

Edgar Filing: GENTA INC DE/ - Form 10-K

GENTA INC DE/
Form 10-K
March 31, 2003

=====

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, 2002

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.

Indicate by check mark whether the registrant is an accelerated filer (as
defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes No

The approximate aggregate market value of the voting and non-voting common

Edgar Filing: GENTA INC DE/ - Form 10-K

equity held by non-affiliates of the registrant was \$385,800,211 as of June 28, 2002 (the last business day of the registrant's most recently completed second fiscal quarter). For purposes of determining this number, 28,856,050 shares of common stock held by affiliates are excluded. For purposes of making this calculation, the registrant has defined affiliates as including all directors, executive officers and beneficial owners of more than ten percent of the common stock of the Company.

As of March 21, 2003, the registrant had 73,810,345 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, 2003 pursuant to Regulation 14A are incorporated by reference in Items 10 through 13 of Part III of this Annual Report on Form 10-K.

=====

1

Genta Incorporated Table of Contents

Part I	
Item 1.	Business
Item 2.	Properties
Item 3.	Legal Proceedings
Item 4.	Submission of Matters to a Vote of Security Holders
Part II	
Item 5.	Market For Registrant's Common Equity and Related Stockholder Matters
Item 6.	Selected Consolidated Financial Data
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations
Item 7A.	Quantitative and Qualitative Disclosure about Market Risk
Item 8.	Financial Statements and Supplemental Data
Part III	
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure
Item 10.	Directors and Executive Officers of the Registrant (1)
Item 11.	Executive Compensation (1)
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder (1)
Item 13.	Certain Relationships and Related Transactions (1)
Item 14.	Controls and Procedures
Part IV	
Item 15.	Exhibits, Financial Statement Schedules and Reports on Form 8-K
Signatures
Certifications

(1) The information required in these items is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 2003 pursuant to Regulation 14A of the General Rules and Regulations under the Securities Exchange Act of 1934, as amended.

2

Edgar Filing: GENTA INC DE/ - Form 10-K

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:

- o the Company's ability to develop, manufacture and sell its products;
- o the potential efficacy of the Company's products;
- o the commencement and completion of pre-clinical and clinical trials;
- o the Company's ability to obtain necessary regulatory approvals;
- o the Company's contractual collaborative arrangements;
- o the adequacy of the Company's capital resources;
- o the ability to obtain sufficient financing to maintain the Company's planned operations;
- o the possibility and effect of patent infringement claims;
- o the impact of competitive products and market conditions;
- o 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
- o 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.

3

PART I

Item 1. Business

A. Overview

Genta Incorporated ("Genta" or the "Company") was incorporated in Delaware on February 4, 1988. Genta is a biopharmaceutical company that is dedicated to the identification, development, and commercialization of novel drugs for cancer and related diseases. The Company's research portfolio is comprised of two components: Oligonucleotide Medicines, which are drugs based on chemical modifications of either deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) and Small Molecules. At present, the Oligonucleotide Medicines portfolio includes technologies based on antisense and decoy aptamers, whereas the Small Molecule portfolio includes gallium-based products and Androgenics compounds.

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

Edgar Filing: GENTA INC DE/ - Form 10-K

reference into this Form 10-K.

The Company's lead investigational antisense drug is called Genasense(TM) (oblimersen sodium), a molecule that is designed to block the production of a protein known as Bcl-2. Current science suggests that Bcl-2 is a fundamental (although not sole) cause of the inherent resistance of cancer cells to current anticancer treatments, such as chemotherapy, radiation, or monoclonal antibodies. While Genasense(TM) has displayed some anticancer activity when used by itself, the Company is developing the drug solely as a means of amplifying the effects of other anticancer therapy by pre-treating patients with Genasense(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 for melanoma and multiple myeloma, and "Orphan Drug" designation for 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 prior to application to the FDA, which is called "Phase 3". Randomized Phase 3 trials are currently being conducted on a multinational basis that include patients with malignant melanoma, multiple myeloma, and chronic lymphocytic leukemia. The Company has other randomized and non-randomized clinical trials involving patients with other types of cancer.

In addition to the antisense program, the Company's other platform technology from the Oligonucleotide Medicines group involves decoy aptamers. Decoys are designed to bind proteins (known as "transcription factors") that can selectively turn genes on or off. This type of control could potentially be used to regulate genes that are critically involved in cancer progression. A lead target, known as the cyclic adenosine monophosphate response element-binding protein (CRE-BP), has been identified and a decoy has been created. Preclinical studies with this compound have shown broad anticancer activity, with very low toxicity to normal cells. The CRE-BP decoy is currently undergoing optimization and additional preclinical testing by the Company.

From its Small Molecule franchise, the Company is developing two drugs based on elemental gallium, an intravenous drug known as Ganite(TM) (gallium nitrate injection), and a novel oral formulation of a gallium-containing compound. Ganite(TM) has previously been approved for marketing in the U.S. and Canada by the FDA for the treatment of cancer-related hypercalcemia. In April 2000, Genta assumed ownership of the New Drug Application ("NDA") from an asset purchase agreement (Note 9), and the Company is seeking to launch the drug for its approved indication, cancer-related hypercalcemia. Hypercalcemia is a life-threatening condition caused by excessive buildup of calcium in the bloodstream. Based on previously published data, the Company believes that Ganite(TM) may also be an active treatment for patients with certain types of cancer, particularly non-Hodgkin's lymphoma. The Company has filed an Investigational New Drug ("IND") exemption with the Division of Oncology Products at the FDA, and has initiated a new clinical trial of Ganite(TM) for treatment of patients with relapsed non-

4

Hodgkin's lymphoma. The Company has also filed an Orphan Drug Application for this use and plans to seek expanded marketing approval for this indication.

The Company is concurrently seeking to develop 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 type of drug

Edgar Filing: GENTA INC DE/ - Form 10-K

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, which are intended to be used in the early, "hormone-sensitive" stage of prostate cancer. These compounds are currently undergoing additional preclinical testing.

B. Summary of Business and Research and Development Programs

Antisense Technology

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

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

The Company has devoted significant resources towards the development of antisense oligos that contain a phosphorothioate "backbone." However, the Company also has patents 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 greater stability in the circulatory system and urinary excretion relative to earlier compounds. This higher degree of stability suggests that third-generation oligos may ultimately be more effective than the Company's second-generation oligos.

Apoptosis

Cancer is commonly 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 is central to the process of programmed cell death (known as "apoptosis").

The programmed death of cells is necessary to accommodate the billions of new cells produced daily, and also to eliminate aged or damaged cells. However, abnormal regulation of the apoptotic process can result in disease. For instance, cancer, autoimmune disorders, and many viral infections are associated with decreased apoptosis (i.e., the programmed death of cells is occurring too slowly). Conversely, AIDS and certain neurodegenerative diseases are associated with increased apoptosis (i.e., cell death occurs too rapidly). The process of programmed cell death is regulated by a large number of proteins, particularly members of the Bcl-2 protein family.

