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GENTA INCORPORATED /DE/  
Form 10-K  
April 01, 2002

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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

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001

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  
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)

33-0326866  
(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  No

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.

The approximate aggregate market value of the voting common equity held by

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non-affiliates of the registrant was \$403,346,448 as of March 8, 2002. For purposes of determining this number, 25,209,153 shares of common stock held by affiliates are excluded. For purposes of making this calculation, the registrant 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 8, 2002, the registrant had 66,565,781 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, 2002 pursuant to Regulation 14A are incorporated by reference in Items 10 through 13 of Part III of this Annual Report on Form 10-K.

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The statements contained in this Annual Report on Form 10-K that are not historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the expectations, beliefs, intentions or strategies regarding the future. The Company intends that all forward-looking statements be subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect the Company's views as of the date they are made with respect to future events and financial performance, but are subject to many risks and uncertainties, which could cause actual results to differ materially from any future results expressed or implied by such forward-looking statements. Forward-looking statements include, without limitation, statements about:

- the Company's ability to develop, manufacture and sell its products;
- the potential 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 detailed in the Certain Trends and Uncertainties section of Management's Discussion and Analysis of Financial Condition and Results of Operations in this Annual Report on Form 10-K; and
- 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.

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### PART I

#### ITEM 1. BUSINESS

##### A. OVERVIEW

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Genta Incorporated ("Genta" or the "Company") was incorporated in Delaware on February 4, 1988. Genta is a biopharmaceutical company that 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, including the Company's gallium products and androgenics compounds.

The Company's lead investigational antisense drug is Genasense(TM) (oblimersen), a molecule designed to block the production of a protein known as Bcl-2, which the Company believes contributes to the inherent resistance of cancer cells to being killed by current types of anticancer treatment, such as chemotherapy, radiation, or monoclonal antibodies. While Genasense(TM) may have some anticancer activity when used by itself, the Company is developing the drug solely as a means of amplifying the effects of other treatments. All current Company research programs seek to increase the effectiveness of cancer chemotherapy by pre-treating patients with Genasense(TM).

The U.S. Food and Drug Administration ("FDA") has granted several designations to Genasense(TM) that may in the future serve to expedite its regulatory review, assuming the clinical trials have yielded a positive result. These designations include "Fast Track" status in melanoma and multiple myeloma, and "Orphan Drug" designation in myeloma, melanoma, and chronic lymphocytic leukemia. The Company has applied for similar designation from regulatory agencies in Europe. Genasense(TM) is undergoing the last stage of clinical testing, which is called "Phase 3". Randomized Phase 3 trials are currently being conducted in multinational trials that encompass patients with malignant melanoma, multiple myeloma, and chronic lymphocytic leukemia. The Company also has other randomized and non-randomized clinical trials involving patients with other types of cancer.

The Company is developing two small molecule drugs containing gallium: an intravenous drug identified as gallium nitrate (Ganite(R)) and an oral formulation of a gallium-containing compound. Ganite(R) had previously received marketing approval in the U.S. and Canada for treatment of patients with cancer-related hypercalcemia, a life-threatening condition caused by excessive buildup of calcium in the bloodstream. Based on previously published data, the Company believes that Ganite(R) may be active as a treatment for patients with certain types of cancer, particularly non-Hodgkin's lymphoma. Toward that end, the Company has filed an Investigational New Drug (IND) exemption with the FDA that will enable the Company to initiate a new clinical trial of Ganite(R) for treatment of myelosuppressed patients with relapsed non-Hodgkin's lymphoma. The Company is also developing an oral formulation of a gallium-containing compound that is intended to permit the use of lower doses to be administered over extended periods. The Company believes this new drug may be useful for patients who have accelerated loss of bone, such as persons with bone metastases (i.e., cancer that has spread into bone) and Paget's disease.

The Company is also developing androgenics compounds for the treatment of the hormone-sensitive stage of prostate cancer. A lead compound (G20,000) has been identified and is currently undergoing additional testing to improve its formulation for oral absorption. If these tests are successful, the Company intends to advance this drug into animal toxicology testing, which would be the last step prior to testing the drug in patients.

The Company is also developing decoy aptamer technology, which is designed to bind proteins known as transcription factors that selectively can turn genes either on or off. This type of control might be used to regulate genes that are critically involved in cancer progression. A lead target, known

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as the cyclic adenosine monophosphate response element-binding protein (CRE-BP), has been identified and a decoy has been created. The CRE-BP decoy is currently undergoing preclinical testing.

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### B. SUMMARY OF BUSINESS AND RESEARCH AND DEVELOPMENT PROGRAMS

#### ANTISENSE TECHNOLOGY

Antisense is a relatively new approach to drug development involving genes that are comprised of DNA which carry the genetic code for all cells. However, most of a cell's functions, including whether the cell lives or dies, are carried out by proteins. In both healthy and cancer cells, DNA consist of nucleotides that are arranged in a specific sequence that encodes the production of a specific protein. In order for the DNA code to be translated into the production of protein, an intermediate step is required. In this step, DNA is transcribed into RNA (the so called "message", or mRNA). The sequence of mRNA nucleotides that encode protein are oriented in direction (known as a "sense").

Antisense drugs are short sequences of chemically modified DNA nucleotides that are called "oligonucleotides" (oligos). The oligos are engineered in a sequence that is exactly opposite (hence "anti") to the "sense" coding sequence of mRNA. Because antisense drugs need to attack only short regions of the mRNA (rather than the whole message itself), antisense drugs contain far fewer nucleotides than the whole gene and therefore should bind only to the matching sequence of nucleotides in the mRNA. As a result, antisense drugs can be used to attack production of a single, disease-causing protein.

Cancer is associated with the over or under-production of many types of proteins. The Company believes that the ability to selectively halt the production of certain proteins may make the treatment of certain diseases more effective. In an effort to make existing cancer therapy more effective, Genta is developing Genasense(TM) to target the production of Bcl-2, a protein that the Company believes is central to the process of programmed cell death (known as "apoptosis").

The Company has devoted significant resources towards the development of "second generation" antisense oligos that contain a phosphorothioate "backbone." However, the Company also has patents and technology covering later "third generation" technologies that involve mixed phosphorothioate and methylphosphonate backbones that may further enhance the molecule's ability to bind to the intended target. In preclinical studies, these "mixed backbone" oligos have effectively down-regulated targeted mRNA sequences inside cells. When injected intravenously into certain animals, these third generation oligos have also demonstrated substantially greater stability in the circulatory system and urinary excretion relative to earlier compounds. This higher degree of stability suggests that these third generation oligos may ultimately be more effective than the Company's second generation oligos.

#### APOPTOSIS

The programmed death of cells, or apoptosis, is essential for proper development of embryos and of many of the body's systems, including the central nervous system, immune regulation and others. Apoptosis is necessary to accommodate the billions of new cells produced daily and to eliminate aged or damaged cells. Abnormal regulation of the apoptosis process can result in disease. For instance, cancer, autoimmune disorders, and many viral infections are associated with inhibited apoptosis (the programmed death of cells is occurring too slowly). Conversely, AIDS and certain neurodegenerative diseases are associated with increased apoptosis (the programmed death of cells is

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occurring too rapidly). This process of programmed cell death is genetically regulated, the Company believes primarily by the Bcl-2 protein family.

### BCL-2: ANTI-APOPTOTIC MECHANISMS

The Bcl-2 protein inhibits the programmed death of cancer cells and allows those cells to survive. Many cancer cells have an excess of this protein, making them resistant to most current types of anticancer treatment (including chemotherapy, radiation and monoclonal antibodies). Overcoming resistance to chemotherapy poses a major challenge for cancer treatment. Antisense technology has been developed to prevent resistance to cancer therapy by blocking the production of Bcl-2, thereby dramatically increasing the sensitivity of cancer cells to chemotherapy, radiation, and immunotherapy.

Normally, when a cancer cell is exposed to treatment (i.e. with chemotherapy, radiation or immunotherapy) a "death signal" is sent to the mitochondrion. The mitochondrion then releases a substance known as cytochrome C that

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activates enzymes (called caspases). These enzymes then cause widespread fragmentation of the cellular proteins, 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 the major hematologic cancers (e.g., lymphomas, myeloma, and leukemia) and solid tumors (e.g., cancers of the lung, colon, breast, and prostate). In these diseases, Bcl-2 blocks the release of cytochrome C which would ordinarily be triggered by cancer therapy. Bcl-2 also appears to be a major contributor to both the inherent and acquired resistance to anticancer treatments.

Observations that support these conclusions include:

- Chemotherapy and radiotherapy sensitive cancerous cells can be made resistant to apoptosis-inducing treatments by inserting the Bcl-2 protein into those cells.
- Higher levels of Bcl-2 correlate with an inferior prognosis and/or poor response to therapy in many diseases.
- Higher levels of Bcl-2 coincide with the shift from androgen-dependent to androgen-independent tumor growth in prostate cancer.
- The capability of cells to cause tumors can be substantially increased by inserting the Bcl-2 protein into those cells.

GENASENSE(TM) (OBLIMERSEN; G3139; BCL-2 ANTISENSE OLIGONUCLEOTIDE)

Genasense(TM) blocks production of Bcl-2, thereby potentially restoring the integrity of the apoptotic process and enabling the cancer cell to be killed with current anticancer therapy. Genasense(TM) is comprised of a phosphorothiate (i.e., second generation) backbone linking 18 modified DNA bases (i.e., an "18-mer"). This oligo targets the first six codons of Bcl-2 mRNA to form a DNA/RNA duplex. A certain enzyme recognizes the DNA/RNA duplex as foreign and then cleaves the Bcl-2 mRNA strand, thereby destroying the ability of the message to be transplanted into Bcl-2 protein. Due to the natural degradation of proteins, halting the production of the protein eventually reduces its intracellular levels, thus preventing the protein from being able to function. The fragments of Bcl-2 mRNA are themselves degraded by enzymes subsequently

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destroyed by ribonucleases.

### OVERVIEW OF PRECLINICAL AND CLINICAL STUDIES OF GENASENSE(TM)

#### GENASENSE(TM) PRECLINICAL STUDIES

In order to affect DNA activity (and thus cell activity), Genasense(TM) must be incorporated into the cell. After intravenous or subcutaneous injection, Genasense(TM) distributes rapidly to highly perfused organs, especially lung and bone marrow. Oligonucleotides are generally excreted unchanged, predominantly by the kidney. Biodistribution studies of Genasense(TM) in vivo have demonstrated high tissue:plasma ratios, particularly in kidney and liver but also significant distribution to the bone marrow and spleen. In addition, in vitro and in vivo studies showed both biologic and antitumor activity with sub-micromolar concentrations (e.g., approximately 170 nanomolar).

A number of in vitro and in vivo studies have shown synergistic enhancement of tumor cell killing when Bcl-2 antisense was used to reduce Bcl-2 protein content in combination with standard antisense therapy (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 immunodeficient mice that were engrafted with xenografts of human cancers and treated with Bcl-2 antisense followed by antitumor agents that induce apoptosis. These studies include human lymphoma, melanoma, breast cancer, and prostate cancers treated with Genasense(TM) in combination with cyclophosphamide, dacarbazine, docetaxel, and paclitaxel, respectively.

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#### GENASENSE(TM) CLINICAL STUDIES

GenasenseTM has been in clinical trials since 1995 in both the United States and Europe. These studies have been conducted in patients with a wide variety of tumor types, including non-Hodgkin's lymphoma, malignant melanoma, several types of leukemia, and cancers of the prostate, colon, lung, and breast. In 1999, the Company executed a Cooperative Research and Development Agreement with the U.S. National Cancer Institute (NCI). In 2001, this agreement was extended until 2003. In addition to the Genta-sponsored trials, NCI has sponsored additional clinical trials in a number of diseases. In aggregate, results of clinical trials performed to date suggest that GenasenseTM can be safely administered to patients with cancer, and that such treatment may reduce the level of Bcl-2 protein in cancer cells.

#### GENASENSE(TM) PHASE 3 RANDOMIZED CLINICAL TRIALS

In 2000 and 2001, the Company initiated a series of randomized clinical trials that employed GenasenseTM in combination with cytotoxic chemotherapy. These trials are all similarly designed and each employs Genasense(TM) in an effort to improve the outcome achieved by the partner chemotherapy agents(s) alone. The studies are comprised of the following:

- a trial in patients with advanced malignant melanoma treated with dacarbazine;
- a trial in patients with multiple myeloma treated with high-dose dexamethasone;

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- a trial in patients with chronic lymphocytic leukemia treated with fludarabine and cyclophosphamide; and
- a trial in patients with advanced non-small cell lung cancer treated with docetaxel.

The melanoma trial is directed to patients who have not been previously treated with chemotherapy. The primary end-point of the trial is to increase overall survival of patients treated with Genasense™ plus dacarbazine compared with patients treated with dacarbazine alone. A minimum of 270 patients are intended to be enrolled in this study. The myeloma and CLL studies are similarly designed. They are directed towards patients who have previously been treated with chemotherapy and have developed progressive disease, and each is intended to enroll a minimum of 200 patients. The lung cancer study is also directed toward patients who have failed prior chemotherapy. A minimum of 75 patients are currently projected to be enrolled in an "embedded Phase 2" stage of this trial. If those data appear favorable, the study will be expanded for additional enrollment into a Phase 3 stage trial.

NON-HODGKIN'S LYMPHOMA AND CHRONIC LYMPHOCYTIC LEUKEMIA: A Phase 1 study of 21 patients with B-cell non-Hodgkin's lymphoma (NHL) was conducted in the U.K. using Genasense(TM) administered by continuous subcutaneous infusion. The results of this study demonstrated that Genasense(TM) infusions could down-regulate Bcl-2 protein within five days of reaching steady-state plasma levels. In the study, thrombocytopenia, infusion site reactions, and fatigue were felt to be dose limiting in two patients treated at a level of 5.3 mg/kg/day. However, the tolerance to treatment in this study may have been closely linked to the prolonged (2-week) infusion schedule given by the subcutaneous route. Other studies have safely escalated the Genasense(TM) doses to 7 mg/kg/day when given intravenously in combination with cytotoxic chemotherapy. Although the administered drug dose was quite low in most patients (i.e., substantially below doses that are now known to be both safe and optimally effective with respect to Bcl-2 down-regulation), several major responses were observed. One patient with low-grade lymphoma who had progressive disease in nodes and bone marrow after two prior regimens attained a complete response using Genasense(TM) alone, which has been maintained for longer than four years. These results were initially published in The Lancet in 1997 and updated in 2000 in The Journal of Clinical Oncology.

More recently, the M.D. Anderson Cancer Center conducted a Phase 1 trial of Genasense(TM) in patients with chronic lymphocytic leukemia (CLL). Similar to the previous NHL study, this trial showed that CLL patients (like NHL patients) exhibited disease-specific side effects to Genasense™, including exaggerated fever, hypotension, and back pain. Together, these studies have indicated that the appropriate initial dose for extended Phase 2 and Phase 3

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testing in these two diseases is 3.5 mg/kg/day. Data from the CLL study were presented in 2001 at the annual meeting of the American Society of Hematology.

ACUTE LEUKEMIA: A Phase 1 study at Ohio State University evaluated a constant intravenous (IV) infusion dose of Genasense(TM) with escalating doses of fludarabine, cytosine arabinoside, and filgrastim in patients with acute leukemia. Results showed that Genasense(TM) could be safely combined with these agents in patients with relapsed leukemia. These data have been presented at several national meetings, including the annual meeting of the American Society of Hematology in 2001.

MALIGNANT MELANOMA: A Phase 1 clinical study of Genasense(TM) combined with dacarbazine (DTIC) was conducted at the University of Vienna. Daily IV infusions

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(or twice daily subcutaneous injections) of Genasense(TM) were given at doses ranging from 1.7 to 12 mg/kg/day. Serial biopsies of cutaneous melanoma metastases showed reduced Bcl-2 protein content (assayed by Western analysis) in tumor cells by day five of treatment. Durable responses and prolonged (greater than 1 year) progression-free survival were also observed in this study, even though most patients had failed both immunotherapy and chemotherapy. Six of the first 14 patients treated showed objective responses. The Genasense(TM)/DTIC regimen was well tolerated up to the dose level of 7 mg/kg/day. Details of this study were reported in The Lancet in 2000.

