of first commercial sale.

11. Accounts Payable and Accrued Expenses

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

	December 31, 2003	2002
Accounts payable	$ 6,462	$ 27,683
Accrued compensation	2,516	1,826
Accrued interest	1,235	384
Other accrued costs	5,106	2,530
	$ 15,319	$ 32,423

12. Collaborative Agreement

In April 2002, the Company entered into a development and commercialization agreement (Collaborative Agreement) with Aventis Pharmaceuticals Inc. (Aventis). Under the terms of the Collaborative Agreement, the Company and Aventis will jointly develop and commercialize Genasense in the U.S. (the Alliance), and Aventis will have exclusive development and marketing rights to the compound in all countries outside of the U.S. The Company will retain responsibility for global manufacturing and for regulatory filings within the U.S., while Aventis will assume all regulatory responsibilities outside the U.S. Joint management teams, including representatives from both Genta and Aventis, will oversee the Alliance. Collectively, this Collaborative Agreement could provide up to $476.9 million in cash, equity and convertible debt proceeds to the Company. In addition, under the Collaborative Agreement, Genta is entitled to royalties on any worldwide sales of Genasense , from which Genta is required to pay third-party pass-through royalties to the University of Pennsylvania (UPenn) and The National Institutes of Health (NIH) based on net worldwide sales. Furthermore, under the Collaborative Agreement, Aventis will pay 75% of U.S. NDA-directed development costs incurred by either Genta or Aventis subsequent to the execution of the Collaborative Agreement, and 100% of all other development, marketing, and sales costs incurred within the U.S. and elsewhere as subject to the Collaborative Agreement. An analysis of expenses reimbursed under the Collaborative Agreement follows ($ thousands):

	Twelve Months Ended December 31, 2003	2002	2001
Research and development expenses, gross	$ 82,875	$ 86,645	$ 39,355
Less expense reimbursement	(55,891)	(27,746)	--
Research and development expenses, net	$ 26,984	$ 58,899	$ 39,355
Selling, general and administrative expenses, gross	$ 29,604	$ 20,052	$ 8,215
Less expense reimbursement	--	(705)	--
General and administrative expenses, net	$ 29,604	$ 19,347	$ 8,215

As of December 31, 2003, the Company has received a total of $235.7 million in initial and near-term funding, which included a $10.0 million licensing fee and $40.0 million in development funding, $10.0 million in convertible debt proceeds (Note 14), $71.9 million pursuant to an at-market equity investment in the Company s common stock, $68.8 million in paid expense reimbursements and $35.0 million in line of credit proceeds. A further $15.5 million in acquired expense reimbursement is due for receipt during the first quarter of 2004. The remaining amounts that could be received under the Collaborative Agreement, $280.0 million in cash and $65.0 million in convertible note proceeds, are contingent upon the achievement of certain research and development milestones.

13. Deferred Revenues

As of December 31, 2003, the Company had recorded $41.4 million, net of amortization in deferred revenues relating to the initial $10.0 million licensing fee and $40.0 million development funding received from Aventis under the Collaborative Agreement (Note 12), of which $5.3 million is included in current liabilities and $36.1 million is classified as long-term deferred revenues, which will be recognized on a straight-line basis over the estimated original useful life of the related first-to-expire patent of 115 months, in accordance with SAB 104. Any subsequent milestone payments that may be received from Aventis will also be recognized over the then remaining estimated useful life of the related first-to-expire patent.

14. Convertible Debt

At December 31, 2003, the Company had $10.0 million in convertible debt that was issued in connection with the Collaborative Agreement (Note 12). The Company received $10.0 million in debt proceeds from Aventis, and issued a $10.0 million convertible promissory note to Aventis (Aventis Note). Interest accrues at the rate of 5.63% per annum until April 26, 2009 (the Maturity Date) and compounds annually on each anniversary date of the Aventis Note through the Maturity Date. The Company may redeem the Aventis Note for cash in whole or in part (together with any accrued and unpaid interest with respect to such principal amount) in amounts of not less than $0.5 million. In addition, the Company may convert the Aventis Note on or prior to the Maturity Date in whole or in part into fully paid and non-assessable shares of common stock. As of any date, the number of shares of common stock into which the Aventis Note may be converted shall be determined by a formula based on the then market value of the common stock (the Conversion Price), subject to a minimum Conversion Price of $8.00 per share.