Edgar Filing: GENTA INC DE/ - Form 10-K

Bcl-2 as an Inhibitor of Apoptosis

5

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

Bcl-2 is normally found in the mitochondrial membrane where it regulates the release of cytochrome C. High levels of Bcl-2 are associated with most types of human cancer, including 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 acts as a blocking factor that inhibits the release of cytochrome C triggered by cancer therapy. Thus, Bcl-2 appears to be a major contributor to both inherent and acquired resistance to anticancer treatments.

In cancer cells, the Bcl-2 protein inhibits the process of apoptosis, thereby allowing cells to survive for much longer than normal cells. Many cancer cells have an excess of Bcl-2, which contributes to making them resistant to current types of anticancer treatment (including chemotherapy, radiation, and monoclonal antibodies). Overcoming resistance to chemotherapy poses a major challenge for cancer treatment. The Company's lead antisense compound, Genasense(TM), has been developed to block production of Bcl-2, thereby dramatically increasing the sensitivity of cancer cells to standard forms of anticancer treatment.

Scientific support for these conclusions include:

- o Cancerous cells that are known to be sensitive to chemotherapy and radiotherapy can be made resistant to these treatments by inserting the Bcl-2 protein into those cells.
- o Higher levels of Bcl-2 are known to correlate with an inferior prognosis and/or poor response to therapy in many diseases.
- o Higher levels of Bcl-2 coincide with the shift from androgen-dependent to androgen-independent tumor growth in prostate cancer.
- o The ability of cells to develop into tumors can be substantially increased by inserting the Bcl-2 protein into those cells.

Genasense(TM) (oblimersen sodium; G3139; Bcl-2 antisense)

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 phosphorothioate (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. An enzyme recognizes this DNA/RNA duplex as foreign and then cleaves the Bcl-2 mRNA strand, thereby destroying the ability of the message to be translated into the Bcl-2 protein. Halting protein production eventually reduces its intracellular levels, thus preventing the protein from functioning normally. The fragments of Bcl-2 mRNA are themselves degraded by other enzymes.

Edgar Filing: GENTA INC DE/ - Form 10-K

Overview of Preclinical and Clinical studies of Genasense(TM)

Genasense(TM) Preclinical Studies

In order to affect Bcl-2 function, 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, like Genasense(TM), are generally excreted from the body unchanged, predominantly by the kidney. Biodistribution studies of Genasense in vivo have demonstrated high tissue to plasma ratios, particularly in kidney and liver, but also demonstrate significant distribution to the bone marrow and spleen. In vitro and in vivo studies also show 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 in combination with standard anticancer therapies, including anti-metabolites, alkylating agents, corticosteroids, other cytotoxic chemotherapy, radiation, and monoclonal antibodies. Several studies have

6

demonstrated enhanced antitumor activity and durable tumor regression in animals engrafted with human cancers that were treated with Bcl-2 antisense followed by antitumor agents that induce apoptosis. These studies include human lymphoma, melanoma, breast cancer, and prostate cancers, which were treated with Genasense(TM) in combination with cyclophosphamide, dacarbazine, docetaxel and paclitaxel, respectively.

Genasense(TM) Clinical Studies

Genasense(TM) 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 (CRADA) with the U.S. National Cancer Institute (NCI). Since 2001, Genta and NCI have jointly approved the initiation of approximately 20 new clinical trials. In addition to enabling more physicians and patients access to the drug, these trials allow the Company to evaluate Genasense(TM) in certain diseases (and in combination with other chemotherapy drugs) that would otherwise be outside the Company's initial priorities for clinical development. To date, more than 900 patients have been treated with Genasense(TM). In aggregate, results of clinical trials performed to date suggest that Genasense(TM) can be administered to cancer patients with an acceptable degree of side-effects, and that such treatment may reduce the level of Bcl-2 protein in cancer cells.

Genasense(TM) Phase 3 Randomized Clinical Trials

In 2001 and 2000, the Company initiated a series of randomized clinical trials that employed Genasense(TM) in combination with cytotoxic chemotherapy. These trials are all similarly designed, and each employs Genasense(TM) in an effort to improve the outcome achieved above that which would be achieved by using chemotherapy by itself. The studies comprise the following:

- o a trial in patients with advanced malignant melanoma evaluating dacarbazine alone versus dacarbazine plus Genasense(TM);
- o a trial in patients with multiple myeloma evaluating high-dose

Edgar Filing: GENTA INC DE/ - Form 10-K

dexamethasone alone versus high-dose dexamethasone plus Genasense(TM);

- o a trial in patients with chronic lymphocytic leukemia (CLL) evaluating fludarabine and cyclophosphamide alone versus fludarabine and cyclophosphamide plus Genasense(TM); and
- o a trial in patients with advanced non-small cell lung cancer (NSCLC) evaluating docetaxel alone versus docetaxel (Taxotere(R), Aventis) plus Genasense(TM).

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(TM) plus dacarbazine compared with patients treated with dacarbazine alone. The myeloma and CLL studies are similarly designed. Each of these trials are directed towards patients who have previously been treated with chemotherapy and have developed progressive disease. The primary endpoint of the myeloma trial is to increase the duration of response (or time to relapse) treated with Genasense(TM) plus high-dose dexamethasone compared to dexamethasone alone. The primary endpoint of the CLL trial is to increase the proportion of patients who achieve a complete response treated with Genasense(TM) and fludarabine and cyclophosphamide compared to fludarabine and cyclophosphamide alone. The primary endpoint of the NSCLC trial is to increase survival of patients treated with Genasense(TM) and docetaxel over docetaxel alone.

Non-Randomized Trials of Genasense(TM)

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. This study demonstrated that Genasense(TM) down-regulated Bcl-2 protein. In the study, thrombocytopenia, infusion site reactions, and fatigue were felt to be dose limiting in 2 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 up to 12 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

7

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 Company conducted a Phase 1-2 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(TM), including exaggerated fever, hypotension, and back pain. Together, these studies have indicated that the appropriate initial dose for extended Phase 2 and Phase 3 testing in these two diseases is 3 mg/kg/day. Preliminary results from the first 23 patients showed that 2 patients (9%) achieved partial responses, despite having failed 4 or more prior treatment regimens; 11 patients (48%) achieved stabilization of their disease, 5 of whom had failed 4 or more prior treatments. Circulating CLL cells

Edgar Filing: GENTA INC DE/ - Form 10-K

were reduced by more than 50% in 9 patients (39%). Eight of 19 patients (42%) achieved greater than 50% decrease in the size of enlarged lymph nodes, and 8 of 16 patients (50%) achieved greater than 50% decrease in the size of enlarged liver or spleen. To date, the major side effects of Genasense(TM) have been fatigue and fever.

Acute Leukemia: A Phase 1 study at Ohio State University evaluated a continuous intravenous (IV) infusion dose of Genasense(TM) with escalating doses of fludarabine, cytosine arabinoside, and filgrastim (FLAG) in patients with acute leukemia. Results showed that Genasense(TM) could be safely combined with these agents in patients with relapsed leukemia and that several refractory patients were able to achieve complete remissions. A second study has been initiated that tests Genasense(TM) in combination with daunorubicin and cytosine arabinoside (Ara-C). To date, the combined Genasense(TM) /chemotherapy program has not caused more side effects than expected from using chemotherapy alone. Overall, 5 of the first 11 evaluable patients have achieved complete remission (CR).