**OTHER PHASE 1 STUDIES IN PATIENTS WITH ADVANCED CANCER:** Thirty-five patients (mostly with genitourinary cancer) were entered into a dose-escalation trial using both a 14-day and 21-day intravenous infusion schedule of Genasense(TM), either alone or in combination with paclitaxel. This study, conducted at Memorial Sloan-Kettering Cancer Center, showed that fatigue and fever were observed after two weeks at doses ranging from 4.1 to 7 mg/kg/day for 14 days. Similar reactions were observed on the 21-day infusion schedule. Transient elevation of liver enzymes (i.e., serum transaminase) was observed at the 7 mg/kg-dose level. These data have been published in Clinical Cancer Research. Other dose-ranging combination studies of Genasense(TM) have been conducted in patients receiving mitoxantrone or docetaxel for advanced prostate cancer, docetaxel for breast cancer, multi-drug chemotherapy for non-Hodgkin's lymphoma, and irinotecan for colorectal cancer. Results from most of these clinical trials have been presented at national scientific meetings and published in the proceedings of these conferences.

**SUMMARY OF PHASE 1-2 STUDIES:** In general, Genasense(TM) appears to be safe when combined with full doses of standard cytotoxic chemotherapy using a daily Genasense(TM) dose of 7 mg/kg/day for five to seven days. Exceptions to these dosing regimen have been noted above in patients with NHL and CLL. Significant thrombocytopenia, liver function abnormalities, or fatigue have not been dose limiting in Phase 1-2 studies (including studies where the drug was combined with myelosuppressive chemotherapy) that have used these shorter infusions (i.e. five to seven days) at a dose of 7 mg/kg/day. Current data suggest that reduction of Bcl-2 protein may be observed within the first three to five days. Thus, current studies are generally using a five to seven-day schedule in combination with chemotherapy, using Genasense(TM) administered at least three days prior to the initiation of other therapy. As previously noted, the Company, either alone or in conjunction with the U.S. National Cancer Institute, has initiated a number of additional non-randomized Phase 2 trials of Genasense(TM) in combination with chemotherapy in patients with a variety of cancer types.

### GALLIUM PRODUCTS

Gallium nitrate was originally studied by the U.S. National Cancer Institute as a new type of cancer chemotherapy. In the course of these studies, gallium nitrate was shown to strongly inhibit bone resorption (breakdown). Gallium nitrate underwent additional clinical testing and was approved by the FDA in 1991 as a treatment for patients with cancer-related hypercalcemia that has not responded to hydration. Hypercalcemia occurs due to rapid loss of bone that releases large amounts of calcium into the bloodstream of patients, which can be acutely lethal. Clinical testing has been performed in patients with other, less extreme bone-losing conditions, including bone metastases (i.e. cancer that has spread to bone), Paget's disease (an affliction of older patients that causes pain and disability), and osteoporosis.

In April 2000, Genta acquired assets, rights, licenses to patents, and technology relating to gallium-containing compounds for treatment of bone-losing conditions, and to Ganite(R) (gallium nitrate injection), a liquid injectable solution that had been approved for marketing by regulatory authorities in the United States and Canada for treatment of cancer-related hypercalcemia. The acquired assets included the ownership of an approved New Drug Application



(NDA). The Company is currently engaged with outside contractors in the remanufacture of the Ganite(R) product. If test data from these processes are acceptable from a regulatory standpoint, the Company intends to file a supplemental NDA that will update changes in chemistry and manufacturing for approval to market Ganite(R) in the United States and Canada for the treatment of hypercalcemia.

In December 2001, the Company filed a new Investigational New Drug exemption request (IND) for Ganite (R) with the FDA for the treatment of patients with relapsed non-Hodgkin's lymphoma. The Company intends to begin a clinical trial of Ganite(R) as a treatment for patients with refractory non-Hodgkin's lymphoma who have myelosuppression (bone marrow impairment that leads to low blood counts). These patients often may need additional treatment but cannot tolerate standard chemotherapy treatment because it will lead to further myelosuppression. Since previously published clinical trials of Ganite(R) showed that it does not cause significant myelosuppression, the Company believes that this drug may address a significant unmet medical need. The Company plans to begin a new clinical trial in non-Hodgkin's lymphoma in 2002, and if the clinical tests are positive, the Company plans to submit a supplemental NDA (sNDA) to the FDA for this indication. Genta also intends to submit an application to the FDA in order to designate gallium nitrate as an "Orphan Drug."

The Company is also developing new formulations of gallium-containing compounds designed to be taken orally. The Company believes that such formulations will be useful for the treatment of patients who have chronic bone-losing diseases, such as bone metastases, Paget's disease, and osteoporosis. Such patients are commonly afflicted by bone pain and susceptibility to fractures. If the formulation program is successful, the Company would then intend to commence animal toxicology testing with a lead compound.

#### DECOY APTAMERS

Decoy aptamers, like antisense technology, are also based on oligonucleotide chemistry. However, while antisense technology uses oligonucleotides to bind to and destroy mRNA, decoy aptamers employ oligonucleotides to bind to specific proteins known as transcription factors. Normally, transcription factors bind to specific portions of DNA known as response elements, thereby regulating the functions of genes in a positive or negative fashion (i.e., they can turn genes "on" or "off"). Decoy aptamers technology creates artificial forms of response elements. When a cell is flooded with an excess of aptamers, transcription factors are fooled into binding to the decoys rather than the normal response elements found in genes. By selectively inactivating the transcription factor, the function of the gene can be regulated.

Genta licensed patents and technology relating to decoy aptamers from the U.S. National Institute of Health in December 2000. In the Company's initial pre-clinical program, it is targeting a transcription factor known as the cyclic adenosine monophosphate response element binding protein (CRE-BP). Inactivation of this protein in pre-clinical studies indicates selectivity for cancer cells relative to normal cells. A lead drug from our decoy aptamer portfolio has been identified.

#### ANDROGENICS TECHNOLOGIES

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Genta is developing androgenics compounds to treat patients with prostate cancer. These compounds have two principal actions: first, they block the synthesis of androgen hormones, such as testosterone, that simulate the growth of prostate cancer cells; second, they inactivate androgen receptors, proteins that bind androgen hormones and thereby mediate their effects. These types of activities suggest that these drugs could be useful therapy for patients with early stage "hormone-sensitive" prostate cancer. In connection with the acquisition of Androgenics Technologies, Inc. in 1999, the Company acquired licensing rights to a series of Androgenics compounds. The Company has engaged in a pre-clinical program of drug synthesis, formulation and anti-tumor testing with these compounds. A lead compound, currently known as G20,000, has been selected for further development. The Company currently anticipates commencing animal toxicology tests using G20,000 in 2002. If results of these and other pre-clinical tests are positive, Genta could then file an IND with the FDA to begin clinical testing of G20,000.

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### PATENTS AND PROPRIETARY TECHNOLOGY

The Company's policy is to protect its technology by, among other things, filing patent applications with respect to technology considered important to the development of its business. The Company also relies upon trade secrets, unpatented know-how, continuing technological innovation and the pursuit of licensing opportunities to develop and maintain its competitive position.

Genta has a portfolio of intellectual property rights, including a series of applications, to aspects of oligonucleotide technology, which includes novel compositions of matter, methods of large-scale synthesis, methods of controlling gene expression and cationic lipid delivery systems. In addition, foreign counterparts of certain applications have been filed or will be filed at the appropriate time. In the United States, allowed patents generally would not expire until 17 years after the date of allowance if filed before June 8, 1995 or, in other cases, 20 years from the date of application. Generally, it is the Company's strategy to apply for patent protection in the United States, Canada, Western Europe, Japan, Australia and New Zealand.

Since its incorporation, Genta has filed numerous patent applications in the United States and overseas covering new compositions and improved methods to use, synthesize and purify oligonucleotides, linker-arm technology, and compositions for their delivery. There are currently 86 United States and foreign patent applications pending.

Genta also gained access to certain rights from the National Institutes of Health ("NIH") covering phosphorothioate oligonucleotides. This includes rights to three United States issued patents, one issued European patent, one issued in Japan and other corresponding foreign applications that are still pending. In addition, under an agreement with the University of Pennsylvania, Genta has acquired 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 United States patents were issued encompassing the Company's licensed antisense oligonucleotide compounds targeted against the Bcl-2 mRNA and in vitro uses of those compounds. These claims cover the Company's proprietary antisense oligonucleotide molecules, which target the Bcl-2 mRNA including its lead clinical candidate, Genasense(TM). Other related United States and corresponding foreign patent applications are still pending.

In May 2000, the Company entered into a licensing arrangement with Molecular Biosystems, Inc. ("MBI") for a broad portfolio of patents and

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technology that relate to antisense for therapeutic and diagnostic applications. The arrangement includes grants of both exclusive and non-exclusive rights from MBI 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 involve complex legal and factual questions. Consequently, even though Genta is currently prosecuting its patent applications with the United States and foreign patent offices, the Company does not know whether any of its applications will result in the issuance of any patents or if any issued patents will provide significant proprietary protection or will be circumvented or invalidated. Since patent applications in the United States are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature tend to lag behind actual discoveries by several months, Genta cannot be certain that others have not filed patent applications directed to inventions covered by its pending patent applications or that it was the first to file patent applications for such inventions.

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 the Company. Accordingly, there can be no assurance that the Company's patent applications will result in issued patents or that, if issued, the patents will afford protection against competitors with similar technology; nor can there be any assurance that any patents issued to Genta will not be infringed or circumvented by others; nor can there be any assurance that others will not obtain patents that the Company would need to license or design around. There can be no assurance that the Company will be able to obtain a license to technology that it may require or that, if obtainable, such a license would be available on reasonable terms.

Even if issued, patents can be challenged in the courts. Moreover, the Company may become involved in interference proceedings declared by the United States Patent and Trademark Office (or comparable foreign office or process) in connection with one or more of its patents or patent applications to determine priority of invention, which could result in substantial cost to the Company, as well as a possible adverse decision as to priority of invention of the patent or patent application involved.

The Company also relies upon unpatented trade secrets and no assurance can be given that third parties will not independently develop substantially equivalent proprietary information and techniques or gain access to the Company's trade secrets or disclose such technologies to the public, or that the Company can meaningfully maintain and protect unpatented trade secrets.

Genta requires its employees, consultants, outside scientific collaborators and sponsored researchers and other advisors to execute a confidentiality agreement upon the commencement of an employment or consulting relationship with the Company. 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, the Company. There can be no assurance, however, that these agreements will provide meaningful protection for the Company's trade secrets or adequate remedies in the event of unauthorized use or disclosure of such information, or in the event of an employee's refusal to assign any patents to the Company in spite of such contractual obligation.

RESEARCH AND DEVELOPMENT

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In addition to the Company's current focus in the four areas already described and in an effort to focus its research and development efforts 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 it will continue to do so in the future. The Company recorded research and development expenses of \$39.4 million, \$6.8 million and \$4.2 million during 2001, 2000 and 1999, respectively.

### SALES AND MARKETING

The Company intends to be a direct marketer or co-marketer of its pharmaceutical products by building a sales and marketing infrastructure in the United States to launch and fully realize the commercial potential of our products. For international product sales, the Company intends to distribute its products through collaborations with third parties.

### MANUFACTURING

The Company's ability to conduct clinical trials on a timely basis, to obtain regulatory approvals and to commercialize its products will depend in part upon its ability to manufacture its 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 (cGMP) regulations.

We currently rely on third parties to manufacture our products. In December 2000, the Company signed a two-year agreement with Avecia Ltd., a leading multinational manufacturer of pharmaceutical products, to supply quantities of its lead antisense compound, Genasense(TM). The Company is currently negotiating a longer term supply agreement to accommodate an anticipated increase in its product needs for expanded clinical trials and potential marketing launch.

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### SUBSIDIARIES AND AFFILIATES

#### ANDROGENICS TECHNOLOGIES, INC.

Androgenics Technologies, Inc. ("Androgenics"), acquired in 1999, is a wholly-owned subsidiary of Genta with license rights to a series of compounds invented at the University of Maryland at Baltimore to treat prostate cancer. A lead compound, known as G20,000, has been selected for further development and the Company currently anticipates commencing animal toxicology tests using G20,000 in 2002. If results of these and other pre-clinical tests are positive, Genta could then file an IND with the FDA to begin clinical testing of G20,000.

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#### JBL SCIENTIFIC, INC.

Prior to 1999, the Company had manufactured and marketed specialty biochemicals and intermediate products to the in vitro diagnostic and

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pharmaceutical industries through its manufacturing subsidiary, JBL Scientific, Inc. ("JBL"), a California corporation that was acquired in February 1991. On March 19, 1999, the Company entered into an Asset Purchase Agreement with Promega Corporation whereby its wholly owned subsidiary, Promega Biosciences, Inc. ("Promega"), acquired substantially all of the assets and assumed certain liabilities of JBL. JBL has been reported as a discontinued operation in the accompanying consolidated financial statements for the year ended December 31, 1999 (Note 15).

### GENTA EUROPE

During 1995, Genta Pharmaceuticals Europe S.A. ("Genta Europe"), a wholly-owned subsidiary of Genta, received funding in the form of a loan from ANVAR, a French government agency, in the amount of FF5.4 million (or approximately US\$.729 million at December 31, 2001) with a scheduled maturity of December 31, 2002. Pursuant to the loan agreement with ANVAR, the utilization of the proceeds was 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 February 1998, ANVAR asserted that Genta Europe was not in compliance with the ANVAR Agreement, and that ANVAR might request immediate repayment of the loan. In July 1998, ANVAR notified Genta Europe of its demand for accelerated repayment of the loan in the amount of FF4.2 million (or approximately US\$.567 million at December 31, 2001) and subsequently notified us that Genta was liable as a guarantor on the note. Based on the advice of French counsel, we do not believe that ANVAR is entitled to accelerated repayment under the terms of the ANVAR Agreement. We also believe it to be unlikely that Genta will incur any liability in this matter, although there can be no assurance thereof.

In June 1998, Marseille Amenagement, a company affiliated with the city of Marseilles, France, filed suit in France to evict Genta Europe from its facilities in Marseilles and to demand payment of alleged back rent due and of a lease guarantee for nine years rent. Following the filing of this claim and in consideration of the request for repayment of the loan from ANVAR, Genta Europe's Board of Directors directed the management to declare a "Cessation of Payment." Under this procedure, Genta Europe ceased operations and terminated its only remaining employee. A liquidator was appointed by the Court to take control of any assets of Genta Europe and to make payment to creditors. In December 1998, the Court in Marseilles dismissed the case against Genta Europe and indicated that it had no jurisdiction against Genta Incorporated. In August 1999, Marseille Amenagement instituted legal proceedings against us in the Commercial Court of Marseilles, alleging back rent and early termination receivables aggregating FF2.5 million (or approximately US\$.338 million at December 31, 2001). On October 8, 2001, the Commercial Court of Marseilles rendered their decision which declared the action brought by Marseille Amenagement as admissible and ordered us to pay an amount of FF1.9 million (or approximately US\$.260 million at December 31, 2001). The Company does not believe that Marseille Amenagement is entitled to payment and it is currently considering whether to appeal this decision or negotiate with Marseille Amenagement to achieve a mutually satisfactory resolution.

At December 31, 2001, the Company has accrued a net liability of \$.350 million related to the liquidated subsidiary and related matters which management believes is adequate to provide for these contingencies.

### 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

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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. Pursuant to the terms of the agreement, earnings of the joint venture are to be allocated equally between the two parties. Accordingly, Genta recognized \$.502 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 no earnings or losses of the joint venture to be allocated between the two parties and we are currently seeking to terminate our involvement with the joint venture.

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### HUMAN RESOURCES

As of March 2002, Genta had 60 employees, nine of whom hold doctoral degrees. There are 40 employees engaged in development activities and 20 are in administration. Most of the management and professional employees of the Company have had prior experience and positions with pharmaceutical and biotechnology companies. Genta believes it maintains satisfactory relations with its employees.