As of December 31, 2003, the Company has accrued interest of $1.0 million on the Aventis Note.

15. Long Term Debt

At December 31, 2003, the Company had $35.0 million outstanding on a line of credit that was issued in connection with an amendment, dated March 14, 2003, to the Collaborative Agreement (Note 12) that established an up to $40.0 million line of credit related to the development, manufacturing and commercialization of Genasense (Aventis Line of Credit). This revolving debt is considered an advance against both past and future costs. At the time of Genasense NDA approval in the U.S., any outstanding balance will be offset against the first milestone payment that is due to Genta from Aventis. The terms of the Aventis Line of Credit provide for a favorable interest rate, which is set two days prior to the first day of each calendar quarter. The Aventis Line of Credit terminates upon the earlier of (i) the receipt of Genasense NDA approval in the U.S. or (ii) December 31, 2004, all amounts payable under the agreement are due six months after termination. As security for the repayment of the Aventis Line of Credit, Genta has granted Aventis a security interest in all of its accounts and/or other rights to payments under the Collaborative Agreement as well as all inventory related to Genasense .

As of December 31, 2003, the Company has accrued interest of $0.3 million on the Aventis Line of Credit.

16. Income Taxes

In 2003, the Company s tax provision is comprised of the Minimum Tax related to California, Massachusetts and New Jersey. In 2002, the Company s tax provision was comprised of $0.2 million of current state taxes related to the New Jersey Alternative Minimum Assessment (AMA) Tax. Significant components of the Company s deferred tax assets as of December 31, 2003 and 2002 and related valuation reserves are presented below ($ thousands):

	December 31, 2003	December 31, 2002
Deferred tax assets:		
Deferred compensation	$ 658	$ 6,152
Net operating loss carryforwards	90,861	68,407
Research and development credits	75,028	52,630
Purchased technology and license fees	4,850	4,850
Deferred revenue - current	2,326	2,304
Deferred revenue - non-current	15,869	18,196
New Jersey Alternative Minimum Assessment (AMA) Tax	182	184
New Jersey R&D credit	4,093	--
Other, net	241	212
	194,108	152,935
Valuation allowance for deferred tax assets	(193,491)	(152,775)
Net deferred tax assets	617	160
Deferred tax liabilities:		
Depreciation, net	(617)	(160)
	(617)	(160)
Net deferred tax assets (liabilities)	$ --	$ --

A full valuation allowance has been provided at December 31, 2003 and 2002 to reserve for deferred tax assets, as it appears more likely than not that net deferred tax assets will not be realized.

At December 31, 2003, the Company has federal and state net operating loss carryforwards of approximately $222.2 million and $145.6 million, respectively. The difference between the federal and state tax loss carryforwards is primarily attributable to the fact that the Company relocated from California to Massachusetts in 1998, and from Massachusetts to New Jersey in 2000. Net operating losses for state income tax purposes, previously generated in California and Massachusetts, cannot be utilized in New Jersey. The federal tax loss carryforwards began expiring in 2003. The Company also has federal research and development tax credit carryforwards of $75.0 million, which began expiring in 2003.

Federal and New Jersey tax laws limit the utilization of income tax net operating loss and credit carryforwards that arise prior to certain cumulative changes in a corporation s ownership resulting in a change of control of the Company. The Company s future annual utilization of their net operating loss carryforwards and research and development tax credits will be limited due to ownership changes which occurred previously.

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

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

The market value of common stock issued for the purchase of Salus (Note 5) was $13.0 million.

The value of treasury stock (Note 19) retired was $2.8 million.

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18. Operating Leases

At both December 31, 2003 and December 31, 2002, the Company maintained $0.5 million in restricted cash balances with a financial institution related to lease obligations on its corporate facilities and leased fleet vehicles. Such restricted cash balances collateralize letters of credit issued by the financial institution 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, 2003 are as follows ($ thousands):

	Operating Leases
2004	$ 2,571
2005	2,566
2006	2,669
2007	2,661
2008	2,595
Thereafter	3,005
Total	$ 16,067

19. Stockholders Equity

Common Stock

In November 2001, the Company sold 2.5 million shares of common stock through a private placement and received proceeds of approximately $32.2 million, net of placement agent commissions of $0.4 million and related expenses.