Malignant Melanoma: A Phase 1 clinical study of Genasense(TM) combined with dacarbazine (DTIC) was conducted at the University of Vienna. Daily IV infusions (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: 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 showed that fatigue and fever were observed after 2 weeks of continuous treatment at doses ranging from 4.1 to 7 mg/kg/day for 14 days. Similar reactions were observed on the 21-day schedule. Transient elevation of liver enzymes (i.e., serum transaminase) was also 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 generally well tolerated when combined with full doses of standard cytotoxic chemotherapy using a daily Genasense(TM) dose of 7 mg/kg/day for 5 to 7 days. Exceptions to these dosing regimens have been noted in patients with NHL and CLL, who appear more sensitive to the drug, and for whom doses are currently employed. Significant thrombocytopenia, liver function abnormalities, or fatigue have not been dose-limiting in most Phase 1-2 studies. Current data suggest that reduction of Bcl-2 protein may be observed within the first 3 to 5 days. Thus, current studies are generally using a 5 to 7 day schedule in combination with chemotherapy, using Genasense(TM) administered at least 3 days prior to the initiation of other therapy. As previously noted, the Company, either alone or in conjunction with NCI, 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 (Ganite(TM); gallium nitrate injection) was originally studied by NCI as a new type of cancer chemotherapy. In the course of these studies, gallium nitrate was shown to strongly inhibit bone resorption. Gallium nitrate underwent additional clinical testing and was approved by the FDA in 1991 as a treatment for patients with a condition known as "cancer-related hypercalcemia". Hypercalcemia occurs due to rapid loss of bone that releases large amounts of calcium into the bloodstream of patients, which can be lethal. Lower doses of Ganite(TM) were also tested in patients with 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(TM) (gallium nitrate injection), the liquid injectable product. The acquired assets included the ownership of an approved NDA. Since this acquisition, the Company has worked with the FDA to address certain regulatory issues and to update certain aspects of drug manufacturing. In December 2002, the Company made its first submission to this NDA, which was sent to the Metabolism and Endocrine Division of FDA. The Company has announced that it intends to complete its NDA filings for Ganite(TM) in the first quarter of 2003. The Division has advised Genta that these supplements will be subject to a four-month review period from the last filing date. Assuming there are no serious delays in the review of its submissions, or of any information related to submissions or activities conducted by the prior Sponsor, Genta anticipates that it will market Ganite(TM) under its own auspices in the United States in the second half of 2003.

Given the extensive published anticancer activity for gallium nitrate, the Company filed a new Investigational New Drug (IND) exemption request for Ganite(TM) with the Oncology Drug Products Division at FDA for the treatment of patients with relapsed non-Hodgkin's lymphoma (NHL). Under that IND, the Company initiated a new clinical trial of Ganite(TM) in NHL patients in 2002. Genta has also submitted an application to the FDA in order to designate gallium nitrate as an "Orphan Drug" in NHL. Since previous clinical trials of Ganite(TM) showed that it does not cause significant myelosuppression, the Company believes that this drug may address a significant unmet medical need. The Company intends to pursue additional clinical trials of Ganite(TM) in NHL, and possibly other neoplastic diseases.

The Company also seeks to develop new formulations of gallium-containing compounds that can be taken by mouth. 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.

Decoy Aptamers

As described above, decoy aptamers - like antisense drugs - 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 proteins that are 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"). 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.

Edgar Filing: GENTA INC DE/ - Form 10-K

By selectively inactivating the transcription factor, the function of the gene can be regulated in a positive or negative manner. In December 2000, Genta licensed patents and technology relating to decoy aptamers from the U.S. National Institute of Health. The Company's current program 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.

Androgenics Technologies

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

9

pre-clinical program of drug synthesis, formulation and anti-tumor testing with these compounds.

Patents and Proprietary Technology

The Company's policy is to protect its technology by 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, the pursuit of licensing opportunities to develop and maintain its competitive position, and certain other regulatory or legal means (such as "Orphan Drug" designations).

Genta has a portfolio of intellectual property rights and applications to numerous aspects of oligonucleotide technology, which include novel compositions of matter, methods of large-scale synthesis, methods of controlling gene expression, and delivery systems. In addition, foreign counterparts of many applications have been filed and will continue to be filed as deemed desirable. 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 later 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 more than 70 United States and foreign patent applications currently pending.

To further protect its interests, Genta seeks to license patents or intellectual property rights from other entities. The Company has licensed certain rights from the National Institutes of Health covering phosphorothioate oligonucleotides. Genta also acquired exclusive rights to antisense oligonucleotides directed against the Bcl-2 mRNA, as well as methods of their use for the treatment of cancer, from the University of Pennsylvania. 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

Edgar Filing: GENTA INC DE/ - Form 10-K

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 technology that relate to antisense for therapeutic and diagnostic applications. The arrangement included a grant 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 can 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 even if successful that these patents will not be circumvented or invalidated. Since applications in the United States are maintained in secrecy until an actual patent issues, 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. The Company cannot provide 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, even if obtainable, such a license would be available on reasonable terms.

10

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. 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, sponsored researchers, and other advisors to execute confidentiality agreements 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

Edgar Filing: GENTA INC DE/ - Form 10-K

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

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 net research and development expenses of \$58.9 million, \$39.4 million and \$6.8 million during 2002, 2001 and 2000, respectively.

Collaborative Agreement

In April 2002, the Company entered into a development and commercialization agreement ("Collaborative Agreement") with Aventis Pharmaceuticals Inc. ("Aventis"). Under the terms of the Collaborative Agreement, the Company and Aventis will jointly develop and commercialize Genasense(TM) in the U.S. ("the Alliance"), and Aventis will have exclusive development and marketing rights to the compound in all countries outside of the U.S.

Sales and Marketing

Either alone or in partnership with other companies, 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 2002, the Company signed a five-year Manufacturing and Supply Agreement ("Supply Agreement") with Avecia Ltd., a leading multinational manufacturer of pharmaceutical products, to supply quantities of our lead antisense compound, Genasense(TM). This agreement is also renewable beyond the initial five-year period.

Edgar Filing: GENTA INC DE/ - Form 10-K

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 by The University of Maryland at Baltimore to treat prostate cancer. These compounds are currently undergoing additional preclinical testing.

JBL Scientific, Inc.

Prior to 1999, the Company had manufactured and marketed specialty biochemicals and intermediate products to the in vitro diagnostic and 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 20).

Genta Europe

Genta Pharmaceuticals Europe S.A. ("Genta Europe"), was a wholly owned subsidiary of Genta in France. Genta Europe was established in 1993 to deal with research relating to dermatology, geomatrix and antisense. Genta reduced Genta Europe's staff in 1996 and 1997, and in 1998 closed the entire operation in France. For a description of certain legal proceedings affecting our subsidiary, Genta Europe, see (Note 19).