### C. GOVERNMENT REGULATION

Regulation by governmental authorities in the United States and foreign countries is a significant factor in the Company's ongoing research and product development activities and in the manufacture and marketing of the Company's proposed products. All of the Company's therapeutic products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical testing and pre-market approval procedures by the FDA and similar authorities in foreign countries. Various federal, and in some cases state, statutes and regulations also govern or influence the development, testing, manufacturing, safety, labeling, storage, record keeping 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 the expenditure of substantial resources. Any failure by the Company, its collaborators or its licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the marketing of any products developed by the Company and its ability to receive product or royalty revenue.

The activities required before a new pharmaceutical agent may be marketed in the United States begin with preclinical testing. Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of the product and its formulations. The results of these studies must be submitted to the FDA as part of an Investigational New Drug Application ("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. Typically, clinical testing involves a three-phase process. In Phase 1, clinical trials are conducted with a small number of subjects to determine the early safety profile and the pattern of drug distribution and metabolism. In Phase 2, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase 3, large-scale, multi-center, comparative clinical trials are conducted with patients afflicted with a target disease in order to provide enough data for the statistical proof of efficacy and safety required by the FDA and others. In the case of products for life-threatening diseases, the initial human testing is

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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. These trials are frequently referred to as "Phase 1/2A" trials.

The results of the preclinical and clinical testing, together with chemistry, manufacturing and control information, are then submitted to the FDA for a pharmaceutical product in the form of a New Drug Application ("NDA"), for a biological product in the form of a Biologics License Application ("BLA") for approval to commence commercial sales. In responding to an NDA, BLA or PMA, 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 the Company in the future will be granted on a timely basis, if at all, or if granted will cover all the clinical indications for which the Company is 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 preclinical testing requirements may not be as extensive. Limited additional data about the safety and/or effectiveness of the proposed new drug formulation, along with chemistry and manufacturing information and public information about the active ingredient, may be satisfactory for product approval. Consequently, the new product formulation may receive marketing approval more rapidly than a traditional full NDA, 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, the Company is 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

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country. The Company's approach is to design its European clinical trial studies to meet FDA, European Economic Community ("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, the Company's clinical trials will be designed to develop a regulatory package sufficient for multi-country approval in the Company's 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 preclinical pharmacology studies, prior to formal regulatory approval.

Prior to the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (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 an NDA. Instead, the manufacturer only

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needed to provide an Abbreviated New Drug Application ("ANDA") 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, effective approval of such ANDAs 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 ANDA approval. Under these procedures the applicant is required to submit the clinical efficacy and/or safety data necessary to support the changes from the ANDA eligible drug (without submitting the basic underlying safety and efficacy data for the chemical entity involved) plus manufacturing and chemistry data and information. Effective approval of a 505(b)(2) application is dependent upon the ANDA-eligible drug upon which the applicant relies for the basic safety and efficacy data being subject to no outstanding patent or non-patent exclusivity. As compared to an NDA, an ANDA 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.

The Company is also subject to various foreign, federal, state and local laws, regulations and recommendations relating to safe working conditions, 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 the Company's research and development work and manufacturing processes. Although the Company believes it is in compliance with these laws and regulations in all material respects, there can be no assurance that the Company will not be required to incur significant costs to comply with such regulations in the future.

#### D. COMPETITION

In many cases, the Company's 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. The Company competes 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 the Company.



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The Company's competition will be determined in part by the potential indications for which the Company's products are developed and ultimately approved by regulatory authorities. For certain of the Company's potential products, an important factor in competition may be the timing of market introduction of the Company's or competitors' products. Accordingly, the relative speed with which Genta 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. The Company expects 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 the Company's products under development non-competitive or obsolete.

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

### E. CERTAIN RISKS AND UNCERTAINTIES RELATED TO THE COMPANY'S BUSINESS

In addition to the other information contained in this Annual Report on Form 10-K, the following factors should be considered carefully.

We may be unsuccessful in our efforts to commercialize our pharmaceutical products, such as Ganite(R) and Genasense(TM).

The commercialization of our pharmaceutical products involves a number of significant challenges. In particular, our ability to commercialize products, such as Ganite(R) and Genasense(TM), depends, in large part, on the success of our clinical development programs, our efforts to obtain regulatory approval 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 have utility and are safe;
- 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.

Ultimately, our efforts may not prove to be as effective as the efforts of our competitors. In the United States and elsewhere, our products will face significant competition. The principal conditions on which our product

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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 not be successful in

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commercializing our products, in which case our financial performance will suffer and our long-term viability will be threatened.

We intend to be a direct marketer of products in the United States. 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, 2001, we have incurred a cumulative net loss of \$198.7 million. We may never achieve revenue sufficient for us to attain profitability.

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

Our operations to date have required significant cash expenditures. Based on our current operating plan, we believe that our available resources, including the proceeds from our recent private offering, will be adequate to satisfy our capital needs into 2003. 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 U.S. Food and Drug Administration ("FDA") and other regulatory authorities. In order to commercialize our products, we will need to raise additional financing and we intend to seek additional financing. We may obtain that financing through public and private offerings of our securities, including debt or equity financing, or through collaborative 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. A collaboration or similar arrangement may require us to license valuable intellectual property to, or share substantial economic benefits with, our collaborators. If we raise additional capital by issuing equity, or securities convertible into equity, our stockholders may experience dilution and share prices may decline. Any debt financing may result in restrictions on our spending or payment of dividends.

If we are unable to raise additional financing, 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 ourselves;

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- attempt to sell our company;
- cease operations; or
- declare bankruptcy.

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

Most of our resources have been dedicated to the research and development of potential antisense pharmaceutical products such as Genasense(TM), 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, only Genasense(TM) has 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.

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

Clinical trials are very costly and time-consuming. The length of time required to complete a clinical study depends upon several factors, including the size of the patient population, the ability of patients to get to the site of the clinical study, and the criteria for determining which patients are eligible to join the study. Delays in patient enrollment could delay completion of a clinical study and increase its costs, which could also delay the 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 and our long-term viability would be threatened.

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

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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 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, at best, which would adversely affect our long-term viability.

We may be unable to obtain or enforce patents and other proprietary rights to protect our business; we could become involved in patent litigation 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 involve complex legal and factual questions. As a result, our ability to obtain and enforce patents that protect our drugs is highly uncertain.

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We hold numerous U.S. and international patents covering aspects of our technology, which include novel compositions of matter, use, methods of large-scale synthesis and methods of controlling gene expression. Nevertheless, we may not receive any issued patents based on pending or future applications. Moreover, our issued patents may not contain claims sufficiently broad to protect us against competitors with similar technology. Additionally, our patents, the patents of our business partners and patents for which we have license rights may be challenged, narrowed, invalidated or circumvented. Furthermore, rights granted under our patents may not cover commercially valuable drugs or processes and may not provide us with any competitive advantage.

The pharmaceutical and biotechnology industries have been characterized by time-consuming an 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

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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 expense, 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 rights, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of complex patent 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 importing of drugs that would compete unfairly with our drugs. These types of proceedings could cause us to incur considerable costs.

We rely on our contractual collaborative arrangements with research institutions and corporate partners for development and commercialization of our products, and 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 specific disease targets 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 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, which are intended 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 to develop oral controlled-release drugs, has not resulted in any commercial products, and we intend 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 strategic alliance to achieve its goals, could harm our efforts to develop and commercialize our drugs.

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

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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 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 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 our business.

If we cease doing business and liquidate our assets, we are required to distribute proceeds to holders of our preferred stock before we distribute proceeds to holders of our common stock.

In the event of our dissolution or liquidation, holders of our common stock will not receive any proceeds until holders of the outstanding shares of our Series A Preferred Stock receive a liquidation preference in the amount of approximately \$13.1 million.

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,

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Inc. ("PCAM"). The sole stockholder and chairman of PCAM is also the chairman of Paramount Capital Inc. ("PCI") and of Paramount Capital Investment LLC ("Paramount LLC", and together with PCAM, PCI and their affiliates, the "Paramount Companies"). Together, the Paramount Companies beneficially own approximately 46% of our common stock when calculated on a fully diluted basis. In addition, PCAM is the investment manager for the Aries Funds (comprised of Aries Select I, LLC, Aries Select II, LLC, and Aries Select, Ltd.). The Aries Funds have the right to convert Series A Preferred Stock and exercise warrants that they own into a significant portion of the outstanding common stock. In the regular course of business, the Paramount Companies evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. Due to the ownership and control of the Paramount Companies and the Aries Funds and their involvement with other companies in the life sciences area, some of our current or future officers and directors may

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from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. We cannot assure you that these other companies will not have interests in conflict with ours.

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) beneficially own approximately 54% of our outstanding common stock and preferred stock. They also have, through the exercise of options and warrants, the right to acquire additional common stock and Series A Preferred 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.

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

Our certificate of incorporation gives our board of directors the power to issue shares of preferred stock without approval of the holders of common stock. This preferred stock could have voting rights, including voting rights that could be superior to that of our common stock. The approval 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. In addition, we are subject to Section 203 of the Delaware General Incorporation Law, which contains restrictions on stockholder action to acquire control of Genta. These provisions could discourage third parties from seeking to obtain control of us and, therefore, could prevent our stockholders from receiving a premium for their shares.

### Claims of Genta's Default Under Various Agreements

During 1995, Genta Europe, one of our wholly-owned subsidiaries, received funding in the form of a loan from ANVAR, a French government agency, in the amount of FF5.4 million (or approximately US\$.729 million at December 31, 2001) with a scheduled maturity of December 31, 2002. Pursuant to the loan agreement with ANVAR, the utilization of the proceeds was intended to fund research and development activities. In October 1996, in connection with a restructuring of our operations, Genta terminated all scientific personnel of Genta Europe. In February 1998, ANVAR asserted that Genta Europe was not in compliance with the ANVAR Agreement, and that ANVAR might request immediate repayment of the loan. In July 1998, ANVAR notified Genta Europe of its demand for accelerated repayment of the loan in the amount of FF4.2 million (or approximately US\$.567

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million at December 31, 2001) and subsequently notified us that Genta was liable as a guarantor on the note. Based on the advice of French counsel, we do not believe that ANVAR is entitled to accelerated repayment under the terms of the ANVAR Agreement. We also believe it to be unlikely that Genta will incur any liability in this matter, although there can be no assurance thereof.

On June 30, 1998, Marseille Amenagement, a company affiliated with the city of Marseilles, France, filed suit in France to evict Genta Europe from its facilities in Marseilles and to demand payment of alleged back rent due and of a lease guarantee for nine years' rent. Following the filing of this claim and in consideration of the request for repayment of the loan from ANVAR, Genta Europe's Board of Directors directed the management to declare a "Cessation of Payment." Under this procedure, Genta Europe ceased operations and terminated its only remaining employee. A liquidator was appointed by the Court to take control of any assets of Genta Europe and to make payment to creditors. In December 1998, the Court in Marseilles dismissed the case against Genta Europe and indicated that it had no jurisdiction against Genta Incorporated. In August 1999, Marseille Amenagement instituted legal proceedings against us in the Commercial Court of Marseilles, alleging back rent and early termination receivables aggregating FF2.5 million (or approximately US\$.338 million at December 31, 2001). On October 8, 2001, the Commercial Court of Marseilles rendered their decision which declared the action brought by Marseille Amenagement was admissible and ordered Genta to pay an amount of FF1.9 million (or \$.260 million at October 8, 2001). We do not believe that Marseille Amenagement is entitled to payment and we are currently addressing alternative courses of action, including an appeal of this decision, or negotiations with Marseille Amenagement to achieve a mutually satisfactory resolution.

At December 31, 2001, the Company has accrued a net liability of \$.350 million related to the Liquidated Subsidiary and these related matters.

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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 this 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 assurance that we will be able to attract and retain the qualified personnel necessary for the development of our business.

Our stock price is volatile.

The market price of our common stock, like that of the common stock of many other biopharmaceutical companies, has been and likely will continue to be highly volatile. Factors that could have a significant impact on the future price of our common stock include:

- the results of pre-clinical studies and clinical trials by us or our



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

As of March 8, 2002, the Company had 66,565,781 shares of common stock outstanding. 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

In November 2000, the Company relocated its headquarters from Lexington, MA to Berkeley Heights, NJ and as of March 8, 2002, leases approximately 24,000 square feet of space. Such leases expire in February 2004 and June 2005.

### ITEM 3. LEGAL PROCEEDINGS

Prior to 1999, the Company manufactured specialty biochemical products through its manufacturing subsidiary, JBL Scientific, Inc. ("JBL"). Effective May 10, 1999, substantially all of the assets and certain liabilities of JBL were sold to Promega Biosciences, Inc. ("Promega"). Prior to the sale, in October 1996, JBL retained a chemical consulting firm to advise it with respect to an incident of soil and groundwater contamination (the "Spill"). Sampling conducted at the JBL facility revealed the presence of chloroform and perchloroethylenes ("PCEs") in the soil and groundwater at this site. A semi-annual groundwater-monitoring program is being conducted, under the supervision of the California Regional Water Quality Control Board, for purposes of determining whether the levels of chloroform and PCEs have decreased over time. The results of the latest sampling conducted by JBL show that PCEs and chloroform have decreased in all but one of the monitoring sites. Based on an estimate provided to the Company by the consulting firm, the Company accrued \$65,000 in 1999 relating to remedial costs. Although the Company has agreed to indemnify Promega in respect of this matter, in November 2001, the Company received from the California Regional Water Quality Control Board notification on the completion of site investigation and remedial action for these sites. The notification stated that no further action related to this case is required.

In October, 1998, JBL received notice from Region IX of the Environmental Protection Agency ("EPA") that JBL had been identified as a potentially responsible party ("PRP") at the Casmalia Disposal Site, which is located in Santa

Barbara, California. JBL has been designated as a de minimis PRP by the EPA. Based on volume amounts from the EPA, the Company concluded that it was probable that a liability had been incurred and accrued \$75,000 during 1998. In 1999, the EPA estimated that the Company would be required to pay approximately \$63,200 to settle their potential liability. In December 2001, the Company received a revised settlement proposal from the EPA in the amount of \$32,600, the terms of the settlement with the EPA containing standard contribution protection and release language. This settlement amount of \$32,600 was fully

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paid in January 2002.

During May 2000, Promega notified Genta of two claims against Genta and Genta's subsidiary, Genko Scientific, Inc. (f/k/a JBL Scientific, Inc.) ("Genko"), for indemnifiable damages in the aggregate amount of \$2,820,000 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 and that therefore Genta owed Promega approximately \$1.6 million. On October 16, 2000 Genta filed suit in the US District Court of California against Promega for the non payment of the \$1.2 million note plus interest. On November 6, 2000, Promega filed a countersuit alleging indemnifiable damages in the aggregate amount of \$2,820,000. During the first quarter of 2001, the Company 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 \$.2 million non-interest bearing note due to be repaid by Promega upon final resolution of certain environmental issues related to JBL and forgive all accrued interest.

### 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, 2001.

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## 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
	-----	-----
2001		
First Quarter.....	\$ 8.844	\$5.063
Second Quarter.....	10.120	5.070
Third Quarter.....	12.770	7.900
Fourth Quarter.....	17.700	9.900
2000		
First Quarter.....	\$14.000	\$5.875
Second Quarter.....	11.813	6.438
Third Quarter.....	10.125	5.375
Fourth Quarter.....	10.000	7.250

#### (b) Holders

There were 570 holders of record of the Company's common stock as of March 8, 2002.

#### (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

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currently intends to retain its earnings, if any, for the development of its business.