In March 2002, the Board of Directors approved an amendment to increase the authorized common stock to 120.0 million shares from 95.0 million. In June 2002, shareholders approved this amendment at the annual meeting of stockholders.

In May 2002, the Company sold 6.7 million shares of common stock to Aventis in connection with the Collaborative Agreement (Note 12) and received proceeds of $71.0 million, net of investment banking fees of $0.9 million and related expenses.

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 (Note 5).

Treasury Stock

In June 2002, the Company commenced a stock repurchase program, whereby up to 5.0 million shares of its common stock may be repurchased by the Company at prices deemed desirable by the Company. The Company uses the cost method to account for treasury stock. As of September 2003, the Company had repurchased 444,200 shares of common stock in open-market transactions as follows:

	Shares Repurchased	Average Price per Share
At December 31, 2002	392,700	$ 6.38
Nine months ended September 30, 2003	51,500	5.89
	444,200	$ 6.32

On September 30, 2003, the Company retired all 444,200 shares of treasury stock.

Preferred Stock

The Company has authorized 5.0 million shares of preferred stock and has issued and outstanding 260,500 shares of Series A Convertible Preferred Stock as of December 31, 2003. In 1999, the Board of Directors of the Company and certain holders of common stock, Series A and D preferred stock approved, in accordance with Delaware law, an amendment to the Company s Restated Certificate of Incorporation to remove the Fundamental Change redemption right. The Company has formally amended its Restated Certificate of Incorporation after the expiration of the 20-day period provided for in Rule 14c-5 promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act).

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, 2003 and 2002, each share of Series A Preferred Stock was convertible into 7.3967 and 6.8334 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 $13.0 million at December 31, 2003.

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

Warrants

Summary information with respect to outstanding common stock warrants at December 31, 2003 is presented below:

	Exercise Price	Potential Warrant Exercise Proceeds	Common Equivalents	Expiration Date
June 1997 Private Placement :				
Placement & Advisory Warrants:	$0.86 - $1.10	$ 2,976,767	3,287,851	June 2007
Androgenics Warrants (August 1999):				
Vested December 31, 1999:	$1.25	100,000	80,000	August 2006
Vest upon achievement of various milestones:	$1.50 - $2.50	1,787,500	900,000	5 years after achievement of milestones
December 1999 Private Placement (Common):				
Related Party Warrants:				
Common Stock:	$3.30	885,667	268,384	December 2004
Warrants:	$5.31	356,285	67,097	December 2004
Funding Warrants:	$4.70	2,487,076	529,485	December 2004
Penalty Warrants (May 2000):	$4.70	207,328	44,140	May 2005
September 2000 Private Placement (Common):				
Penalty Warrants:	$6.75	79,205	11,734	September 2005
Placement Agent Warrants:	$7.15	63,728	8,913	September 2005
Placement Agent Warrants:	$7.43	267,901	36,081	September 2005
November 2000 Private Placement (Common):				
Placement Agent Warrants:	$7.43	397,542	53,541	September 2005
		$ 9,608,999	5,287,226	

In June 1997, in connection with an issuance of Premium Preferred Units, the placement agent received warrants (the Placement Warrants) to purchase up to 10% of the units sold in the Private Placement for 110% of the offering price per unit. Furthermore, the Company had entered into a financial advisory agreement with the placement agent pursuant to which the financial advisor received certain cash fees and has received warrants (the Advisory Warrants) to purchase up to 15% of the units sold in the Private Placement for 110% of the offering price per unit. This financial advisory agreement terminated in June 1999. The Placement Warrants and the Advisory Warrants expire on June 29, 2007.

On August 30, 1999, the Company acquired Androgenics Technologies, Inc. (Androgenics), a wholly owned entity of a related party shareholder. As consideration for the acquisition, the Company paid $0.1 million in cash (including reimbursements of pre-closing expenses and on-going research funding) and issued warrants (with exercise prices ranging from $1.25 to $2.50 per share) to purchase an aggregate of 1.0 million shares of common stock, 90% of which will not become exercisable until the successful conclusion of certain development milestones, ranging from the initial clinical patient trial through the submission of an application for marketing authorization. The acquisition was accounted for as a transfer of interest between companies under common control. The cash and warrants were issued in exchange for 100% of the shares of Androgenics and licensed technology and the assumption of a research and development agreement with the University of Maryland at Baltimore. The 1.0 million warrants were accounted for as a deemed distribution based on their fair value of $0.4 million. At December 31, 2003, none of the above-mentioned milestones have been met. Ten percent of the warrants are currently exercisable and expire in August 2006. The remaining 90% of the warrants would be exercisable upon the achievement of certain milestones related to the development of Androgenics products. We recently decided to terminate our Androgenics program.