Genta Jago

Genta Jago Technologies B.V. ("Genta Jago") is a joint venture formed by SkyePharma PLC and Genta. On March 4, 1999, SkyePharma PLC (on behalf of itself and its affiliates) entered into an interim agreement with Genta (the "Interim JV Agreement") pursuant to which the parties to the joint venture released each other from all liability relating to unpaid development costs and funding obligations of Genta Jago. Under the terms of the Interim JV Agreement, SkyePharma PLC assumed responsibility for substantially all the obligations of the joint venture to third parties as well as further development of the product line. In addition, earnings of the joint venture are to be allocated equally between the two parties. Accordingly, Genta recognized \$0.502 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 only \$0.033 million in net earnings of the joint venture allocated to Genta and we are currently seeking to terminate our involvement with the joint venture.

Human Resources

As of February 2003, Genta had 96 employees, 19 of whom hold doctoral degrees. There are 65 employees engaged in development activities and 31 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

Edgar Filing: GENTA INC DE/ - Form 10-K

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,

12

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 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 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 NDA, for a biological product in the form of a Biologics License Application ("BLA"), for a particular medical device in the form of a Premarket Approval Application ("PMA") 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

Edgar Filing: GENTA INC DE/ - Form 10-K

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 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.

13

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 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

Edgar Filing: GENTA INC DE/ - Form 10-K

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.

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.

14

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

Edgar Filing: GENTA INC DE/ - Form 10-K

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(TM) 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(TM) 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:

- o our ability to demonstrate clinically that our products have utility and are safe;
- o delays or refusals by regulatory authorities in granting marketing approvals;
- o our limited financial resources and sales and marketing experience relative to our competitors;
- o actual and perceived differences between our products and those of our competitors;
- o the availability and level of reimbursement for our products by third-party payors;
- o incidents of adverse reactions to our products;
- o side effects or misuse of our products and the unfavorable publicity that could result; and
- o 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 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 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, 2002, we have incurred a cumulative net loss of \$273.2 million. We may never achieve revenue sufficient for us to attain profitability, until Genasense(TM) becomes an approved drug and we receive a full year of royalties from Aventis on worldwide sales.

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

Our operations to date have required significant cash expenditures. Based

Edgar Filing: GENTA INC DE/ - Form 10-K

on our current operating plan, we believe that our available resources will be adequate to satisfy our capital needs to the end of 2004. Additional Aventis milestone payments and other funding available to the Company upon the anticipated NDA approval of Genasense(TM) should provide sufficient capital resources for beyond 2004. Our future capital requirements will depend on the results of our research and

15

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:

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

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

Edgar Filing: GENTA INC DE/ - Form 10-K

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:

- o inability to obtain sufficient quantities of materials for use in clinical trials;
- o inability to adequately monitor patient progress after treatment;
- o unforeseen safety issues;

16

- o the failure of the products to perform well during clinical trials; and
- o 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 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:

- o obtain U.S. and foreign patent or other proprietary protection for our technologies, products and processes;

Edgar Filing: GENTA INC DE/ - Form 10-K

- o preserve trade secrets; and
- o 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.

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

17

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

Edgar Filing: GENTA INC DE/ - Form 10-K

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 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

Edgar Filing: GENTA INC DE/ - Form 10-K

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 \$13.025 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, 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 36% 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 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 38% of

Edgar Filing: GENTA INC DE/ - Form 10-K

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

19

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.

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:

- o the results of pre-clinical studies and clinical trials by us or our competitors;
- o announcements of technological innovations or new therapeutic products by us or our competitors;
- o government regulation;
- o 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

Edgar Filing: GENTA INC DE/ - Form 10-K

biopharmaceutical stocks in general.

As of March 21, 2003, the Company had 73,810,345 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 2002, leased approximately 24,000 square feet of space. Such leases expire in February 2004 and June 2005. In June 2002, the Company signed a new seven-year lease agreement for an additional 69,000 square feet of office space, at a rental cost of \$1.764 million per year. The Company has retained significant existing improvements to that space, including furniture and other furnishings. A security deposit for \$1.029 million was paid in January 2003, and rent payments for portions of this new space began as the Company occupied each portion of the space. The Company began paying for the additional space in its entirety on March 1, 2003. This required security deposit amount may change to (i) \$0.588 million in the event the Company receives approval from the FDA for Genasense(TM), (ii) \$0.294 million in the event the Company receives approval from the FDA for Genasense(TM) and the Company's EBITDA for the immediately preceding four calendar quarters is equal to or greater than \$10.0 million, or (iii) an additional security deposit of approximately \$0.294 will be due if the Company's net worth falls below \$40.0 million or the Company's cash and cash equivalents balance falls below \$50.0 million. All of the Company's other leases for office space have been amended so that the expiration dates coincide with the new lease. At the end of the initial lease term, the Company has the option to renew these leases for five more years at the then prevailing market rental rate.

20

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 \$0.065 million 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 was required.

In October 1998, JBL received notice from Region IX of the Environmental Protection Agency ("EPA") that JBL had been identified as a potentially

Edgar Filing: GENTA INC DE/ - Form 10-K

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 \$0.075 million during 1998. In 1999, the EPA estimated that the Company would be required to pay approximately \$0.063 million to settle their potential liability. In December 2001, the Company received a revised settlement proposal from the EPA in the amount of \$0.033 million, the terms of the settlement with the EPA contained standard contribution protection and release language. This settlement amount of \$0.033 million was fully paid in January 2002. There can be no assurance, however, that the EPA will not reject our settlement offer if there is not a sufficient number of PRP's settling with the EPA.

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 \$2.82 million under the purchase agreement pursuant to which Promega acquired the assets of JBL. Promega's letter stated that it intended to reduce to zero the principal amount of the \$1.2 million promissory note it issued as partial payment for the assets of Genko 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 \$2.82 million. 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 \$0.2 million non-interest bearing note due to be repaid by Promega upon final resolution of certain environmental issues related to JBL and forgave all accrued interest. As of March 21, 2003, the Company is awaiting final acceptance by the EPA of the Company's settlement offer, as noted above, before the remaining note receivable will be repaid by JBL.

In October 2002, a licensing officer from the University of Pennsylvania ("UPenn") asserted a claim to a portion of the initial \$40.0 million development funding (Note 19) the Company received from Aventis pursuant to the Collaborative Agreement. The Company has disputed this claim and has filed a petition for binding arbitration for this matter, as provided in the original licensing agreement between the Company and UPenn. At the current time the Company cannot reasonably estimate the outcome of this claim; however, the Company does not believe that this claim will have a material adverse impact on the Company's financial results and liquidity. As such, the Company has not reserved any amount for royalty payments that could be due to UPenn as a result binding arbitration.

For a description of certain legal proceedings affecting our subsidiary, Genta Europe, see (Note 19).

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, 2002.