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ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

	YEARS ENDED	
(In thousands, except per share data)	2001	2000
Consolidated Statements of Operations Data(3):		
Revenues:		
License revenue .....	\$ 97	\$ 177
Royalties .....	49	5
Related party contract revenue .....	--	--
Collaborative research and development .....	--	--
	-----	-----
	146	22
	-----	-----
Costs and expenses:		
Research and development .....	39,355	6,830
General and administrative .....	8,215	3,323
Equity related compensation .....	1,074	8,605
Promega Settlement .....	1,000	--
LBC Settlement .....	--	--
	-----	-----
	49,644	18,758
	-----	-----
Loss from operations .....	(49,498)	(18,736)
Equity in net income (loss) of joint venture .....	--	502
Net loss of liquidated foreign subsidiary .....	--	--
Other income, principally interest .....	2,785	5,783
	-----	-----
Loss from continuing operations .....	\$ (46,713)	\$ (12,451)
Loss from discontinued operations .....	--	--
Gain on sale of discontinued operations .....	--	--
	-----	-----
Net loss .....	46,713)	(12,451)
Preferred stock dividends .....	--	(3,443)
	-----	-----
Net loss applicable to common shares .....	\$ (46,713)	\$ (15,894)
	=====	=====
Continuing operations .....	\$ (0.84)	\$ (0.41)
Discontinued operations .....	--	--
	-----	-----
Net loss per share (1) .....	\$ (0.84)	\$ (0.41)
	=====	=====
Weighted average shares used in computing net loss per share .....	55,829	38,659
	=====	=====
Deficiency of earnings to meet fixed charges(2)		

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	----- 2001 -----	2000 -----
CONSOLIDATED BALANCE SHEET DATA(3):		
Cash, cash equivalents and short-term investments .....	\$54,086	\$50,199
Working capital .....	42,709	48,321
Total assets .....	60,630	57,208
Notes payable and capital lease obligations, less current portion .	--	--
Total stockholders' equity .....	48,310	53,567

- (1) Computed on the basis of net loss per common share described in Note 2 of Notes to Consolidated Financial Statements.
- (2) The Company has incurred losses and, thus, has had a deficiency in fixed charge coverage since inception.
- (3) The above selected financial data reflects discontinued operations and balance sheet data of JBL as of May 10, 1999. See Note 15 to consolidated financial statements.

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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, research and development. 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 its inception to December 31, 2001, the Company has incurred a cumulative net loss of \$198.7 million. The Company has experienced significant quarterly fluctuations in operating results and it expects that these fluctuations in revenues, expenses and losses will continue.

Genta's strategy is to build a product and technology portfolio primarily focused on its oncology products. In this regard, effective March 1999, the Company significantly reduced its involvement with respect to Genta Jago, its 50% owned R & D joint venture. The Company also sold substantially all of the assets and certain liabilities of the Company's wholly owned specialty chemicals subsidiary JBL Scientific, Inc. ("JBL") for cash, a promissory note and certain pharmaceutical development services in support of Genta's Genasense(TM) development project in May 1999. During 1998, the Company ceased its European operations and liquidated Genta Europe, its European subsidiary. During 1999, the Company closed its facilities in San Diego, California and moved its headquarters to Lexington, Massachusetts. In October 2000, the Company relocated its entire operation to Berkeley Heights, New Jersey.

RESULTS OF OPERATIONS

Genta has focused its resources on the development of its lead antisense

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oligonucleotide, Genasense(TM). The following discussion of results of operations relates to the Company's continuing operations:

### SUMMARY OPERATING RESULTS FOR THE YEARS ENDED DECEMBER 31,

(\$ thousands)	2001	INCREASE (DECREASE)	2000	INCREASE (DECREASE)	1999
	----	-----	----	-----	----
Revenues:					
License fees	\$ 97	\$ 80	\$ 17	\$ 17	\$ -
Royalties	49	44	5	5	-
	-----	-----	-----	-----	-----
	146	124	22	22	-
Costs and expenses:					
Research and development	39,355	32,525	6,830	2,625	4,205
General and administrative	8,215	4,892	3,323	(731)	4,054
Promega settlement	1,000	1,000	-	-	-
Equity related compensation	1,074	(7,531)	8,605	5,531	3,074
	-----	-----	-----	-----	-----
	49,644	30,886	18,758	7,425	11,333
	-----	-----	-----	-----	-----
Loss from operations	(49,498)	30,762	(18,736)	7,403	(11,333)
Equity in net income of					
joint venture	-	(502)	502	(1,946)	2,448
Other income	2,785	(2,998)	5,783	5,760	23
	-----	-----	-----	-----	-----
Net loss from continuing operations	\$ (46,713)	\$ 34,262	\$ (12,451)	\$ 3,589	\$ (8,862)
	=====	=====	=====	=====	=====

Operating revenues consisting of license fees and royalties were \$.146 million in 2001 compared to \$.022 million in 2000. These revenues were derived from non-exclusive sub-license agreements involving antisense technology. These agreements were initiated with Atugen AG and EpeGenesis Pharmaceuticals, Inc. in 2001, and Sequitur Incorporated and Oasis Biopharmaceuticals, Inc. in 2000. The disposition of substantially all JBL assets in 1999 resulted in a significant decrease in ongoing revenues, as all of the Company's historical product sales were attributable to JBL.

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Costs and expenses totaled \$49.6 million in 2001 compared to \$18.8 million in 2000 and \$11.3 million in 1999. These increases reflect additional clinical trial activity and related drug supply, salaries and non-cash stock compensation charges. 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, the Genasense(TM) antisense oligonucleotide program and increased regulatory costs. The Company will continue to assess the potential cost benefit ratio of

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developing its own antisense oligonucleotide manufacturing, and marketing and sales activities if and as such products are successfully developed and approved for marketing.

Research and development expenses totaled \$39.4 million in 2001 compared to \$6.8 million in 2000 and \$4.2 million in 1999. The increase from 1999 through 2001 is due primarily to drug supply costs, investigator and monitor fees related to expanded clinical trials, along with increased patent amortization costs relating to intellectual property acquisitions in 2000. It is anticipated that research and development expenses will continue to increase in the future, as the development program for Genasense(TM) expands. 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.

General and administrative expenses were \$8.2 million in 2001 compared to \$3.3 million in 2000 and \$4.1 million in 1999. Such expenses do not include charges related to non-cash equity related compensation. The \$4.9 million increase from 2000 to 2001 reflects increased payroll costs associated with additional headcount and increased marketing expenses offset by reduced patent abandonment costs. The Company recorded charges to general and administrative expenses of \$.523 million in 1999 to account for the carrying value of abandoned patents no longer related to the research and development efforts of the Company. The amounts recorded in 2001 and 2000 were immaterial. The Company's policy is to evaluate the appropriateness of carrying values of the unamortized balances of long-lived and intangible assets on the basis of estimated future cash flows (undiscounted) and other factors. If such evaluation were to identify a material impairment of these assets, such impairment would be recognized by a write-down of the applicable assets. The Company continues to evaluate the continuing value of patents and patent applications, particularly as expenses to prosecute or maintain these patents come due. Through this evaluation, the Company may elect to continue to maintain these patents, seek to out-license them, or abandon them.

The Company recorded charges to non-cash equity related compensation of \$1.1 million in 2001 compared to \$8.6 million in 2000 and \$3.1 million in 1999. This decrease is primarily due to the acceleration of outstanding stock options for the four members of the Company's Board of Directors who resigned in March 2000 (Note 13).

The Company had no equity in earnings of its joint venture (Genta Jago) in 2001 compared to \$.5 in 2000 and \$2.4 million in 1999. 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. Pursuant to the terms of the agreement, earnings of the joint venture are to be allocated equally between the two parties. Accordingly, Genta recognized \$.502 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 no earnings or losses of the joint venture to be allocated between the two parties.

Interest income has fluctuated significantly each year and is anticipated to continue to fluctuate primarily due to changes in the levels of cash, investments and interest rates during each period.

The Company recorded a gain on the sale of marketable securities of approximately \$.061 million in 2001 compared to \$4.9 million in 2000, which reflects a non-recurring gain on the disposition of securities in September 2000. Genta exercised 66,221 warrants to purchase shares of common stock of CV Therapeutics, Inc. ("CV"). These warrants, which were restricted and not traded, were issued to Genta by CV in connection with a licensing arrangement entered into in 1993. The Company received approximately \$4.9 million in cash upon the sale of such common shares.

#### RECENT ACCOUNTING PRONOUNCEMENTS

The Company has adopted all required Statements of Financial Accounting Standards issued subsequent to December 31, 2000, as more fully discussed in Note 2 to the Consolidated Financial Statements. Adoption of these standards did not or are not expected to have a material 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. In preparing our financial statements, 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. We believe that our most critical accounting policies relate to:

- Revenue recognition. The Company's 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 has been determined to be fixed and determinable, and collectibility is reasonably assured. Royalties are recognized when earned.
- Research and development costs. All such costs are expensed or incurred, including raw material costs required to manufacture drugs for clinical trials.
- Intangible assets. The Company's intangible assets consist primarily of licensed technology and capitalized patent costs, and are amortized using the straight-line method over their estimated useful lives. 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 intangible assets, such impairment would be recognized by a write-down of the applicable assets. The Company evaluates the continuing value of patents and patent applications each financial reporting period. As a result of this evaluation, the Company may elect to continue to maintain, seek to out-license, or abandon these patents.

#### LIQUIDITY AND CAPITAL RESOURCES

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Since inception, the Company has financed its operations primarily from private placements and public offerings of its equity securities. Cash provided from these offerings totaled approximately \$207.8 million through December 31, 2001, including net proceeds of \$32.2 million received in 2001, \$40.0 million received in 2000 and \$10.4 million received in 1999. The Company used \$35.0 million in operating activities during 2001, resulting from a net loss of \$46.7 million, offset by non-cash charges and improved working capital aggregating \$11.7 million. At December 31, 2001, the Company had cash, cash equivalents and short-term investments totaling \$54.1 million compared to \$50.2 million at December 31, 2000. Management believes that at the current rate of spending, primarily in support of on-

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going and anticipated clinical trials, the Company will have sufficient cash funds to maintain its present operations into the first quarter of 2003.

If the Company successfully secures sufficient levels of collaborative revenues and other sources of financing, it expects to use such financing to continue to expand its ongoing research and development activities, preclinical testing and clinical trials, costs associated with the market introduction of potential products, and expansion of its administrative activities.

The Company anticipates that significant additional sources of financing, including equity financing, will be required in order for the Company to continue its planned operations. The Company also anticipates seeking additional product development opportunities from external sources. Such acquisitions may consume cash reserves or require additional cash or equity. The Company's working capital and additional funding requirements will depend upon numerous factors, including: (i) the progress of the Company's research and development programs; (ii) the timing and results of pre-clinical testing and clinical trials; (iii) the level of resources that the Company devotes to sales and marketing capabilities; (iv) technological advances; (v) the activities of competitors; and (vi) the ability of the Company 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.

Future minimum obligations at December 31, 2001 are as follows (\$ thousands):

	OPERATING LEASES	DRUG PURCHASE COMMITMENTS
	-----	-----
2002.....	\$ 589	\$11,750
2003.....	694	-
2004.....	432	-
2005.....	322	-
2006.....	15	-
Thereafter.....	-	-
	-----	-----
Total.....	\$2,052	\$11,750

### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

The Company's carrying values of cash, marketable securities, accounts payable and accrued expenses are a reasonable approximation of their fair value. The estimated fair values of financial instruments have been determined by the Company using available market information and appropriate valuation methodologies.



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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 the Company could realize in a current market exchange. The Company has not entered into, and does not expect to enter into, financial instruments for trading or hedging purposes. The Company does not currently anticipate entering into interest rate swaps and/or similar instruments.

Since the Company has liquidated its Genta Europe subsidiary, the Company has no material currency exchange or interest rate risk exposure as of December 31, 2001. With the liquidation, there will be no ongoing exposure to material adverse effect on the Company's business, financial condition, or results of operation for sensitivity to changes in interest rates or to changes in currency exchange rates.

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### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

GENTA INCORPORATED  
INDEX TO FINANCIAL STATEMENTS COVERED  
BY REPORT OF INDEPENDENT AUDITORS

Genta Incorporated	
Report of Independent Auditors.....	
Consolidated Balance Sheets at December 31, 2001 and 2000.....	
Consolidated Statements of Operations for the years ended December 31, 2001, 2000 and 1999.....	
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2001, 2000 and 1999.....	
Consolidated Statements of Cash Flows for the years ended December 31, 2001, 2000 and 1999.....	
Notes to Consolidated Financial Statements.....	

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### 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 its subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. 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.

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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 the Company as of December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States of America.

DELOITTE & TOUCHE LLP

Parsippany, New Jersey  
February 21, 2002

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### GENTA INCORPORATED CONSOLIDATED BALANCE SHEETS

(Dollars in thousands, except per share data)

#### ASSETS

##### Current assets:

Cash and cash equivalents .....	
Short term investments .....	
Notes receivable .....	
Prepaid expenses and other current assets .....	

Total current assets .....

Property and equipment, net .....	
Intangibles, net .....	
Prepaid royalties .....	
Deposits and other assets .....	

Total assets .....

#### LIABILITIES AND STOCKHOLDERS' EQUITY

##### Current liabilities:

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Accounts payable .....	
Accrued expenses .....	
Other current liabilities .....	
Total current liabilities .....	
Commitments and contingencies	
Stockholders' equity:	
Series A convertible preferred stock, \$.001 par value; 5,000,000 shares authorized, 261,200 shares issued and outstanding at December 31, 2001 and 2000, respectively; liquidation value is \$13,050 .....	
Common stock; \$.001 par value; 95,000,000 shares authorized, 66,000,210 and 51,085,375 shares issued and outstanding at December 31, 2001 and 2000, respectively .....	
Additional paid-in capital .....	
Accumulated deficit .....	
Deferred compensation .....	
Accumulated other comprehensive (loss) income .....	
Total stockholders' equity .....	
Total liabilities and stockholders' equity .....	

See accompanying notes to consolidated financial statements.

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GENTA INCORPORATED  
CONSOLIDATED STATEMENTS OF OPERATIONS

	YEARS ENDED	
(Dollars in thousands, except per share data)	2001	2000
Revenues:		
License fees .....	\$ 97	\$ 97
Royalties .....	49	49
	-----	-----
	146	
Costs and expenses:		
Research and development .....	39,355	
General and administrative .....	8,215	
Promega settlement .....	1,000	
Equity related compensation .....	1,074	
	-----	-----
	49,644	
Loss from operations .....	(49,498)	
Equity in net income of joint venture .....	--	
Other income .....	2,785	
	-----	-----
Loss from continuing operations .....	(46,713)	
Loss from discontinued operations .....	--	
Gain on sale of discontinued operations .....	--	

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Net loss .....	(46,713)	
Preferred stock dividends .....	--	
Net loss applicable to common shares .....	\$ (46,713)	\$
Net (loss) income per share:		
Continuing operations .....	\$ (0.84)	\$
Discontinued operations .....	--	
Net loss per common share .....	\$ (0.84)	\$
Shares used in computing net loss per common share .....	55,829	

See accompanying notes to consolidated financial statements.

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GENTA INCORPORATED  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
For the Years Ended December 31, 1999, 2000 and 2001

(In thousands)	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accrued Dividends Payable	De
	Shares	Amount	Shares	Amount				
BALANCE AT JANUARY 1, 1999.....	633	\$--	10,426	\$11	\$131,260	\$(132,054)	\$ 4,476	
Comprehensive loss:								
Net loss.....	--	--	--	--	--	(7,444)	--	
Total comprehensive loss...								
Issuance of common stock upon conversion of convertible preferred stock .....	(233)	--	8,918	9	1,634	--	(1,643)	
Issuance of common stock in connection with a private placement, net of issuance costs of \$1,071.....	--	--	3,810	4	10,353	--	--	
Issuance of common stock in connection with exercise of warrants and stock options.....	--	--	293	--	1,392	--	--	
Preferred stock dividends .....	--	--	2,010	2	(2,435)	--	2,301	
Deferred compensation related to stock options ..	--	--	--	--	4,659	--	--	
BALANCE AT DECEMBER 31, 1999...	400	--	25,457	26	146,863	(139,498)	5,134	

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Comprehensive loss:							
Net loss.....	--	--	--	--	--	(12,451)	--
Unrealized investment gain.	--	--	--	--	--	--	--
Total comprehensive loss...							
Issuance of common stock upon conversion of convertible preferred stock .....	(139)	--	14,486	15	(14)	--	--
Issuance of common stock in connection with two private placements, net of issuance costs of \$2,548.....	--	--	6,458	6	40,095	--	--
Issuance of common stock in connection with exercise of warrants and stock options.....	--	--	3,345	3	3,254	--	--
Issuance of common stock in payment of preferred stock dividends .....	--	--	953	1	5,133	--	(5,134)
Deferred compensation related to stock options ..	--	--	--	--	7,368	--	--
Issuance of common stock in connection with rights to Relgen license agreement ..	--	--	10	--	84	--	--
Issuance of common stock in connection with MBI asset purchase .....	--	--	376	--	2,400	--	--
Value of shares to be issued related to license agreement.....	--	--	--	--	1,268	--	--
	-----	-----	-----	-----	-----	-----	-----
BALANCE AT DECEMBER 31, 2000...	261	--	51,085	51	206,451	(151,949)	--
Comprehensive loss:							
Net loss.....	--	--	--	--	--	(46,713)	--
Unrealized investment gain.	--	--	--	--	--	--	--
Total comprehensive loss...							
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	--	--
Issuance of common stock in connection with exercise of warrants and stock options.....	--	--	12,245	12	8,309	--	--
Issuance of common stock as hiring bonus .....	--	--	6	--	--	--	--
Issuance of common stock related to license agreement.....	--	--	162	--	--	--	--
Deferred compensation related to stock options ..	--	--	--	--	1,705	--	--

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BALANCE AT DECEMBER 31, 2001...	261	\$--	66,000	\$66	\$248,685	\$(198,662)	\$ --
	=====	===	=====	===	=====	=====	=====

See accompanying notes to consolidated financial statements.