On November 5, 1999, the Company issued 550,000 Bridge Warrants to the Aries Funds in full settlement of the Company s obligation under a 1997 note and warrant purchase agreement. The settlement of this obligation was accounted for as a capital distribution, since the Aries Funds are a shareholder of the Company. Accordingly, these warrants were accounted for at their fair value of $1.8 million and included in accrued dividends at December 31, 1999. In September 2001, these warrants were exercised for $0.2 million.

In December 1999, as described above, in connection with the 1999 Private Placement, the placement agent, a related party shareholder, received warrants (the Related Party Warrants) to purchase up to 10% of the Units sold in the Private Placement for 110% of the offering price per Unit. The Related Party Warrants expire on December 23, 2004. The Related Party Warrants have a fair value at the time of their issuance approximating $1.3 million, resulting in no net effect to stockholders equity. During 2001, also in connection with the 1999 Private Placement, 57,147 penalty warrants were issued, as a result of an SEC registration statement not becoming effective within the prescribed 120 day period after closing.

In September 2000, as discussed above, in connection with the September 2000 private equity placement, 135,639 warrants were issued to the placement agent. The value of such warrants of $0.9 million was considered part of the cost of the placement. In addition, 20,641 penalty warrants were issued as a result of an untimely filing of an SEC registration statement within the prescribed 30-day period after closing.

Common Stock Reserved

At December 31, 2003, an aggregate of 19,083,303 shares of common stock were reserved for the conversion of preferred stock and the exercise of outstanding options and warrants.

20. Employee Benefit Plans

1991 Plan

At December 31, 2003, options granted under the 1991 Plan to purchase 4,388 shares of common stock were exercisable with a weighted average price of approximately $22.41.

1998 Plan

Pursuant to the Company s 1998 Stock Plan as amended (the 1998 Plan), 17.0 million shares have been provided for the grant of stock options to employees, directors, consultants and advisors of the Company. On April 16, 2003, 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 17.0 million shares from 15.6 million. In June 2003, the stockholders approved this amendment at the annual meeting of the stockholders. In March 2002, 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 15.6 million shares from 12.1 million. In June 2002, 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 10 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.

Grants to Employees and Directors 1998 Plan

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, $0.7 million and $0.7 million as non-cash equity related compensation expense in 2003, 2002 and 2001.

The Company s employees were granted 2,468,300, 1,274,400 and 1,392,300 stock options with exercise prices equal to the fair value on the date of grant in 2003, 2002 and 2001, respectively.

Grants to Non-Employees 1998 Plan

In 2001, the Company also granted 50,000 options to purchase common stock to members of Genta s Scientific Advisory Board, for which the Company recorded a total of $3.0 million in deferred compensation, of which $0.2 million, $0.3 million and $0.3 million was amortized as non-cash equity related compensation expense in 2003, 2002 and 2001, 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, 2000	9,696,427	$ 2.39
Granted	1,392,300	8.56
Exercised	(2,363,983)	1.29
Canceled	(429,500)	2.94
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

At December 31, 2003, options to purchase 5,133,948 shares of common stock were exercisable at a weighted average exercise price of approximately $3.95 per share and 3,953,831 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. In March 2002, the Board of Directors approved an amendment to increase the total number of shares of common stock authorized for issuance under the Directors Plan to 3.3 million shares from 2.9 million and an amendment to change the amount and the time when stock options are granted under the Directors Plan. In June 2002, shareholders approved both amendments at the annual meeting of stockholders. 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 at the first Board of Directors meeting they attend in person. 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 184,000, 174,667, and 170,769 shares of common stock in 2003, 2002 and 2001, respectively, with an exercise price equal to the fair market value of the common stock on the date of grant.