PART II

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

(a) Market Information

Edgar Filing: GENTA INC DE/ - Form 10-K

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 ---
2002		
First Quarter	\$ 18.250	\$10.880
Second Quarter	17.740	6.291
Third Quarter	8.699	6.150
Fourth Quarter	11.500	6.140
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

On March 21, 2003, the closing price of our common stock was \$7.590.

(b) Holders

There were 571 holders of record of the Company's common stock as of March 21, 2003.

(c) Dividends

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

22

Item 6. Selected Consolidated Financial Data

	Years Ended		
(In thousands, except share data)	2002	2001	2000
Consolidated Statements of Operations Data (2):			
Revenues:			
License revenue	\$ 3,498	\$ 97	\$
Royalties	61	49	
Related party contract revenue	--	--	
Collaborative research and development	--	--	
	3,559	146	---
Costs and expenses:			
Research and development	58,899	39,355	
General and administrative	19,347	8,215	
Equity related compensation	1,016	1,074	
Promega Settlement	--	1,000	
LBC Settlement	--	--	
	-----	-----	-----

Edgar Filing: GENTA INC DE/ - Form 10-K

	79,262	49,644	
	-----	-----	---
Loss from operations	(75,703)	(49,498)	(
Equity in net income (loss) of joint venture	33	--	
Net loss of liquidated foreign subsidiary	--	--	
Other income (loss)	1,326	2,785	
Income taxes	(184)	--	
	-----	-----	---
Loss from continuing operations	(74,528)	(46,713)	(
Loss from discontinued operations	--	--	
Gain on sale of discontinued operations	--	--	
	-----	-----	---
Net loss	(74,528)	(46,713)	(
Preferred stock dividends	--	--	
	-----	-----	---
Net loss applicable to common shares	\$ (74,528)	\$ (46,713)	\$ (
	=====	=====	=====
Continuing operations	\$ (1.05)	\$ (0.84)	\$
Discontinued operations	--	--	
	-----	-----	---
Net loss per share (1)	\$ (1.05)	\$ (0.84)	\$
	=====	=====	=====
Weighted average shares used in computing net loss per share	70,656	55,829	
	=====	=====	=====

		Years Ended	
		-----	-----
		2002	2001
		-----	-----
Consolidated Balance Sheet Data (2):			
Cash, cash equivalents and short-term investments	\$ 113,716	\$ 54,086	\$
Working capital	91,586	42,709	
Total assets	136,419	60,630	
Notes payable and capital lease obligations, less current portion	--	--	
Total stockholders' equity	46,703	48,310	

(1) Computed on the basis of net loss per common share described in Note 2 of Notes to Consolidated Financial Statements.

(2) The above selected financial data reflects discontinued operations and balance sheet data of JBL as of May 10, 1999. See Note 20 to consolidated financial statements.

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

Overview

Since its inception in February 1988, Genta has devoted its principal efforts toward drug discovery and research and development. Genta 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,

Edgar Filing: GENTA INC DE/ - Form 10-K

regulatory activities, and establishment of a sales and marketing organization. From its inception to December 31, 2002, the Company has incurred a cumulative net loss of \$273.2 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. 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 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)	2002	Increase (Decrease)	2001	Increase (Decrease)
	-----	-----	-----	-----
Revenues:				
License fees	\$ 3,498	\$ 3,401	\$ 97	\$ 80
Royalties	61	12	49	44
	-----	-----	-----	-----
	3,559	3,413	146	124
Costs and expenses:				
Research and development	58,899	19,544	39,355	32,525
General and administrative	19,347	11,132	8,215	4,892
Promega settlement	--	(1,000)	1,000	1,000
Equity related compensation	1,016	(58)	1,074	(7,531)
	-----	-----	-----	-----
	79,262	29,618	49,644	30,886
Loss from operations	(75,703)	26,205	(49,498)	30,762
Equity in net income of joint venture	33	33	--	(502)
Other income	1,326	(1,459)	2,785	(2,998)
Income taxes	(184)	(184)	--	--
	-----	-----	-----	-----
Net loss	\$ (74,528)	\$ 27,815	\$ (46,713)	\$ 34,262
	=====	=====	=====	=====

Operating revenues consisting of license fees and royalties were \$3.559 million in 2002 compared to \$0.146 million in 2001 and \$0.022 million in 2000. These revenues were derived mainly from the initial \$10.0 million licensing fee and \$40.0 million development funding received from Aventis under the Collaborative Agreement (Note 12), along with non-exclusive sub-license agreements involving antisense technology. These initial payments received from Aventis will be recognized over the estimated useful life of the related first-to-expire patent of 115 months. The non-exclusive sub-license agreements

Edgar Filing: GENTA INC DE/ - Form 10-K

were initiated with Atugen AG and EpiGenesis Pharmaceuticals, Inc. in 2001, and Sequitur Incorporated and Oasis Biopharmaceuticals, Inc. in 2000.

Costs and expenses totaled \$79.3 million in 2002, net of Aventis reimbursement of \$28.451 million, compared to \$49.6 million in 2001 and \$18.8 million in 2000. These increases reflect additional clinical trial activity and related drug supply and salaries. 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

24

future years due to requirements for pre-clinical studies, clinical trials and increased regulatory costs. The Company will continue to assess the potential cost benefit ratio of developing its own antisense oligonucleotide manufacturing, and marketing and sales activities if and as such products are successfully developed and approved for marketing.

Research and development expenses totaled \$58.9 million in 2002, net of Aventis reimbursement of \$27.746 million, compared to \$39.4 million in 2001 and \$6.8 million in 2000. The increase from 2000 through 2002 is due primarily to drug supply costs and investigator and monitor fees related to expanded clinical trials. It is anticipated that research and development expenses will continue to increase in the future, as Genta expands its other product development programs. Furthermore, the Company is also pursuing other opportunities for new product development candidates, which, if successful, will require additional research and development expenses.

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

General and administrative expenses were \$19.4 million in 2002, net of Aventis reimbursement of \$0.705 million, compared to \$8.2 million in 2001 and \$3.3 million in 2000. The increase is primarily related to financial advisory services, royalty payments and legal fees relating to the Collaborative Agreement (Note 12), personnel costs and increased marketing-related spending. The Company records charges to general and administrative expense for the carrying value of abandoned patents no longer related to the research and development efforts of the Company. There were no abandoned patent charges in 2002 and the amounts recorded in 2001 and 2000 were immaterial.

The Company recorded charges to non-cash equity related compensation of \$1.0 million in 2002 compared to \$1.1 million in 2001 and \$8.6 million in 2000. This decrease in 2001 was 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 18).

Equity in earnings of joint venture (Genta Jago) was \$0.033 million in 2002 compared to none in 2001 and \$0.502 in 2000. Since the first quarter of 2000, there have been only \$0.033 million in net earnings of the joint venture allocated to Genta and we are currently seeking to terminate our involvement

Edgar Filing: GENTA INC DE/ - Form 10-K

with the joint venture.