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GENTA INCORPORATED  
CONSOLIDATED STATEMENTS OF CASH FLOWS

(Dollars in thousands)

OPERATING ACTIVITIES:

Net loss .....	\$ (46)
Items reflected in net loss not requiring cash:	
Depreciation and amortization .....	1
Equity in net income of joint venture .....	
Gain on sale of discontinued operations .....	
Loss on disposition of patents and equipment .....	
Promega settlement .....	1
Non-cash equity related compensation .....	1
Changes in operating assets and liabilities:	
Accounts and notes receivable .....	
Other assets .....	
Accounts payable, accrued and other expenses .....	8
Net cash used in operating activities .....	(34)

INVESTING ACTIVITIES:

Purchase of available-for-sale short-term investments .....	(14)
Maturities of available-for-sale short-term investments .....	29
Purchase of property and equipment .....	(1)
Proceeds from sale of discontinued operations, net .....	
Purchase of intangibles .....	
Deposits and other .....	
Net cash provided by (used in) investing activities .....	13

FINANCING ACTIVITIES:

Proceeds from private placements of common stock, net .....	32
Proceeds from exercise of warrants and options .....	8
Proceeds from equipment conversion to lease .....	
Net cash provided by financing activities .....	40
(Decrease) increase in cash and cash equivalents .....	19
Less cash at liquidated foreign subsidiary .....	

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Cash and cash equivalents at beginning of year .....	19
Cash and cash equivalents at end of year .....	\$ 38

See accompanying notes to consolidated financial statements.

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## GENTA INCORPORATED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2001, 2000 AND 1999

### 1. ORGANIZATION AND BUSINESS

Genta Incorporated ("Genta" of the "Company"). Genta 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 previously manufactured and marketed specialty biochemicals and intermediate products through its manufacturing subsidiary, JBL Scientific, Inc. ("JBL"). Substantially all of the subsidiary's assets were sold in May 1999, and accordingly, JBL is presented as a discontinued operation for the year ended December 31, 1999 (Note 15). The Company also has a 50% equity interest in Genta Jago Technologies B.V. ("Genta Jago"), a drug delivery system joint venture with SkyePharma, PLC ("SkyePharma"). In March 1999, Genta and SkyePharma entered into an interim agreement pursuant to which the parties to the joint venture released each other from all liability relating to unpaid development costs and funding obligations. Since the first quarter of 2000, there has been no activity within the joint venture and we are currently seeking to terminate our involvement. In August 1999, the Company acquired Androgenics Technologies, Inc. ("Androgenics"), which developed a proprietary series of compounds that act to inhibit the growth of prostate cancer cells. In April 2000, the Company entered into an asset purchase agreement with Relgen LLC, a privately held corporation and a party related to Genta, in which the Company acquired all assets, rights and technology to a portfolio of gallium containing compounds, including Ganite(R).

The Company has had recurring operating losses since inception and management expects that such losses will continue for the next several years. Although no assurances can be expressed, management believes that at the current rate of spending, the Company will have sufficient cash funds to maintain its present operations into the first quarter of 2003.

The Company is also actively seeking 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 generally accepted accounting principles recognized in the United States. All professional accounting standards that are effective as of December 31, 2001 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.

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### Revenue Recognition

In 2001 and 2000, the Company entered into worldwide non-exclusive license agreements. The license agreements each have initial terms which expire in 2010 and include upfront payments in cash, annual licensing fee payments for two years, and future royalties on product sales. The Company's policy is to recognize revenues under these arrangements when delivery has occurred or services have been rendered, persuasive evidence of an arrangement exists, the fee has been determined to be fixed and determinable and collectibility is reasonably assured. Since each of the aforementioned licensing arrangements have variable payment terms extending beyond one year, such fees are recognized as earned.

### Research and Development

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

### Cash, Cash Equivalents and Short-Term Investments

Cash and cash equivalents consisted entirely of money market funds. The carrying amounts of cash, cash equivalents and short-term investments approximate fair value due to the short-term nature of these instruments. Marketable short-term investments consisted primarily of corporate notes, 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 with "AA" or greater credit ratings as defined by Standard & Poors. 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



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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.

### 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.

### 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.

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### Stock Options

The Company has elected to follow Accounting Principles Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for its employee stock options as provided for under SFAS No. 123, "Accounting for Stock-Based Compensation," including pro forma disclosures.

Stock option grants and similar equity instruments granted to non-employees are accounted for under the fair value method provided for in SFAS No. 123 and Emerging Issues Task Force ("EITF"), 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."

### 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.

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Net loss per common share for the three years ended December 31, 2001 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 17.2 million, 28.3 million and 45.1 million in 2001, 2000 and 1999, respectively, have been excluded in 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 October 2001, the FASB issued Statement of Financial Accounting Standards 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets". SFAS 144 requires that one accounting model be used for long-lived assets to be disposed of by sale whether previously held and used or newly acquired, and by broadening the presentation of discontinued operations to include more disposal transactions. SFAS 144 will be effective for fiscal years beginning after December 15, 2001. The adoption of SFAS 144 as of the effective date did not have a material effect on the Company's financial position or results of operations.

In August 2001, the FASB issued Statement of Financial Accounting Standards 143 ("SFAS 143"), "Accounting for Asset Retirement Obligations". SFAS 143 requires that the liability for an asset retirement obligation should be recognized at its fair market value when these liabilities are incurred. SFAS 143 will be effective for fiscal years beginning after June 15, 2002 and the Company intends to adopt the provisions of SFAS 143 as of the effective date but does not expect SFAS 143 to have a material effect on the Company's financial position or results of operations.

In July 2001, the Financial Accounting Standards Board issued SFAS 142, "Goodwill and Other Intangible Assets". SFAS 142 requires periodic evaluation of goodwill and indefinite lived intangible assets for impairment and discontinues amortization of such intangibles. SFAS 142 will be effective for fiscal years beginning after December 15, 2001. The adoption of SFAS 142 as of the effective date did not have a material impact on the Company's financial position or results of operations.

In June 2001, the Financial Accounting Standards Board approved for issuance Statement of Financial Accounting Standards 141 (SFAS 141), "Business Combinations". This standard eliminated the pooling method of accounting for

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business combinations initiated after June 30, 2001. The Company has adopted the provisions of SFAS 141 as of the effective date but does not expect SFAS 141 to have a material effect on the Company's financial position or results of operations.

### 3. SHORT-TERM INVESTMENTS

The carrying amounts of short-term investments 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):

DECEMBER 31, 2001

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	Amortized costs	Unrealized gains	Unrealized losses	Estima fair v
Corporate debt securities.....	\$16,054 =====	\$23 ===	\$ (89) =====	\$15,9 =====
DECEMBER 31, 2000				
Corporate debt securities.....	\$31,079	\$ 31	\$ -	\$31,1
Equity securities.....	-	64	-	
	\$31,079 =====	\$95 ===	\$ - ===	\$31,1 =====

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

	DECEMBER 31,	
	2001	2000
Due in one year or less.....	\$15,988	\$18,9
Due after one year.....	-	12,2
	\$15,988 -----	\$31,1 =====

The estimated fair value of each marketable security has been compared to its cost, and therefore, an unrealized loss of approximately \$.066 million has been recognized in accumulated other comprehensive loss at December 31, 2001.

4. PROPERTY AND EQUIPMENT

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

	ESTIMATED USEFUL LIVES	DECEMBER 2001
Computer equipment.....	3	\$ 599
Software.....	3	256
Leasehold improvements.....	5	523
Equipment.....	5	74
Furniture and fixtures.....	5	764
		2,216
Less accumulated depreciation and amortization.....		(368)
		\$1,848 =====

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5. NOTES RECEIVABLE

In May 1999, the Company accepted a \$1.2 million 7% promissory note (the "JBL Note") from Promega as partial consideration for the JBL Agreement (Note 15). The principal of the note plus accrued interest was due as follows: \$.700 million on June 30, 2000 and \$.500 million on the later of June 30, 2000 or the Environmental Compliance Date as defined in the JBL Agreement. Accrued interest due the Company was \$.138 million at December 31, 2000. During the first quarter of 2001, the Company 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 \$.2 million non-interest bearing note due upon final resolution of certain environmental issues related to JBL and forgive all accrued interest. The transaction resulted in a non-recurring charge of \$1.0 million for the quarter ended March 31, 2001.

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6. GENTA JAGO JOINT VENTURE

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. Pursuant to the terms of the agreement, earnings of the joint venture are to be allocated equally between the two parties. Accordingly, Genta recognized \$.502 million and \$2.448 million as its equity in net income of the joint venture in 2000 and 1999, respectively. Since the first quarter of 2000, there have been no earnings or losses of the joint venture to be allocated between the two parties.

	YEAR ENDED DECEMBER 31, 1999
	-----
(In thousands)	
STATEMENTS OF OPERATIONS DATA:	
Collaborative research and development revenues.....	\$ 1,000
Costs and expenses.....	473
	-----
Income for operations.....	527
Extraordinary items - extinguishment of debt.....	21,229
	-----
Net (loss)/income.....	\$21,756
	=====

Financial statements of the joint venture for the year ended December 31, 2001 and 2000 were not available.

7. INTANGIBLES

Intangible assets consist of the following (\$ thousands):

	DECEMBER 31,	
	-----	-----
	2001	2000
	-----	-----

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Patent and patent applications .....	\$ 3,905	\$ 3,952
Other amortizable costs .....	87	87
	-----	-----
	3,992	4,039
Less accumulated amortization .....	(1,872)	(1,116)
	-----	-----
	\$ 2,120	\$ 2,923
	=====	=====

In May 2000, the Company entered into a worldwide licensing arrangement with Molecular Biosystems, Inc. ("MBI"), for a broad portfolio of antisense patents and technologies for therapeutic and diagnostic applications. The arrangement includes grants of both exclusive and non-exclusive license rights to Genta on a royalty-free basis in return for cash and common stock. The Company has recorded the fair value of the consideration paid as intangible assets, which assets are being amortized over five years.

In April 2000, the Company entered into an asset purchase agreement with Relgen LLC, a privately held corporation and a related party of Genta, in which the Company acquired all assets, rights and technology to a portfolio of gallium containing compounds, in exchange for common stock valued at \$.084 million. The consideration paid was recorded as an intangible asset and is being amortized over five years.

The Company wrote-off \$.361 million of fully amortized patents for the year ended December 31, 2000.

8. PREPAID ROYALTIES

In December 2000, the Company recorded \$1.268 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. These shares were issued in the first quarter of 2001. The Company will amortize the prepaid royalties upon the commercialization of Genasense(TM), the Company's leading antisense drug, through the term of the arrangement, which expires twelve years from the date of first commercial sale.

9. ACCRUED EXPENSES

Accrued expenses is comprised of the following (\$ thousands):

	DECEMBER 31,	
	2001	2000
	-----	-----
Accrued expenses relating to clinical trials....	\$ 792	\$ 834
Accrued placement agent commission.....	-	549
Accrued compensation.....	822	225
Accrued costs relating to new offices.....	-	195
Other accrued costs.....	695	650
	-----	-----
	\$2,309	\$2,453
	=====	=====

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10. INCOME TAXES

Significant components of the Company's deferred tax assets as of December 31, 2001 and 2000 and related valuation reserves are presented below (\$ thousands):

	DECEMBER 31,	
	2001	2000
DEFERRED TAX ASSETS:		
Deferred compensation.....	\$ 5,292	\$ 4,834
Net operating loss carryforwards.....	3,414	30,725
Research and development credits.....	5,554	3,359
Purchased technology and license fees.....	4,519	4,503
Depreciation, net.....	18	-
Other, net.....	246	275
	-----	-----
	69,043	43,696
Valuation allowance for deferred tax assets.....	(68,999)	(43,553)
	-----	-----
Net deferred tax assets.....	44	143
DEFERRED TAX LIABILITIES:		
Patent expenses.....	(44)	(134)
Depreciation, net.....	-	(9)
	-----	-----
	(44)	(143)
	-----	-----
Net deferred tax assets (liabilities).....	\$ -	\$ -
	=====	=====

A full valuation allowance has been provided at December 31, 2001 and 2000 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, 2001, the Company has federal and state net operating loss carryforwards of approximately \$142.0 million and \$59.5 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 will begin expiring in 2003, unless previously utilized. The Company also has federal research and development tax credit carryforwards of \$5.5 million, which will begin expiring in 2003, unless previously utilized.

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 future annual utilization of net operating loss carryforwards and research and development tax credits will be limited due to such ownership changes.

11. OPERATING LEASES

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At December 31, 2001 and 2000, the Company maintained \$.365 and \$.247 million, respectively, in restricted cash balances with a financial institution related to lease obligations on its corporate facilities. 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.

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Future minimum obligations under operating leases at December 31, 2001 are as follows (\$ thousands):

	OPERATING LEASES
	-----
2002.....	\$ 589
2003.....	694
2004.....	432
2005.....	322
2006.....	15
	-----
Thereafter.....	-
	-----
Total.....	\$2,052
	=====

### 12. STOCKHOLDERS' EQUITY

#### Common Stock

In March 1999, the Company agreed to grant 50,000 shares of common stock to Georgetown University (the "University") as consideration for services to be performed pursuant to a clinical trials agreement. (the "Agreement"). According to the terms of the Agreement, the University was to perform studies of the Company's leading antisense drug, Genasense(TM), on 24 patients, commencing in April 1999. Pursuant to the terms of the agreement, Genta would issue 25,000 of the shares to the University upon the completion of the first 12 patient studies, with the remaining shares to be issued upon the completion of the remaining patients. During 2000, the first 12 patient studies were completed. Accordingly, the estimated fair value of these shares of \$.363 million, which was included as a charge to non-cash equity related compensation in the amounts of \$.215 million and \$.148 million in 2000 and 1999, respectively.

In August 1999, the Company acquired Androgenics Technologies, Inc. ("Androgenics"), a wholly owned entity of the Company's majority stockholder. Androgenics is a company with license rights to a series of compounds invented at the University of Maryland, Baltimore to treat prostate cancer. As consideration for the acquisition, the Company paid \$.132 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 1,000,000 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. As of December 31, 2001, the above-mentioned milestones have not been met.

In August 1999, the Company settled lawsuits with Johns Hopkins University ("Johns Hopkins") and Drs. Paul Ts'o and Paul Miller ("Ts'o/Miller Partnership") for \$.380 million. As part of the settlement of claims, the Company paid \$.180

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million in cash and issued 69,734 shares of common stock to Johns Hopkins, acting on its behalf and on behalf of Ts'o/Miller Partnership. A broker sold the stock under an agreement between the Company and Johns Hopkins, with the proceeds from such sales delivered to Johns Hopkins.