Summary information with respect to the Company s 1998 Non-Employee Director s Plan is as follows:

1998 Directors' Plan	Shares Under Option	Weighted Average Exercise Price Per Share
Balance at December 31, 2000	1,620,300	$ 3.30
Granted	170,769	10.70
Exercised	(501,400)	1.33
Canceled	--	--
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

At December 31, 2003, options granted under the Directors Plan to purchase 834,335 shares of common stock were exercisable at a weighted average exercise price of approximately $6.70 per share and 429,478 shares of common stock were available for grant or sale under the Directors Plan.

In 2001, a total of 1,563,069 options were granted pursuant to the 1998 Plan and the 1998 Directors Plan, of which 1,513,069 were granted at fair market value with a weighted average grant date fair value of $8.53 per share, and 50,000 were granted below fair market value with a weighted average grant date fair value of $6.64 per share. In 2002, a total of 1,449,067 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 $11.81 per share. No options were granted below fair market value. In 2003, a total of 2,652,300 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 $9.72 per share. No options were granted below fair market value.

An analysis of all options outstanding as of December 31, 2003 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
$0.00 - $3.65	5,072,762	5.71	$ 2.61	4,278,885	$ 2.60
$5.48 - $7.00	1,233,283	7.10	6.47	766,121	6.56
$7.01 - $9.13	1,579,458	7.90	7.92	516,146	8.06
$9.14 - $10.95	1,285,500	9.30	9.91	52,112	10.05
$10.96 -$18.25	1,628,419	8.45	13.39	390,269	14.13
	10,799,422	7.00	$ 6.32	6,003,533	$ 4.39

The weighted-average estimated fair value of employee stock options granted were $9.72 and $11.81 per share during 2003 and 2002, respectively

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 $0.6 million, $0.3 million and $0.1 million for 2003, 2002 and 2001, respectively.

21. Commitments and Contingencies

Litigation and Potential Claims

JBL Scientifics, Inc.

During May 2000, Promega notified Genta of two claims against Genta and Genta s subsidiary, Genko Scientific, Inc. (formerly known as JBL Scientifics, Inc.), for indemnifiable damages in the aggregate amount of $2.82 million under the purchase agreement pursuant to which Promega acquired the assets of JBL. Promega s letter stated that it intended to reduce to zero the principal amount of the $1.2 million promissory note it issued as partial payment for the assets of Genko Scientific, Inc. and that therefore Genta owed Promega approximately $1.6 million. On October 16, 2000 Genta filed suit in a U.S. District Court in California against Promega for the non-payment of the $1.2 million note plus accrued interest. On November 6, 2000, Promega filed a counterclaim alleging indemnifiable damages in the aggregate amount of $2.82 million. During the first quarter of 2001, we agreed to resolve the matter with Promega, and, in connection therewith, agreed to restructure its $1.2 million promissory note receivable to provide for a $0.2 million non-interest bearing note due to be repaid by Promega upon final resolution of certain environmental issues related to JBL and forgave all accrued interest. While we have resolved one of these environmental issues, we are awaiting final acceptance by the EPA of our settlement offer on the other environmental issue before the restructured note will be repaid by Promega. We are uncertain as to whether and when the EPA will issue such final acceptance.

Genta Pharmaceutical Europe S.A.

During 1995, Genta Pharmaceutical Europe S.A., or Genta Europe, a wholly-owned subsidiary of Genta, received funding in the form of a loan from ANVAR, a French government agency, of which the proceeds were intended to fund research and development activities. In October 1996, in connection with a restructuring of Genta s operations, Genta terminated all scientific personnel of Genta Europe. In 1998, ANVAR asserted that Genta Europe was not in compliance with the ANVAR Agreement, notified Genta Europe of its demand for accelerated repayment of the loan and notified Genta that it was liable as a guarantor on the note. Based on the advice of French counsel, Genta does not believe that ANVAR is entitled to payment under the terms of the ANVAR Agreement and that Genta will likely not incur any liability in this matter, although there can be no assurances thereof. During the quarter ended September 30, 2003, we reversed the accrued net liability of $0.2 million related to this matter, as management believes that a loss is not probable.