Net other income, principally interest income decreased over the comparable periods in 2001 and 2000, as a result of significantly lower investment balances and decreased yields on investments. The proceeds received from Aventis were not placed into any investment instruments until October 2002. Interest expense is attributable to interest being accrued on the \$10.0 million convertible promissory note issued to Aventis (Note 14). 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 no gain on the sale of marketable securities in 2002 compared to approximately \$0.061 million in 2001 and 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 publicly 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, 2001, as more fully discussed in Note 2 to the consolidated financial statements. Adoption of these standards did not or is 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 in accordance with accounting principles generally accepted in the United States of

25

America, management is required to make estimates and assumptions that, among other things, affect the reported amounts of assets and liabilities and reported amounts of revenues and expenses. These estimates are most significant in connection with our critical accounting policies, namely those of our accounting policies that are most important to the portrayal of our financial condition and results and require management's most difficult, subjective or complex judgments. These judgments often result from the need to make estimates about the effects of matters that are inherently uncertain. Actual results may differ from those estimates under different assumptions or conditions. We believe that our most critical accounting policies relate to:

- o 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 is fixed and determinable, and collectibility is reasonably assured. Royalties are recognized when earned. Consistent with Staff Accounting Bulletin No. 101 "Revenue Recognition" ("SAB 101"), initial funding of ongoing development received from Aventis after the achievement of certain research and development milestones (Note 12) will be recognized on a straight-line basis over the estimated useful life of the related first-to-expire patent of 115 months. Any subsequent milestone payments that may be received from Aventis will also be recognized over the then, remaining estimated useful life of

Edgar Filing: GENTA INC DE/ - Form 10-K

the related first-to-expire patent.

- o Research and development costs. All such costs are expensed as incurred, including raw material costs required to manufacture drugs for clinical trials. Once Genta has submitted an NDA, which includes the results of the preclinical and clinical testing, chemistry, manufacturing and control information, to the FDA for approval to commence commercial sales, Genta will then include the sales launch product, consisting of raw materials and all subsequent processing costs required to produce finished goods, as inventory on Genta's balance sheet in anticipation of approval by the FDA. Reimbursements for applicable Genasense(TM) related costs, under the Collaborative Agreement (Note 12), will continue to be recorded as a reduction to expense.
- o 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

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 \$278.8 million through December 31, 2002, including net proceeds of \$71.0 million received in 2002, \$32.2 million received in 2001 and \$40.1 million received in 2000. The Company used \$19.7 million in operating activities during 2002, resulting from a net loss of \$74.5 million, offset by deferred revenues received from Aventis, non-cash charges and improved working capital aggregating \$54.8 million. At December 31, 2002, the Company had cash, cash equivalents and short-term investments totaling \$113.7 million compared to \$54.1 million at December 31, 2001. In March 2003, the Company and Aventis negotiated a line of credit for an amount up to \$40.0 million. Management believes that at the current rate of spending, primarily in support of on-going and anticipated clinical trials, coupled with the amounts to be reimbursed by Aventis and the available line of credit, the Company should have sufficient cash funds to maintain its present operations to the end of 2004. Additional Aventis milestone payments and other funding available to the Company upon the anticipated NDA approval of Genasense(TM) should provide sufficient capital resources for beyond 2004.

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, primarily expense reimbursement from Aventis, 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, 2002 are as follows (\$ thousands):

	Operating Leases -----	Drug Purchase Commitments -----	Convertible Debt -----
2003	\$ 2,199	\$27,500	\$ -
2004	2,478	27,500	-
2005	2,476	-	-
2006	2,585	-	-
2007	2,613	-	-
Thereafter	5,581	-	10,000
	-----	-----	-----
Total	\$ 17,932	\$55,000	\$10,000
	=====	=====	=====

The drug purchase commitments are the maximum per the terms of the Supply Agreement (Note 19). The Supply Agreement provides for mechanisms to mitigate costs should requirements be lower than anticipated and various performance criteria, which could lower the 2003 and 2004 commitments.

Item 7A. Quantitative and Qualitative Disclosures 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 (Note 3).

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, 2002. 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.

Edgar Filing: GENTA INC DE/ - Form 10-K

Item 8. Financial Statements and Supplemental Data

Genta Incorporated
Index to Financial Statements Covered
Independent Auditors' Report

Genta Incorporated
 Independent Auditors' Report
 Consolidated Balance Sheets at December 31, 2002 and 2001
 Consolidated Statements of Operations for the years ended December 31, 2002, 2001 and 2000
 Consolidated Statements of Stockholders' Equity for the years ended December 31, 2002, 2001 and 2000
 Consolidated Statements of Cash Flows for the years ended December 31, 2002, 2001 and 2000
 Notes to Consolidated Financial Statements

INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders of
Genta Incorporated

We have audited the accompanying consolidated balance sheets of Genta Incorporated and subsidiaries (the "Company") as of December 31, 2002 and 2001, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Genta Incorporated as of December 31, 2002 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey
February 13, 2003
(except Note 21, as to which the date is March 17, 2003)

Edgar Filing: GENTA INC DE/ - Form 10-K

GENTA INCORPORATED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value data)

	December 31,	Dece
ASSETS	2002	
Current assets:		
Cash and cash equivalents (Note 2)	\$ 32,700	\$
Short term investments (Note 3)	81,016	
Accounts receivable (Note 4)	14,574	
Notes receivable (Note 5)	200	
Prepaid expenses and other current assets (Note 6)	1,458	
Total current assets	129,948	
Property and equipment, net (Note 7)	3,256	
Intangibles, net (Note 9)	1,440	
Prepaid royalties (Note 10)	1,268	
Deposits and other assets (Note 16)	507	
Total assets	\$ 136,419	\$
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 27,683	\$
Notes payable (Note 6)	490	
Accrued expenses (Note 11)	4,740	
Deferred revenues, current portion (Note 13)	5,237	
Other current liabilities	212	
Total current liabilities	38,362	
Deferred revenues (Note 13)	41,354	
Convertible debt (Note 14)	10,000	
Total liabilities	89,716	
Commitments and contingencies (Note 19)		
Stockholders' equity (Note 17):		
Series A convertible preferred stock, \$.001 par value; 5,000 shares authorized, 261 shares issued and outstanding at December 31, 2002 and December 31, 2001, respectively; liquidation value of \$13,025 and \$13,050, respectively	--	
Common stock, \$.001 par value; 120,000 shares authorized, 74,168 and 66,000 shares issued and outstanding at December 31, 2002 and December 31, 2001, respectively	74	
Additional paid-in capital	322,997	2
Accumulated deficit	(273,190)	(1
Deferred compensation	(697)	
Accumulated other comprehensive (loss) income	25	

Edgar Filing: GENTA INC DE/ - Form 10-K

	49,209
Less cost of treasury stock: 393 shares at December 31, 2002	(2,506)
Total stockholders' equity	46,703
Total liabilities and stockholders' equity	\$ 136,419

See accompanying notes to consolidated financial statements.