In December 1999, the Company received net proceeds of approximately \$10.4 million through the private placement of 114 units (the "1999 Private Placement"). Each unit sold in the 1999 Private Placement consisted of (i) 33,333 shares of common stock, par value \$.001 per share ("common stock"), and (ii) warrants to purchase 8,333 shares of the Company's common stock at any time prior to the fifth anniversary of the final closing (the "Warrants"). The Warrants are convertible at the option of the holder into shares of common stock at an initial conversion rate equal to \$4.83 per share, subject to antidilution adjustment. There were a total of 3.809 million shares of common stock, and 952,388 warrants issued in connection with the 1999 Private Placement. The placement agent, a related party, received cash commissions equal to 7.5% of the gross sales price, reimbursable expenses up to \$.125 million and 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. During 2000, 57,147 penalty warrants were issued to the 1999 private placement investors as a result of an SEC registration statement not becoming effective within the prescribed 120 day period after closing.

In January 2000, the Board of Directors approved an amendment to increase the authorized common stock to 95,000,000 shares from 65,000,000. In May 2000, shareholders approved this amendment at the annual meeting of stockholders.

In April 2000, the Company entered into an asset purchase agreement with a privately held corporation and a party related of Genta, in which the Company acquired all assets, rights and technology to a portfolio of gallium containing compounds, known as Ganite(R), in exchange for common stock valued at \$.084 million. These compounds are used to treat cancer-related hypercalcemia.

In May 2000, the Company entered into a worldwide licensing arrangement for a broad portfolio of patents and technologies that relate to antisense for therapeutic and diagnostic applications. The arrangement includes grants of both exclusive and non-exclusive rights from the licensor to Genta on a royalty-free basis in return for cash and shares of common stock.

In September 2000, the Company sold 2.163 million shares of common stock through a private placement and received net proceeds of approximately \$13.7 million, net of placement costs. The placement agent received cash commissions equal to 7.0% of the gross sales price. In connection with the financing, 135,639 warrants valued at \$.867 million were issued to the placement agent. In addition, 20,641 penalty warrants were subsequently issued as a result of untimely filing of an SEC registration statement within the prescribed 30 day period after closing.

In November 2000, the Company sold 4.285 million shares of common stock through a private placement and received net proceeds of approximately \$26.8 million, net of placement costs. The placement agents, one a related party shareholder, received cash commissions equal to 7.0% of the gross sales price.

In December 2000, the Company recorded \$1.268 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, concerning antisense technology licensed by such 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.



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In November 2001, the Company sold 2.5 million shares of common stock through a private placement and received net proceeds of approximately \$32.2 million, net of placement agent commissions of \$.420 million and related expenses.

### Preferred Stock

The Company has authorized 5,000,000 shares of preferred stock and has issued and outstanding 261,000 shares of Series A Convertible Preferred Stock as of December 31, 2001. 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

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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, 2001 and 2000, each share of Series A Preferred Stock was convertible into 7.1573 and 7.3967 shares of common stock, respectively.

Terms of the Company's Series A Preferred Stock required the payment of annual dividends as follows: \$3 per share for the first year, \$4 per share in the second year, and \$5 per share in the third and fourth years, payable in cash or in shares of common stock converted at fair market value at the option of the Company's Board of Directors. Dividends were paid in common stock in September 1996, for the first and second year, pursuant to these terms. During 1999, the Company issued 1,085,420 shares of common stock to Series A Preferred Stockholders in payment of accrued dividends for the third and fourth year. There are no further dividend requirements after September 30, 1998.

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.

### Series D Preferred Stock

In June 1997, the Company received gross proceeds of approximately \$16.2 million (approximately \$14.0 million net of placement costs) through the private placement of 161.58 Premium Preferred Units(TM). Each unit sold in the private placement consisted of (i) 1,000 shares of Premium Preferred Stock(TM), par value \$.001 per share, stated value \$100 per share (the "Series D Preferred Stock"), and (ii) warrants to purchase 5,000 shares of the Company's common stock, (the "Class D Warrants") at any time prior to the fifth anniversary of the final closing (the "Class D Warrants").

In May 1998, the Company requested, and subsequently received, consents (the "Letter Agreements") from the holders of a majority of the Series D

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Preferred Stock to waive the Company's obligation to use best efforts to obtain the effectiveness of a registration statement with the SEC as to common stock issuable upon conversion of Series D Preferred Stock and exercise of Class D Warrants. In exchange, the Company agreed to waive the contractual "lock-up" provisions to which such consenting holders were subject and which provisions would have prevented the sale of up to 75% of their securities for a nine-month period following the effectiveness of the registration statement. The Company also agreed to extend the Reset Date referred to in the Certificate of Designation of the Series D Preferred Stock to January 29, 1999 from June 29, 1998. In addition, through the Letter Agreements, the Company agreed to issue to such holder's warrants to purchase at \$0.94375 per share, an aggregate of up to 807,900 shares of common stock, subject to certain anti-dilution adjustments, exercisable until June 29, 2002. The Company had conditioned the effectiveness of such consent on its acceptance by a majority of the Series D Preferred Stockholders.

In March 2000, the Board of Directors approved the mandatory conversion of all Series D Convertible Preferred Stock, par value \$.001 per share ("Series D Preferred Stock"), and the mandatory redemption of all outstanding Class D Warrants. As a result of the conversion of the Series D Preferred Stock, the Company issued approximately 14.4 million shares of common stock. The Company realized approximately \$1.4 million from the exercise of the Class D Warrants and issued 2.0 million shares of common stock. The Company intends to redeem the remaining 155,640 Class D Warrants at \$0.10 per warrant for approximately \$.016 million. No dividends have been accrued after January 29, 2000 due to the mandatory conversion of the Series D Preferred Stock.

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Subsequent to the Reset Date of January 29, 1999, Series D Preferred Stock earned dividends, payable in shares of the Company's common stock, at the rate of 10% per annum, based on a stated value of \$140 per share. In calculating the number of shares of common stock to be paid with respect to each dividend, each share of common stock was deemed to have the value of the Conversion Price at the time such dividend was paid. The Company was restricted from paying cash dividends on common stock until such time as cumulative dividends on outstanding shares of Series D Preferred Stock were paid. Additionally, the Company could not declare a dividend to its common stockholders until such time that a special dividend of \$140 per share was paid on the Series D Preferred Stock. The Company issued 953,000 and 924,519 shares of common stock as payment of dividends in 2000 and 1999, respectively. Accordingly, the Company provided dividends for \$5.1 million and \$2.3 million for the years ended December 31, 2000 and 1999, respectively, based on the fair value of the common stock. As a result of the Mandatory Conversion of Series D Preferred Stock in June 2000, no further dividends were paid or accrued.

In connection with certain warrants issued in 1998 related to Series D Preferred Stock, the Company was contingently liable for \$.150 million in commissions upon the exercise of the warrants, which were exercised in September 2001, resulting in commissions expense of \$.150 million.

### Warrants

Summary information with respect to outstanding common stock warrants at December 31, 2001 is presented below:

EXERCISE	POTENTIAL WARRANT	COMMON
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	PRICE -----	EXERCISE PROCEEDS -----	EQUIVALEN -----
JUNE 1997 PRIVATE PLACEMENT (SERIES D):			
Placement & Advisory Warrants.....	\$0.86465 - \$1.10	\$3,041,535	3,359,387
ANDROGENICS WARRANTS (AUGUST 1999):			
Vested December 30, 1999.....	\$1.25	121,875	97,500
Vest upon achievement of various milestones...	\$1.50 - \$2.50	1,787,500	900,000
DECEMBER 1999 PRIVATE PLACEMENT (COMMON):			
Related Party Warrants:			
Common Stock.....	\$3.30	1,095,897	332,090
Warrants.....	\$5.31	440,857	83,024
Funding Warrants.....	\$4.69716	3,115,796	660,094
Penalty Warrants (May 2000).....	\$4.69716	235,587	49,910
SEPTEMBER 2000 PRIVATE PLACEMENT (COMMON):			
Penalty Warrants.....	\$6.75	97,193	14,399
Placement Agent Warrants.....	\$7.1500	760,839	106,411
Placement Agent Warrants.....	\$7.4250	323,812	43,611
NOVEMBER 2000 PRIVATE PLACEMENT (COMMON):			
Placement Agent Warrants.....	\$7.4250	480,509	64,715
		-----	-----
		\$11,501,400	5,711,141
		=====	=====

In February 1997, the Company issued warrants to purchase 6.4 million shares of common stock at \$0.471875 per share (subject to antidilution adjustments of 1.7 million shares) in connection with \$3.0 million of convertible notes issued. Such warrants were exercised for \$3.0 million in September 2001.

In June 1997, in connection with the issuance of the 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. As of December 31, 2001, 174,272 and 239,242 have been exercised in 2001 and 2000, respectively. The Placement Warrants and the Advisory Warrants expire on June 29, 2007.

On August 6, 1999, as consideration for management consulting services, the Company issued warrants to purchase 105,000 shares of common stock, at prices ranging from \$1.62 to \$2.25 per share. The fair market value of these warrants, aggregating \$.200 million, was charged to non-cash equity related compensation in 1999. As of December 31, 2000, all of these warrants have been exercised.

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 \$.132 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 1,000,000 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

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1,000,000 warrants were accounted for as a deemed distribution based on their fair value of \$.441 million. At December 31, 2001, none of the above-mentioned milestones have been met.

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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 \$.204 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 \$1.377 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 \$.867 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.

On March 27, 2000, as discussed above, the Board of Directors approved the mandatory redemption of all outstanding Series D Preferred Stock and Class D Warrants.

### Common Stock Reserved

At December 31, 2001, an aggregate of 17,170,297 shares of common stock were reserved for the conversion of preferred stock and the exercise of outstanding options and warrants.

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## 13. EMPLOYEE BENEFIT PLANS

### 1991 Plan

The Company's 1991 Stock Plan as amended (the "Plan") provides for the sale of stock and the grant of stock options to employees, directors, consultants and advisors of the Company. 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 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 grant. Common stock sold and options granted pursuant to the Plan generally vest over a period of four to five years.

### Grants to Employees and Directors- 1991 Plan

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In 1998, the Company granted 100,000 non-statutory options with an exercise price below the market value of the Company's stock on the grant date. The Company recorded a charge to stockholders' equity (hereinafter referred to as "deferred compensation") of \$.132 million attributable to the intrinsic value of the options and amortized \$.101 million and \$.031 million as non-equity related compensation expense in 1999 and 1998, respectively.

Summary information with respect to the Company's 1991 Stock Plan is as follows:

1991 PLAN -----	SHARES UNDER OPTION -----	WEIGHTED AVERAGE EXERCISE PRICE PER SHARE -----
BALANCE AT DECEMBER 31, 1998 .....	134,238	\$ 6.85
Granted .....	--	--
Exercised .....	--	--
Canceled .....	(26,670)	17.55
	-----	-----
BALANCE AT DECEMBER 31, 1999 .....	107,568	4.20
Granted .....	--	--
Exercised .....	--	--
Canceled .....	(180)	20.21
	-----	-----
BALANCE AT DECEMBER 31, 2000 .....	107,388	4.18
Granted .....	--	--
Exercised .....	(100,000)	3.00
Canceled .....	(3,000)	16.67
	-----	-----
BALANCE AT DECEMBER 31, 2001 .....	4,388	\$22.41
	=====	=====

At December 31, 2001, all of these outstanding stock options were exercisable. There are no shares of common stock available for grant or sale under the 1991 Stock Plan, as it expired in 2001.

### 1998 Plan

Pursuant to the Company's 1998 Stock Plan as amended (the "1998 Plan"), 12,100,000 shares have been provided for the grant of stock options to employees, directors, consultants and advisors of the Company. 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.

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### Grants to Employees and Directors- 1998 Plan

In May 1998, the Company granted options to purchase 2,236,263 shares of the Company's common stock to the Company's Chief Executive Officer ("CEO"), subject to shareholder approval, which was received in July 1998. As a result of

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an increase in the Company's stock price between May and July 1998, the Company recorded deferred compensation of \$.475 million attributable to these options, and amortized \$.405 million and \$.070 million as non-cash equity related compensation expense in 1999 and 1998, respectively.

During the fourth quarter of 1999, the Company's CEO resigned and pursuant to the terms of his original stock option grant, was subject to forfeiture of his unvested stock options. In connection with a severance agreement, the Company modified the original stock option agreement and allowed 500,000 unvested stock options to continue to vest over the subsequent year. As a result, the Company recorded net non-cash equity related compensation expense of \$.713 million in 1999 related to this matter.

During 1999, the Company granted to certain key employees, including the new CEO and the Chairman of the Board, a total of 6,188,250 options with exercise prices below the market value of the Company's common stock on the date of grant. The Company recorded total deferred compensation of \$2.018 million attributable to the intrinsic value of these options, and amortized \$.417 million, \$.519 million and \$.496 million as non-cash equity related compensation expense in 2001, 2000 and 1999, respectively. In 2000, the Company recorded additional deferred compensation of \$.064 million for the remeasurement of the new CEO's options, of which \$.013 million and \$.027 million was amortized as non-cash equity related compensation expense in 2001 and 2000.

During 2000, the Company granted to certain employee a total of 5,000 options with an exercise price below the market value of the Company's common stock on the date of grant. The Company recorded total deferred compensation of \$.032 million attributable to the intrinsic value of these options, which was amortized as non-cash equity related compensation expense in 2000. In addition, certain employees were granted a total of 320,000 options that had an exercise price below the market value of the Company's common stock on the date of hire. Accordingly, the Company recorded total deferred compensation of \$.934 million attributable to the intrinsic value of these options, and amortized \$.293 million as non-cash equity related compensation expense in 2001.

The Company's employees were granted 1,392,300, 558,362 and 495,000 stock options with an exercise prices equal to fair market value on the date of grant, in 2001 and 2000, respectively.

### Grants to Non-Employees - 1998 Plan

In connection with the JBL Agreement in May 1999 and pursuant to a related lease termination agreement, the Company granted stock options to acquire 450,000 shares of common stock, to the owners of the building previously leased to JBL, some of whom were also employees of JBL. Those options are accounted for pursuant to guidelines in SFAS No. 123, using the Black-Scholes method and has an approximate value of \$1.0 million, which was charged against the gain on the sale of JBL. In addition, a total of 245,500 options were granted to employees of JBL upon the closing of the sale of JBL, in connection with an ongoing service arrangement between Promega and the Company. These options were accounted for pursuant to SFAS No. 123 using the Black-Scholes method. The Company recorded \$.529 million and \$1.175 million of deferred

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compensation relative to these JBL options in 2000 and 1999, respectively, and amortized \$.948 million and \$.757 million as non-cash equity related compensation expense in 2000 and 1999, respectively.

In 1999, the Company also granted 50,000 options to purchase common stock to certain consultants and advisors to the Company, for which the Company recorded a total of \$.033 million and \$.136 million in deferred compensation in

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2000 and 1999, respectively, of which \$.069 million and \$.100 million was amortized as non-cash equity related compensation expense in 2000 and 1999, respectively, as accounted for pursuant to SFAS 123 and EITF 96-18.

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 \$3.049 million in deferred compensation, of which \$.257 million was amortized as non-cash equity related compensation expense.

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, 1998 .....	2,836,263	\$0.94
Granted .....	7,428,750	2.42
Exercised .....	(44,000)	0.95
Canceled .....	(618,131)	0.94
	-----	-----
BALANCE AT DECEMBER 31, 1999 .....	9,602,882	2.08
Granted .....	558,362	7.09
Exercised .....	(461,067)	1.81
Canceled .....	(3,750)	2.41
	-----	-----
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
	=====	=====

At December 31, 2001, options to purchase approximately 4,163,396 shares of common stock were exercisable at a weighted average exercise price of approximately \$2.55 per share and 935,706 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"), 2,900,000 shares have been provided for the grant of stock options to non-employee members of the Board of Directors. Options under the Directors' Plan have a term of up to ten years and must be granted at not less than the fair market value on the date of grant. Each director shall be granted 6,667 options for each Board of Directors meeting they attend in person, with a maximum of 20,000 options granted to each director. Each option granted shall become exercisable in full on the date of grant.