University of Pennsylvania

In October 2002, a licensing officer from the University of Pennsylvania asserted a claim to a portion of the initial $40.0 million development funding we received from Aventis pursuant to the collaborative agreement between Genta and Aventis. In October 2003, we reached a settlement with the University of Pennsylvania with respect to this claim. Under the terms of the settlement, in exchange for an agreement by the University of Pennsylvania to forego any and all claims in the future to any portion of any milestone and other payments (other than royalty payments on sales) made to Genta pursuant to the collaborative agreement, Genta has agreed to make the following payments to the University of Pennsylvania: (i) $750,000 on November 5, 2003, (ii) $250,000 on February 2, 2004, (iii) $1.5 million upon the first new drug application or foreign equivalent approval of Genasense and (iv) provided that the first new drug application or foreign equivalent approval of Genasense has been received by Genta, $750,000 on the earlier of (a) the second new drug application or foreign equivalent approval of Genasense or (b) December 30, 2004.

Contractual Obligations

Future contractual obligations at December 31, 2003 are as follows ($ thousands):

	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Long term debt obligations (1)	$ 35,000	$ --	$ 35,000	$ --	$ --
Convertible debt	10,000	--	--	--	10,000
Operating lease obligations	16,067	2,571	5,235	5,256	3,005
Drug purchase obligations to Avecia (2)	137,500	27,500	110,000	--	--
Drug purchase obligations to JMI (3)	252	46	206	--	--
Total	$ 198,819	$ 30,117	$ 150,441	$ 5,256	$ 13,005

(1) Consists of amounts under our line of credit with Aventis, which are due six months after termination, which will occur on the earlier of FDA approval of Genasense or December 31, 2004. FDA approval of Genasense would trigger a milestone payment from Aventis of $75 million and an obligation by Aventis to purchase at our option $20 million of convertible notes from us.

(2) Consists of drug purchase obligations to Avecia which are subject to FDA approval of Genasense and qualification and validation of Avecia s production facilities expansion. The amounts actually purchased will be dependent upon the aforementioned conditions, as well as the volume purchased in any given year. Pursuant to the collaborative agreement with Aventis, (Note 12), the Company anticipates that it will be reimbursed from 75% to 100% of these purchase commitments after the drug is shipped to Aventis for clinical use or commercial sales. For a further description of our agreement with Avecia, see Part I, Item 1, B. Summary of Business and Research and Development Manufacturing . If Genasense is not approved or Avecia s production facility expansion is not validated our total drug purchase obligations will be $27.5 million. We may terminate our Avecia contract if we determine that Genasense will not be approved by the FDA. In addition, we have committed up to $5.0 million of advance financing to the drug substance manufacturer, for facility expansion, which would be recovered with interest through future payments determined as a function of drug substance purchases to be made by Genta in the future.

(3) Consists of drug purchase obligations to Johnson Matthey Inc. (JMI). Genta is obligated to purchase 80% of drug substance requirements for Ganite from JMI. The sales projections for Ganite are very dependent on the Company s ability to obtain compendial listings and/or approvals for the use of Ganite as a chemotherapy drug. The sales projections reflected in the contractual obligations reflect the current approved hypercalcemia indication and limited sales as a chemotherapy drug. Depending on the Company s ability to obtain additional compendial listings and/or approvals, the sales projections and resulting contractual obligations could be higher.

22. Subsequent Event

In February 2004, the U.S. Food and Drug Administration (FDA) accepted the New Drug Application (NDA) for Genasense (oblimersen sodium), the first systemic antisense therapy for cancer. The NDA proposes the use of Genasense in combination with dacarbazine for the treatment of patients with advanced melanoma who have not previously received chemotherapy. In addition, the FDA granted Priority Review status to the application, which targets an agency action on or before June 8, 2004.

23. Selected Quarterly Financial Data (Unaudited)

2003	Quarter Ended			
($ 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 (1)	11,080	4,809	18,536	22,228
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)

2002				
($ thousands, except per share data)	Mar. 31	Jun. 30	Sep. 30	Dec. 31
Revenues	$ 5	$ 910	$ 1,325	$ 1,319
Gross Margin	5	910	1,325	1,319
Operating expenses (1)	12,639	17,940	16,646	31,021
Net loss	(12,626)	(17,069)	(15,112)	(29,721)
Net loss per common share:				
Basic and diluted	$ (0.19)	$ (0.25)	$ (0.21)	$ (0.40)

(1) Excludes compensation expense related to stock options

PART III

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

Changes in Accountants

None.