30

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)	Years Ended December 31,		
	2002	2001	2000
Revenues:			
License fees (Note 13)	\$ 3,498	\$ 97	\$ 17
Royalties	61	49	5
	3,559	146	22
Costs and expenses:			
Research and development (Note 12)	58,899	39,355	6,830
General and administrative (Note 12)	19,347	8,215	3,323
Equity related compensation (Note 18)	1,016	1,074	8,605
Promega settlement (Note 5)	--	1,000	--
	79,262	49,644	18,758
Loss from operations	(75,703)	(49,498)	(18,736)
Equity in net income of joint venture (Note 8)	33	--	502
Other income	1,326	2,785	5,783
Income taxes (Note 15)	(184)	--	--
Net loss	(74,528)	(46,713)	(12,451)
Preferred stock dividends (Note 17)	--	--	(3,443)
Net loss applicable to common shares	\$ (74,528)	\$ (46,713)	\$ (15,894)
Net loss per common share	\$ (1.05)	\$ (0.84)	\$ (0.41)
Shares used in computing net loss per common share	70,656	55,829	38,659

See accompanying notes to consolidated financial statements.

31

Edgar Filing: GENTA INC DE/ - Form 10-K

GENTA INCORPORATED
 CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
 For the Years Ended December 31, 2000, 2001 and 2002

(In thousands)	Convertible Preferred Stock		Common Stock		Treasury Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Balance at January 1, 2000	400	\$ --	25,457	\$ 26	--	\$ --
Comprehensive loss:						
Net loss	--	--	--	--	--	--
Unrealized investment gain	--	--	--	--	--	--
Total comprehensive loss						
Issuance of common stock upon conversion of convertible preferred stock	(139)	--	14,486	15	--	--
Issuance of common stock in connection with two private placements, net of issuance costs of \$2,548	--	--	6,458	6	--	--
Issuance of common stock in connection with exercise of warrants and stock options	--	--	3,345	3	--	--
Preferred stock dividends	--	--	953	1	--	--
Equity related compensation	--	--	--	--	--	--
Issuance of common stock in connection with rights to Relgen license agreement	--	--	10	--	--	--
Issuance of common stock in connection with MBI asset purchase	--	--	376	--	--	--
Value of shares to be issued related to license agreement	--	--	--	--	--	--
Balance at December 31, 2000	261	--	51,085	51	--	--
Comprehensive loss:						
Net loss	--	--	--	--	--	--
Unrealized investment loss	--	--	--	--	--	--
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	--	--

(In thousands)	Additional Paid-in Capital	Accumulated Deficit	Accrued Dividends Payable	Deferred Compensation	Accumulated Other Comprehensive Income
----------------	----------------------------	---------------------	---------------------------	-----------------------	--

Edgar Filing: GENTA INC DE/ - Form 10-K

	-----	-----	-----	-----	-----
Balance at January 1, 2000	\$ 146,863	\$ (139,498)	\$ 5,134	\$ (2,318)	\$
Comprehensive loss:					
Net loss		(12,451)	--	--	
Unrealized investment gain	--	--	--	--	
Total comprehensive loss					
Issuance of common stock upon conversion of convertible preferred stock	(14)	--	--	--	
Issuance of common stock in connection with two private placements, net of issuance costs of \$2,548	40,095	--	--	--	
Issuance of common stock in connection with exercise of warrants and stock options	3,254	--	--	--	
Preferred stock dividends	5,133	--	(5,134)	--	
Equity related compensation	7,368	--	--	1,237	
Issuance of common stock in connection with rights to Relgen license agreement	84	--	--	--	
Issuance of common stock in connection with MBI asset purchase	2,400	--	--	--	
Value of shares to be issued related to license agreement	1,268	--	--	--	
Balance at December 31, 2000	206,451	(151,949)	--	(1,081)	
Comprehensive loss:					
Net loss	--	(46,713)	--	--	
Unrealized investment loss	--	--	--	--	
Total comprehensive loss					
Issuance of common stock upon conversion of convertible preferred stock	--	--	--	--	
Issuance of common stock in connection with private placement, net of issuance costs of \$502	32,220	--	--	--	

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2000, 2001 and 2002

Convertible
Preferred Stock Common Stock Treasury Stock

Edgar Filing: GENTA INC DE/ - Form 10-K

(In thousands)	Shares	Amount	Shares	Amount	Shares	Amount
Issuance of common stock in connection with exercise of warrants and stock options	--	--	12,245	12	--	--
Issuance of common stock as hiring bonus	--	--	6	--	--	--
Issuance of common stock related to license agreement	--	--	162	--	--	--
Equity related compensation	--	--	--	--	--	--
Balance at December 31, 2001	261	--	66,000	66	--	--
Comprehensive loss:						
Net loss	--	--	--	--	--	--
Unrealized investment loss	--	--	--	--	--	--
Total comprehensive loss						
Issuance of common stock in connection with private placement, net of issuance costs of \$899	--	--	6,665	7	--	--
Issuance of common stock in connection with exercise of warrants and stock options	--	--	1,503	1	--	--
Purchase of treasury stock (Note 17) .	--	--	--	--	(393)	(2,
Equity related compensation	--	--	--	--	--	--
Balance at December 31, 2002	261	\$--	74,168	\$ 74	(393)	\$ (2,

(In thousands)	Additional Paid-in Capital	Accumulated Deficit	Accrued Dividends Payable	Deferred Compensation	Acco Comp Inco
Issuance of common stock in connection with exercise of warrants and stock options	8,309	--	--	--	--
Issuance of common stock as hiring bonus	--	--	--	--	--
Issuance of common stock related to license agreement	--	--	--	--	--
Equity related compensation	1,705	--	--	(632)	--
Balance at December 31, 2001	248,685	(198,662)	--	(1,713)	--
Comprehensive loss:					
Net loss	--	(74,528)	--	--	--
Unrealized investment loss	--	--	--	--	--
Total comprehensive loss					
Issuance of common stock in connection with private placement, net of issuance costs of \$899	71,028	--	--	--	--

Edgar Filing: GENTA INC DE/ - Form 10-K

Issuance of common stock in connection with exercise of warrants and stock options	3,284	--	--	--	--
Purchase of treasury stock (Note 17) .	--	--	--	--	--
Equity related compensation	--	--	--	1,016	--
	-----	-----	-----	-----	-----
Balance at December 31, 2002	\$ 322,997	\$ (273,190)	\$ --	\$ (697)	\$ --
	=====	=====	=====	=====	=====

See accompanying notes to consolidated financial statements.