In May 1998, the Company granted stock options to purchase 1,725,000 shares of common stock, subject to shareholder approval, which was received in July 1998. As a result of an increase in the stock price between May and July 1998, the Company recorded deferred compensation of \$.366 million, of which \$.124 million and \$.153 million was amortized as non-cash equity related compensation expense in 2000 and 1999, respectively.

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In March 2000, four members of the Company's Board of Directors resigned. The Company accelerated the vesting of their outstanding options and extended the exercise period for one year. As a result, the Company recognized \$6.610 million in non-cash equity related compensation expense.

In March 2000, the Company granted to a Company Director, 25,000 options with an exercise price below the market value of the Company's common stock on the date of grant. The Company recorded total deferred

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compensation of \$.052 million attributable to the intrinsic value of these options, of which \$.001 million and \$.051 million was amortized as non-cash equity related compensation expense in 2001 and 2000, respectively.

The Company's directors were granted stock options to purchase a total of 170,769, 450,000 and 350,000 shares of common stock in 2001, 2000 and 1999, 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:

	SHARES UNDER OPTION	WEIGHTED AVERAGE EXERCISE PRICE PER SHARE
<b>1998 DIRECTORS' PLAN</b>		
-----		
BALANCE AT DECEMBER 31, 1998.....	1,725,000	\$ 0.94
Granted.....	350,000	2.88
Exercised.....	--	--
Canceled.....	--	--
-----		
BALANCE AT DECEMBER 31, 1999.....	2,075,000	1.26
Granted.....	450,000	8.37
Exercised.....	(871,887)	1.17
Canceled.....	(32,813)	0.94
-----		
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
=====		

At December 31, 2001, options granted under the Directors' Plan to purchase approximately 1,216,669 shares of common stock were exercisable at a weighted average exercise price of approximately \$4.64 per share and 243,144 shares of common stock were available for grant or sale under the Directors' Plan.

In 1999, a total of 7,778,750 options were granted pursuant to the 1998 Plan and the 1998 Directors Plan, of which 1,570,500 were granted at fair market value with a weighted average grant date fair value of \$1.37 per share, and 6,208,250 were granted below fair market value with a weighted average grant date fair value of \$1.87 per share. In 2000, a total of 1,008,362 options were granted pursuant to the 1998 Plan and the 1998 Directors Plan, of which 928,362 were granted at fair market value with a weighted average grant date fair value of \$7.76 per share, and 80,000 were granted below fair market value with a weighted average grant date fair value of 8.49 per share. 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



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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.

An analysis of all options outstanding as of December 31, 2001 is presented below:

RANGE OF PRICES -----	OPTIONS OUTSTANDING -----	WEIGHTED AVERAGE REMAINING LIFE IN YEARS -----	WEIGHTED AVERAGE EXERCISE PRICE -----	OPTIONS EXERCISABLE -----	WE AV EX P OF EXE
\$ 0.88 - \$ 0.94.....	1,357,132	7.01	\$ 0.93	1,294,632	\$
\$ 2.03 - \$ 3.25.....	5,740,750	7.52	2.60	3,321,625	
\$ 5.63 - \$ 9.90.....	1,988,318	9.01	7.72	710,807	
\$10.20 - \$17.50.....	486,071	9.55	13.39	40,371	
\$20.63 - \$25.00.....	4,019	3.59	22.66	4,019	
	-----	----	-----	-----	
	9,576,290	9.66	\$ 3.89	5,371,454	\$
	=====	=====	=====	=====	=

### Pro Forma Disclosure

Pro forma information regarding net loss is required by SFAS 123, and has been determined as if the Company had accounted for its employee stock options under the fair value method of that Statement. The fair value for these options was estimated at the date of grant using the Black-Scholes method for option pricing with the following weighted-average assumptions for 2001, 2000, and 1999: volatility factors of the expected market value of the

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Company's common stock of 69%, 74% and 90% respectively; risk-free interest rates of 4%; dividend yields of 0%; and a weighted-average expected life of the options of four to five years.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The Company's pro forma information follows:

(\$ thousands, except per share data)	YEARS ENDED DECEMBER 31,		
	2001 -----	2000 -----	1999 -----
Pro forma net loss applicable to common shares.....	\$(52,190)	\$(20,595)	\$(21,000)
Pro forma net loss per share.....	\$(0.93)	\$(0.53)	\$ (0.53)

The results above are not likely to be representative of the effects of applying SFAS 123 on reported net income or loss for future years.

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### Employee Savings Plan

During 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, and contributed \$.144 million as the Company's matching contribution to the Plan for the year ended December 31, 2001.

### 14. COMMITMENTS AND CONTINGENCIES

#### LITIGATION AND POTENTIAL CLAIMS

##### JBL

In October 1996, JBL retained a chemical consulting firm (the "Consulting Firm") to advise it with respect to an incident of soil and groundwater contamination (the "Spill"). Sampling conducted at the JBL facility revealed the presence of chloroform and perchloroethylenes ("PCEs") in the soil and groundwater at this site. A semi-annual groundwater monitoring program is being conducted, under the supervision of the California Regional Water Quality Control Board, for purposes of determining whether the levels of chloroform and PCEs have decreased over time. The results of the latest sampling conducted by JBL show that PCEs and chloroform have decreased in all but one of the monitoring sites. Based on an estimate provided to the Company by the Consulting Firm, the Company accrued \$.065 million in 1999, relating to remedial costs. Prior to 1999, such costs were not estimable, and therefore no loss provisions had been recorded. Pursuant to the JBL agreement the Company has agreed to indemnify Promega in respect of this matter. In November 2001, the Company received from the California Regional Water Quality Control Board notification on the completion of site investigation and remedial action for these sites and that no further action related to this case is required.

JBL received notice on October 16, 1998 from Region IX of the Environmental Protection Agency ("EPA") that it had been identified as a potentially responsible party ("PRP") at the Casmalia Disposal Site, which is located in Santa Barbara, California. JBL has been designated as a de minimis PRP by the EPA. Based on volume amounts from the EPA, the Company concluded that it was probable that a liability had been incurred and accrued \$.075 million during 1998. In 1999, the EPA estimated that the Company would be required to pay approximately \$.063 million to settle their potential liability. In December 2001, Genta received a revised settlement proposal from the EPA in the amount of \$.033 million, the terms of the settlement with the EPA containing standard contribution protection and release language. In January 2002, the Company accepted the proposal and settled this matter.

During May 2000, Promega notified Genta by letter of two claims against Genta and Genta's subsidiary, Genko Scientific, Inc. (f/k/a JBL Scientific, Inc.) ("Genko"), for indemnifiable damages in the aggregate amount of \$2.820 million under the JBL Agreement. 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 (which note provided for a payment of \$.700 million on June 30, 2000) and that therefore Genta owed Promega approximately \$1.6 million. On October 16, 2000 Genta filed suit in the US District Court of California against Promega for the non-payment of the \$1.2 million note plus interest. On November 6, 2000, Promega filed a counter suit against the Company with the US District Court of California. During the first quarter of 2001, the Company agreed to resolve the matter with Promega, and, in

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connection therewith, agreed to restructure its \$1.2 million promissory note receivable to provide for a \$.2 million non-interest bearing note due to be repaid by Promega upon final resolution of certain environmental issues related to JBL as more fully discussed in Note 15, and forgive all accrued interest. The transaction resulted in a non-recurring charge of \$1.0 million for the quarter ended March 31, 2001.

### GENTA EUROPE

During 1995, Genta Pharmaceuticals Europe S.A. ("Genta Europe"), a wholly-owned subsidiary of Genta, received funding in the form of a loan from ANVAR, a French government agency, in the amount of FF5.4 million (or approximately US\$.729 million at December 31, 2001) with a scheduled maturity of December 31, 2002. Pursuant to the loan agreement with ANVAR, the utilization of the proceeds was 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 February 1998, ANVAR asserted that Genta Europe was not in compliance with the ANVAR Agreement, and that ANVAR might request immediate repayment of the loan. In July 1998, ANVAR notified Genta Europe of its demand for accelerated repayment of the loan in the amount of FF4.2 million (or approximately US\$.567 million at December 31, 2001) and subsequently notified us that Genta was liable as a guarantor on the note. Based on the advice of French counsel, we do not believe that ANVAR is entitled to accelerated repayment under the terms of the ANVAR Agreement. We also believe it to be unlikely that Genta will incur any liability in this matter, although there can be no assurance thereof.

In June 1998, Marseille Amenagement, a company affiliated with the city of Marseilles, France, filed suit in France to evict Genta Europe from its facilities in Marseilles and to demand payment of alleged back rent due and of a lease guarantee for nine years rent. Following the filing of this claim and in consideration of the request for repayment of the loan from ANVAR, Genta Europe's Board of Directors directed the management to declare a "Cessation of Payment." Under this procedure, Genta Europe ceased operations and terminated its only remaining employee. A liquidator was appointed by the Court to take control of any assets of Genta Europe and to make payment to creditors. In December 1998, the Court in Marseilles dismissed the case against Genta Europe and indicated that it had no jurisdiction against Genta Incorporated. In August 1999, Marseille Amenagement instituted legal proceedings against us in the Commercial Court of Marseilles, alleging back rent and early termination receivables aggregating FF2.5 million (or approximately US\$.338 million at December 31, 2001). On October 8, 2001, the Commercial Court of Marseilles rendered their decision which declared the action brought by Marseille Amenagement as admissible and ordered us to pay an amount of FF1.9 million (or approximately US\$.260 million at December 31, 2001). The Company does not believe that Marseille Amenagement is entitled to payment and it is currently considering whether to appeal this decision or negotiate with Marseille Amenagement to achieve a mutually satisfactory resolution.

At December 31, 2001, the Company has accrued a net liability of \$.350 million related to the liquidated subsidiary and related matters, which management believes is adequate to provide for these contingencies.

On December 31, 2001, the fair value of the Company's debt obligations pursuant to the aforementioned arrangements is not readily determinable. The carrying value at December 31, 2001, approximating \$.827 million, represents the value of the original issuance of such debt instruments, which may be liquidated against Genta Europe's \$.590 million deposit with such French governmental agency. At December 31, 2000, the Company had \$.575 million of net liabilities of liquidated subsidiary recorded. At December 31, 2001, the Company reduced the net liabilities of liquidated subsidiary to \$.350 million and, therefore,

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pursuant to guidelines established in SFAS No. 5 "Accounting for Contingencies" and Financial Accounting Standards Board Interpretation No. 14 "Reasonable Estimation of the Amount of a Loss," such amount is sufficient to cover any potential liability. Therefore, management believes no additional accrual is necessary. However, there can be no assurance that the Company will not incur additional material costs in relation to this claim.

### PURCHASE COMMITMENTS

At December 31, 2001, the Company was obligated for \$4.0 million under firm commitments for drug substance purchases during 2002. Subsequent to year-end, the Company is obligated for an additional \$7.75 million in firm commitments for drug substance purchases during 2002.

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### 15. DISCONTINUED OPERATIONS

On March 19, 1999 (the "Measurement Date"), the Company entered into an Asset Purchase Agreement (the "JBL Agreement") with Promega whereby its wholly owned subsidiary Promega Biosciences Inc. would acquire substantially all of the assets and assume certain liabilities of JBL for approximately \$4.8 million in cash, a 7% promissory note for \$1.2 million, and certain pharmaceutical development services in support of the Company's development activities. The transaction was completed on May 10, 1999 (the "Disposal Date"), with a gain on the sale of approximately \$1.6 million being recognized, based upon the purchase price of JBL, less its net assets and costs and expenses associated with the sale, including lease termination costs of \$1.1 million, JBL losses of \$.147 million, and legal, accounting, tax and other miscellaneous costs of the sale approximating \$.653 million.

In connection with the JBL Agreement, the residual net assets of JBL were for the year ended December 31, 1999 charged to gain on sale of discontinued operations as of May 10, 1999. The results of operations for the discontinued segment are included in discontinued operations in the consolidated statement of operations for the period January 1, 1999 through the Measurement Date, March 19, 1999. Losses incurred by JBL from the Measurement Date through the Disposal Date were deferred and charged to gain on sale of discontinued operations.

Results of discontinued operations consisted of the following (\$ thousands):

	PERIOD FROM JANUARY 1, 1999 TO MAY 10, 1999 -----
Product sales.....	\$ 1,719
Operating expenses.....	(2,051)
Other income (expense) .....	(4)
Losses from March 19, 1999 through May 10, 1999 charged to Gain on Sale of JBL.....	147
	-----
Loss.....	\$ (189)
	=====

In connection with the JBL Agreement and as more fully discussed in Note 13, the Company granted stock options during 1999 to acquire 450,000 shares of common stock, to the owners of the building previously leased to JBL, some of whom were JBL employees. These options were accounted for pursuant to the Black-Scholes option pricing model and had an approximate value of \$1.0 million

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which was charged against the gain on the sale of JBL. In addition, 245,500 options were granted to former employees of JBL in connection with an ongoing service arrangement between Promega and the Company. The fair value of these options amounting to \$1.7 million was charged to continuing operations as non-cash equity related compensation expense in the amount of \$.948 million and \$.757 for the years ended December 31, 2000 and 1999, respectively.

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### 16. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

2001	QUARTER ENDED		
(\$ thousands, except per share data)	MAR. 31	JUN. 30	SEP. 30
Revenues .....	\$ 70	\$ 12	\$ 23
Operating expenses .....	7,028	11,129	11,210
Loss from continuing operations .....	(7,459)	(10,903)	(10,420)
Net loss .....	(7,459)	(10,903)	(10,420)
Loss per common share from continuing operations:			
Basic .....	\$ (0.15)	\$ (0.21)	\$ (0.19)
Diluted .....	\$ (0.15)	\$ (0.21)	\$ (0.19)
Net loss per common share:			
Basic .....	\$ (0.15)	\$ (0.21)	\$ (0.19)
Diluted .....	\$ (0.15)	\$ (0.21)	\$ (0.19)

2000	QUARTER ENDED		
(\$ thousands, except per share data)	MAR. 31	JUN. 30	SEP. 30
Revenues .....	\$ --	\$ --	\$ 17
Operating expenses .....	1,359	3,025	2,257
Loss from continuing operations .....	(8,738)	(2,939)	(2,304)
Net loss .....	(8,738)	(2,939)	(2,304)
Loss per common share from continuing operations:			
Basic .....	\$ (0.44)	\$ (0.09)	\$ (0.05)
Diluted .....	\$ (0.44)	\$ (0.09)	\$ (0.05)
Net loss per common share:			
Basic .....	\$ (0.44)	\$ (0.09)	\$ (0.05)
Diluted .....	\$ (0.44)	\$ (0.09)	\$ (0.05)

### 17. SUPPLEMENTAL DISCLOSURE OF CASH FLOWS, AND NON-CASH INVESTING AND FINANCING ACTIVITIES

(\$ thousands)	YEAR
	-----
	2001
	-----

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Preferred stock dividend accrued .....	\$ -
Preferred stock dividend imputed on penalty warrants .....	-
Notes Receivable and accrued interest from sale of discontinued operations ..	-
Notes Receivable from sale of equipment .....	-
Dividends imputed in connection with related party acquisition .....	-
Issuance of common stock in connection with legal settlement .....	-
Common stock issued in payment of dividends on preferred stock .....	-
Common stock issued in payment of patent portfolios .....	-
Income receivable on securities to be sold .....	(3)
Market value change on short-term investments .....	(97)
Stock warrants issued to placement agent .....	-
Common stock to be issued in payment of future royalties .....	-
Common stock issued in payment of hiring bonus .....	50

Interest paid during the year ended December 31, 2000 was \$.036 million. No interest was paid in the years ended December 31, 2001 and 1999.

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### PART III

#### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

##### Changes in Accountants

None.

##### Disagreements with Accountants

None.

#### 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, 2002 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, 2002 pursuant to Regulation 14A.

#### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

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, 2002 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, 2002 pursuant to Regulation 14A.

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## PART IV

### ITEM 14. 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 December 3, 2001, the Company filed a Current Report on Form 8-K disclosing two press releases issued in November 2001 regarding the completion of two private placements.

On November 12, 1999, the Company filed a Current Report on Form 8-K disclosing the appointment of a new Chief Executive Officer and a new Chairman of the Board of Directors.