Disagreements with Accountants

None.

Item 9A. ***Controls and Procedures***

Evaluation of disclosure controls and procedures. Genta s Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of the Company s disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report (the Evaluation Date), have concluded that as of the Evaluation Date, our disclosure controls and procedures were adequate and designed to ensure that material information relating to the Company would be made known to them by others within the Company.

Changes in internal controls. There were no significant changes during the Company's fourth fiscal quarter in our internal controls over financial reporting that have materially affected or are reasonably likely to materially affect the Company's internal controls over financial reporting.

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, 2004 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, 2004 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, 2004 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, 2004 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, 2004 pursuant to Regulation 14A.

PART IV

Item 15. ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

(a) Financial statements

(1) Reference is made to the Index to Financial Statements under Item 8 of this report on Form 10-K.

(2) All schedules are omitted because they are not required, are not applicable, or the required information is included in the consolidated financial statements or notes thereto.

(3) Reference is made to Paragraph (c) below for Exhibits required by Item 601 of Regulation S-K, including management contracts and compensatory plans and arrangements.

(b) Reports on Form 8-K. The Company filed the following reports on Forms 8-K:

On November 4, 2003 the Company filed a Current Report on Form 8-K/A disclosing a press release issued in October 2003 regarding the completion of Salus Therapeutics, Inc. acquisition.

(c) Exhibits required by Item 601 of Regulation S-K with each management contract, compensatory plan or arrangement required to be filed identified.

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)

Exhibit Number	Description of Document
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3(ii).1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, 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 4.2 to the Company's Registration Statement on Form S-8, Commission File No. 0-19635)
10.3	1998 Stock Incentive Plan, as amended and restated, effective June 25, 2003 (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)
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	Contract for Regional Aid for Innovation, effective July 1, 1993, between L'Agence Nationale de Valorisation de la Recherche, Genta Pharmaceuticals Europe S.A. and the Company (incorporated by reference to Exhibit 10.98 to the Company's Annual Report on Form 10-K for the year ended December 31, 1996, Commission File No. 0-19635)
10.7	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)
10.8	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)
10.9	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)
10.10	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)
10.11	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)
10.12	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)
10.13	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)
10.14	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)
10.14A	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)

Exhibit Number	Description of Document
10.15	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)
10.16*	U.S. Commercialization Agreement dated April 26, 2002, by and between Genta Incorporated and Aventis Pharmaceuticals Inc.
10.16A*	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 Form10-Q for the quarter ended March 31, 2003).
10.17*	Ex-U.S. Commercialization Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited
10.18*	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)
10.19*	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)
10.20	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);
10.21	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)
10.22	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)
10.23*	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)
10.24*	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)
10.25*	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)
10.26	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)
10.27	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)
10.28*	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)
10.28A*	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)
10.28AA*	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)

Exhibit Number	Description of Document
10.29	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	ertification 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 12th day of March 2004.

Genta Incorporated

/s/ RAYMOND P. WARRELL, JR., M.D.
Raymond P. Warrell, Jr., M.D.
Chairman, President, Chief Executive Officer and Principal 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, President, Chief Executive Officer and Principal Executive Officer	March 12, 2004
/s/ WILLIAM P. KEANE William P. Keane	Vice President and Chief Financial Officer (Principal Accounting Officer)	March 12, 2004
/s/ JEROME E. GROOPMAN, M.D. Jerome E. Groopman, M.D.	Director	March 12, 2004
/s/ BETSY MCCAUGHEY Betsy McCaughey, Ph.D.	Director	March 12, 2004
/s/ PETER TATTLE Peter T. Tattle	Director	March 12, 2004
/s/ DANIEL D. VON HOFF, M.D. Daniel D. Von Hoff, M.D.	Director	March 12, 2004
/s/ HARLAN J. WAKOFF Harlan J. Wakoff	Director	March 12, 2004
/s/ DOUGLAS G. WATSON Douglas G. Watson	Director	March 12, 2004
/s/ MICHAEL S. WEISS Michael S. Weiss	Director	March 12, 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)	
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3(ii).1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, 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 4.2 to the Company's Registration Statement on Form S-8, Commission File No. 0-19635)	
10.3	1998 Stock Incentive Plan, as amended and restated, effective June 25, 2003 (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)	

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