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

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EXHIBIT NUMBER -----	DESCRIPTION OF DOCUMENT -----
3(i).1(7)	Restated Certificate of Incorporation of the Company.
3(i).2(9)	Certificate of Designations of Series D Convertible Preferred Stock of the
3(i).3(15)	Certificate of Amendment of Restated Certificate of Incorporation of the Co
3(i).4(15)	Amended Certificate of Designations of Series D Convertible Preferred Stock
3(i).5(15)	Certificate of Increase of Series D Convertible Preferred Stock of the Comp
3(i).6(13)	Certificate of Amendment of Restated Certificate of Incorporation of the Co
3(i).7(13)	Certificate of Amendment of Restated Certificate of Incorporation of the Co
3(i).8(15)	Certificate of Amendment of Restated Certificate of Incorporation of the Co
3(ii).1(13)	Amended and Restated Bylaws of the Company.
4.1(1)	Specimen Common Stock Certificate.
4.2(4)	Specimen Series A Convertible Preferred Stock Certificate.

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- 4.4(4) Form of Unit Purchase Agreement dated as of September 23, 1993 by and between Purchasers of the Series A Convertible Preferred Stock.
- 10.1(2) Amended and Restated 1991 Stock Plan of Genta Incorporated.
- 10(iii)(A).1(13) Non-Employee Directors' 1998 Stock Option Plan.
- 10(iii)(A).2(13) 1998 Stock Incentive Plan.
- 10.2(1) Form of Indemnification Agreement entered into between the Company and its
- 10.3(1) Preferred Stock Purchase Agreement dated September 30, 1991 and Amendment A 2, 1991.
- 10.4(1)H Development, License and Supply Agreement dated February 2, 1989 between the Gen-Probe Incorporated.
- 10.5(3)H Common Stock Transfer Agreement dated as of December 15, 1992, between the Jacques Gonella.
- 10.6(3) Consulting Agreement dated as of December 15, 1992, between the Company and
- 10.7(3)H Common Stock Transfer Agreement dated as of December 15, 1992, between the
- 10.8(3)H Collaboration Agreement dated as of January 22, 1993, between Jobewol Invest as Genta Jago Technologies B.V.) and Gensia, Inc.
- 10.9(5) Form of Purchase Agreement between the Company and certain purchasers of Co

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- 10.10(5) Common Stock Purchase Warrant dated May 8, 1995 between the Company and Ind
- 10.11(6)H Restated Joint Venture and Shareholders Agreement dated as of May 12, 1995 Jagotec AG, Jago Holding AG, Jago Pharma AG and Genta Jago Technologies B.V.
- 10.12(6)H Limited Liability Company Agreement of Genta Jago Delaware LLC dated as of GPM Generic Pharmaceuticals Manufacturing Inc. and the Company.
- 10.13(6)H Restated Transfer Restriction Agreement dated as of May 12, 1995 between the AG.
- 10.14(6)H Transfer Restriction Agreement dated as of May 12, 1995 between the Company Pharmaceuticals Manufacturing Inc. and Jago Holding AG.
- 10.15(6)H Common Stock Transfer Agreement dated as of May 30, 1995 between the Company Limited.
- 10.16(6)H Stockholders' Agreement dated as of May 30, 1995 between the Company, Jagot Gonella and Jago Finance Limited.
- 10.17(6)H Restated GEOMATRIX Research and Development Agreement dated as of May 12, 1995 Pharma AG, the Company, Genta Jago Delaware, L.L.C. and Genta Jago Technolog
- 10.18(6)H Restated Services Agreement dated as of May 12, 1995 between Jago Pharma AG Jago Delaware, L.L.C. and Genta Jago Technologies B.V.



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- 10.19(6)H Restated Working Capital Agreement dated as of May 12, 1995 and Amendment N Agreement dated as of July 11, 1995 between the Company and Genta Jago Tech
- 10.20(6)H Restated Promissory Note dated as of January 1, 1994 between Genta Jago Tec Company.
- 10.21(6)H Restated License Agreement dated as of May 12, 1995 between Jagotec AG and
- 10.22(6)H Restated GEOMATRIX License Agreement dated as of May 12, 1995 between Jagot Technologies B.V.
- 10.23(6)H GEOMATRIX Manufacturing License Agreement dated as of May 12, 1995 between Jago Technologies B.V.
- 10.24(6)H Restated GEOMATRIX Supply Agreement dated as of May 12, 1995 between Jago P Jago Technologies B.V.
- 10.25(7) Common Stock Purchase Warrant dated December 14, 1995 between the Company a Services, Inc.
- 10.26(8) Common Stock Purchase Warrant for 375,123 shares of Common Stock issued to
- 10.27(8) Common Stock Purchase Warrant for 100,000 shares of Common Stock issued to
- 10.28(9) Note and Warrant Purchase Agreement dated as of January 28, 1997 among the Fund and The Aries Domestic Fund, L.P.
- 10.29(9) Letter Agreement dated January 28, 1997 from the Company to The Aries Fund Fund, L.P.
- 10.30(9) Senior Secured Convertible Bridge Note of the Company dated January 28, 199 issued to The Aries Domestic Fund, L.P.
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- 10.31(9) Senior Secured Convertible Bridge Note of the Company dated January 28, 199 issued to The Aries Trust.
- 10.32(9) Class A Bridge Warrant for the Purchase of 2,730,000 shares of Common Stock Domestic Fund, L.P.
- 10.33(9) Class A Bridge Warrant for the Purchase of 5,070,000 shares of Common Stock Trust.
- 10.34(9) Class B Bridge Warrant for the Purchase of 4,270,000 shares of Common Stock Domestic Fund, L.P.
- 10.35(9) Class B Bridge Warrant for the Purchase of 7,930,000 shares of Common Stock Trust.
- 10.36(9) Security Agreement dated as of January 28, 1997 between the Company and Par as agent for the holders of the Company's Senior Secured Convertible Br
- 10.37(9) Letter Agreement dated January 28, 1997 among the Company, Paramount Capita Domestic Fund, L.P. and The Aries Trust.
- 10.38(10) Executive Compensation Agreement dated as of January 1, 1996 between the Co Sampson.

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- 10.39(10) Collaboration Agreement dated December 26, 1995 between the Company and Johnson & Johnson Consumer Products, Inc.
- 10.40(10) Assignment Agreement (of Gensia Inc.'s rights in the Collaboration Agreement and Gensia, Inc., dated January 23, 1993) to Brightstone Pharma, Inc., dated January 23, 1993, among Gensia, Inc., Genta Jago Technologies B.V., Brightstone Pharma, Inc., and Johnson & Johnson Consumer Products, Inc.
- 10.41(10)H Development and Marketing Agreement effective February 28, 1996 between Apothecon, Inc. and Genta Jago Technologies B.V.
- 10.42(10)H License Agreement effective February 28, 1996 between Apothecon, Inc. and Genta Jago Technologies B.V.
- 10.43(10)H Option, Development & Sub-License Agreement (the Company has requested confidential name of this element) dated as of October 31, 1996 between Genta Jago Technologies B.V. and Krypton Ltd.
- 10.44(10)H Development and Sub-License Agreement (the Company has requested confidential name of this element) dated as of October 31, 1996 between Genta Jago Technologies B.V. and Krypton Ltd.
- 10.45(10)H Development and Sub-License Agreement (the Company has requested confidential name of this element) dated as of October 31, 1996 between Genta Jago Technologies B.V. and Krypton Ltd.
- 10.46(10)H Development and Sub-License Agreement/Diclofenac dated as of October 31, 1996 between Genta Jago Technologies B.V. and Krypton Ltd.
- 10.47(10)H Development and Sub-License Agreement/Naproxen dated as of October 31, 1996 between Genta Jago Technologies B.V. and Krypton Ltd.
- 10.48(10)H Development and Sub-License Agreement/Verapamil dated as of October 31, 1996 between Genta Jago Technologies B.V. and Krypton Ltd.

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- 10.49(10)H License Termination Agreement dated December 2, 1996 between the Company and Johnson & Johnson Consumer Products, Inc.
- 10.50(10) Contract for Regional Aid for Innovation, effective July 1, 1993, between Laboratoire de Valorisation de la Recherche, Genta Pharmaceuticals Europe S.A. and the Company.
- 10.51(11) Warrant for the Purchase of 32,500 shares of Common Stock of the Company, issued to Domestic Fund, L.P.
- 10.52(11) Warrant for the Purchase of 17,500 shares of Common Stock of the Company, issued to Domestic Fund, L.P.
- 10.53(11) Amended and Restated Amendment Agreement dated June 23, 1997 among the Company and The Aries Domestic Fund L.P.
- 10.54(11) Amended and Restated Senior Secured Convertible Bridge Note for \$1.050 million, issued to Domestic Fund, L.P.

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Aries Domestic Fund, L.P.

- 10.55 (11) Amended and Restated Senior Secured Convertible Bridge Note for \$1.950 million Aries Trust.
- 10.56 (11) New Class A Bridge Warrant for the Purchase of 350,000 shares of Common Stock Domestic Fund, L.P.
- 10.57 (11) New Class A Bridge Warrant for the Purchase of 650,000 shares of Common Stock Trust.
- 10.58 (11) New Class B Bridge Warrant for the Purchase of 350,000 shares of Common Stock Domestic Fund, L.P.
- 10.59 (11) New Class B Bridge Warrant for the Purchase of 650,000 shares of Common Stock Trust.
- 10.60 (11) Consulting Agreement dated as of August 27, 1997 by and between the Company and Ph.D.
- 10.61 (11) Consulting Agreement dated as of August 27, 1997 by and between the Company and Webster, Ph.D.
- 10.62 (15) Warrant Agreement, dated as of May 20, 1997, among the Company, ChaseMellon L.L.C., as warrant agent, and Paramount Capital, Inc.
- 10.63 (12) Severance Agreement, Release and Covenant Not to Sue dated May 5, 1998 between Ph.D. and the Company.
- 10.64 (12) Consulting Agreement dated May 5, 1998 between the Company and Thomas H. Adams
- 10.65 (14) Asset Purchase Agreement, dated as of March 19, 1999, among JBL Acquisition Incorporated and the Company.
- 10.66 (14) Agreement of Sublease dated March 31, 1999 between Interneuron Pharmaceutical Company
- 10.67 (15) Warrant Agreement, dated as of December 23, 1999, among the Company, ChaseM Services, L.L.C., as warrant agent, and Paramount Capital, Inc.
- 10.68 (15) Separation Letter Agreement dated December 1, 1999 from the Company to Kenneth

- 10.69 (15) Amendment No. 1 to Stock Option Agreement, dated as of December 1, 1999, to Agreement, dated as of May 28, 1998, between the Company and Kenneth G. Kas

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- 10.70(15) Employment Letter Agreement, dated as of October 28, 1999, from the Company Warrell, Jr., M.D.
- 10.71(15) Stock Option Agreement, dated as of October 28, 1999, between the Company a Jr., M.D.
- 10.72(15) Letter Agreement, dated March 4, 1999, from SkyePharma Plc to the Company.
- 10.73(16) Subscription Agreement executed in connection with the November 26, 2001 s Franklin Small-Mid Cap Growth Fund, Franklin Biotechnology Discovery Fund, Partners Ltd., and the November 30, 2001 sale of common stock to SF Capital
- 10.74(16) Employment Letter Agreement, dated as of March 27, 2001, from the Company t
- 10.75(16) Employment Letter Agreement, dated as of July 24, 2001, from the Company to
- 10.76 Agreement of lease, The Connell Company, dated June 28, 2000.
- 10.77 Agreement of sublease, Expants, Inc., dated August 13, 2000.
- 22.1(10) Subsidiaries of the Registrant.
- 23.1(16) Consent of Deloitte & Touche LLP, Independent Auditors.

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

- (1) Incorporated herein by reference to the exhibits to the Company's Registration Statement on Form S-1, Registration No. 33-43642.
- (2) Exhibit 10.1 is incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8, Registration No. 33-85887.
- (3) Incorporated by reference to the exhibits to the Company's Registration Statement on Form S-3, Registration No. 33-58362.
- (4) Incorporated by reference to the exhibits to the Company's Current Report on Form 8-K dated as of September 24, 1993, Commission File No. 0-19635.
- (5) Incorporated by reference to the exhibits of the same number to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1995, Commission File No. 0-19635.
- (6) Incorporated by reference to the exhibits to the Company's Quarterly Report on Form 10-Q/A for the quarter ended June 30, 1995, Commission File No. 0-19635.
- (7) Incorporated herein by reference to the exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 1995, Commission File No. 0-19635.
- (8) Exhibits 10.26 and 10.27 are incorporated herein by reference to Exhibits 4.1 and 4.2, respectively, to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996, Commission File No. 0-19635.
- (9) Exhibits 3(i).2, 10.28, 10.29, 10.30, 10.31, 10.32, 10.33, 10.34, 10.35, 10.36 and 10.37 are incorporated herein by reference to Exhibits 3(i), 10.1, 10.2, 10.3, 10.4, 10.5, 10.6, 10.7, 10.8, 10.9 and 10.10, respectively, to the Company's Current Report on Form 8-K filed on February

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28, 1997, Commission File No. 0-19635.

- (10) Exhibits 10.38, 10.39, 10.40, 10.41, 10.42, 10.43, 10.44, 10.45, 10.46, 10.47, 10.48, 10.49, 10.50 and 22.1 are incorporated herein by reference to Exhibits 10.86, 10.87, 10.88, 10.89, 10.90, 10.91, 10.92, 10.93, 10.94, 10.95, 10.96, 10.97, 10.98 and 22.1, respectively, to the Company's Annual Report on Form 10-K (Amendment No. 1) for the year ended December 31, 1996, Commission File No. 0-19635.

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- (11) Exhibits 10.51, 10.52, 10.53, 10.54, 10.55, 10.56, 10.57, 10.58, 10.59, 10.60 and 10.61 are incorporated herein by reference to Exhibits 10.99, 10.100, 10.101, 10.102, 10.103, 10.104, 10.105, 10.106, 10.107, 10.108 and 10.109, respectively, to the Company's Annual Report on Form 10-K for the year ended December 31, 1997, Commission File No. 0-19635.
- (12) Exhibits 10.63 and 10.64 are incorporated herein by reference to Exhibits 10.1 and 10.2, respectively, to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1998, Commission File No. 0-19635.
- (13) Exhibits 3(i).6, 3(i).7, 3(ii).1, 10(iii)(A).1 and 10(iii)(A).2 are incorporated herein by reference to Exhibits 3(i).4, 3(i).3, 3(ii).1, 10(iii)(A).1 and 10(iii)(A).2, respectively, to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635.
- (14) Exhibits 10.65 and 10.66 are incorporated herein by reference to Exhibits 10.2 and 10.1, respectively, to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999, Commission File No. 0-19635.
- (15) Exhibits 3(i).3, 3(i).4, 3(i).5, 3(i).8, 10.62, 10.67, 10.68, 10.69, 10.70, 10.71 and 10.72 are incorporated herein by reference to Exhibits 3(i).3, 3(i).4, 3(i).5, 3(i).8, 10.62, 10.67, 10.68, 10.69, 10.70, 10.71 and 10.72 respectively, to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635.
- (16) Filed herewith.

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### 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 29th day of March 2002.

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.

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SIGNATURE -----	CAPACITY -----	
/s/ Raymond P. Warrell, JR., M.D. ----- Raymond P. Warrell, Jr., M.D.	Chairman, President, Chief Executive Officer and Principal Executive Officer	M
/s/ Alfred J. Fernandez ----- Alfred J. Fernandez	Principal Financial and Accounting Officer, Executive Vice President	M
/s/ Betsy McCaughey, Ph.D. ----- Betsy McCaughey, Ph.D.	Director	M
/s/ Daniel D. Von Hoff, M.D. ----- Daniel D. Von Hoff, M.D.	Director	M
/s/ Harlan J. Wakoff ----- Harlan J. Wakoff	Director	M
/s/ Michael S. Weiss ----- Michael S. Weiss	Director	M
/s/ Patrick Zenner ----- Patrick Zenner	Director	M