33

GENTA INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)	Years Ended December	
	2002	2001
Operating activities:		
Net loss	\$ (74,528)	\$ (46,713)
Items reflected in net loss not requiring cash:		
Depreciation and amortization	1,646	1,131
Loss on disposition of equipment	13	19
Promega settlement (Note 5)	--	1,000
Non-cash equity related compensation (Note 18)	1,016	1,074
Changes in operating assets and liabilities:		
Accounts, notes and loan receivable (Note 4 & 5)	(14,538)	102
Other assets (Note 6)	(751)	(282)
Accounts payable, accrued and other expenses	20,895	8,679
Deferred revenue (Note 13)	46,501	--
Net cash used in operating activities	(19,746)	(34,990)
Investing activities:		
Purchase of available-for-sale short-term investments (Note 3) .	(88,317)	(14,521)
Maturities of available-for-sale short-term investments (Note 3)	23,380	29,546
Purchase of property and equipment	(2,387)	(1,438)
Purchase of intangibles	--	--
Deposits and other	(142)	(68)
Net cash (used in) provided by investing activities	(67,466)	13,519
Financing activities:		
Proceeds from private placements of common stock, net (Note 17)	71,035	32,223
Proceeds from convertible debt (Note 14)	10,000	--
Purchase of treasury stock (Note 17)	(2,506)	--
Proceeds from exercise of warrants and options (Note 17 & 18) ..	3,285	8,321
Net cash provided by financing activities	81,814	40,544
(Decrease) increase in cash and cash equivalents	(5,398)	19,073
Cash and cash equivalents at beginning of year	38,098	19,025

Edgar Filing: GENTA INC DE/ - Form 10-K

Cash and cash equivalents at end of year	\$ 32,700	\$ 38,098	\$
	=====	=====	=====

See accompanying notes to consolidated financial statements.

GENTA INCORPORATED
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended December 31, 2002, 2001 and 2000

1. Organization and Business

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

The Company 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 20). 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 immaterial 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(TM).

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

The Company may also seek collaborative agreements, equity financing and other financing arrangements with potential corporate partners and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available on favorable terms, if

Edgar Filing: GENTA INC DE/ - Form 10-K

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, 2002 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.

35

Revenue Recognition

In April 2002, the Company entered into a development and commercialization agreement ("Collaborative Agreement") with Aventis Pharmaceuticals Inc. ("Aventis"). Under the terms of the Collaborative Agreement, the Company and Aventis will jointly develop and commercialize Genasense(TM) in the U.S. ("the Alliance"), and Aventis will have exclusive development and marketing rights to the compound in all countries outside of the U.S. Under the Collaborative Agreement, Aventis will pay 75% of U.S. NDA-directed development costs incurred by either Genta or Aventis, subsequent to the execution of the Collaborative Agreement, and 100% of all other development, marketing, and sales costs incurred within the U.S. and elsewhere as subject to the Collaborative Agreement (Note 12). Reimbursements are to be made pursuant to a single net payment from one party to the other. Such payments are due and payable 60 days following the end of the quarter in which such expenses are incurred.

Consistent with Staff Accounting Bulletin No. 101 "Revenue Recognition" ("SAB 101"), initial funding of ongoing development received from Aventis after the achievement of certain research and development milestones (Note 12) will be recognized on a straight-line basis over the estimated useful life of the related first-to-expire patent of 115 months. Any subsequent milestone payments that may be received from Aventis will also be recognized over the then, remaining estimated useful life of the related first-to-expire patent.

In 2001 and 2000, the Company entered into worldwide non-exclusive license agreements. The license agreements each have initial terms that 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 is 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 products for clinical trials. Once Genta

Edgar Filing: GENTA INC DE/ - Form 10-K

has submitted an NDA, which includes the results of the preclinical and clinical testing, chemistry, manufacturing and control information, to the FDA for approval to commence commercial sales, Genta will then include the sales launch product, consisting of raw materials and all subsequent processing costs required to produce finished goods, as inventory on Genta's balance sheet in anticipation of approval by the FDA.

Reimbursements for applicable Genasense(TM)-related costs, under the Collaborative Agreement (Note 12), will continue to be recorded as a reduction to research and development expense.

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 and government securities, all of which are classified as available-for-sale marketable securities. Management determines the appropriate classification of debt and equity securities at the time of purchase and reassesses the classification at each reporting date. The Company invests its excess cash primarily in debt instruments of domestic corporations with "AA" or greater credit ratings as defined by Standard & Poors and government backed securities. The Company has established guidelines relative to diversification and maturities that attempt to maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

Property and Equipment

Property and equipment is stated at cost and depreciated on the straight-line method over the estimated useful lives of the assets, ranging from three to five years. Leasehold improvements incurred in the renovation of the Company's current offices are being amortized over the remaining life of the leases. The Company's policy is to evaluate the appropriateness of the carrying value of the undepreciated value of long-lived assets on the basis of estimated future cash flows (undiscounted) and other factors. If such evaluation were to indicate an impairment of these intangible assets, such impairment would be recognized by a write-down of the applicable assets. Since the Company signed a new seven-year lease for additional office space in June 2002, the Company's previous leases for office space have been amended so that the expiration dates coincide with the new lease term.

36

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

Edgar Filing: GENTA INC DE/ - Form 10-K

The Company uses the liability method of accounting for income taxes. Deferred income taxes are determined based on the estimated future tax effects of differences between the financial statement and tax bases of assets and liabilities given the provisions of the enacted tax laws.

The Company may record valuation allowances against net deferred tax assets, if based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and when temporary differences become deductible. The Company considers, among other available information, uncertainties surrounding the recoverability of deferred tax assets, scheduled reversals of deferred tax liabilities, projected future taxable income, and other matters in making this assessment. At December 31, 2002 the Company has reviewed its deferred tax assets and believes that the valuation allowance reduces such assets to an amount that is more likely than not to be realized.

Stock Options

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

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - Amendment of FASB Statement No. 123," to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of Statement No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results.

The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

37

	Years Ended December 31,		
(\$ thousands, except per share data)	2002	2001	2000
Net loss applicable to common shares, as reported	\$(74,528)	\$(46,713)	\$(15,8
Add: Equity related compensation expense included in reported			

Edgar Filing: GENTA INC DE/ - Form 10-K

net income, net of related tax effects	1,016	1,074	8,6
Deduct: Total stock-based employee compensation expense determined under fair values based method for all awards, net of related tax effects	6,840	5,477	4,7
	-----	-----	-----
Pro forma net loss	\$ (80,352)	\$ (51,116)	\$ (11,9
	=====	=====	=====
Net loss per share attributable to common shareholders:			
As reported: Basic and diluted	\$ (1.05)	\$ (0.84)	\$ (0.
Pro forma: Basic and diluted	\$ (1.14)	\$ (0.92)	\$ (0.

Net Loss Per Common Share

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

Net loss per common share for the three years ended December 31, 2002 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 16.7 million, 17.2 million and 28.3 million in 2002, 2001 and 2000, respectively, have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would be antidilutive. Net loss per common share is based on net loss adjusted for imputed and accrued dividends on preferred stock.

Recently Issued Accounting Standards

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations." SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS No. 143 requires that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset. The Company adopted SFAS No. 143 effective January 1, 2003. The adoption did not have a material impact on the Company's results of operations, financial position or cash flows.

In April 2002, the FASB issued SFAS No. 145, "Recission of FASB Statements 4, 44 and 64, Amendment of FASB Statement 13, and Technical Corrections". SFAS No. 145 rescinds the provisions of SFAS No. 4 that requires companies to classify certain gains and losses from debt extinguishments as extraordinary items, eliminates the provisions of SFAS No. 44 regarding transition to the Motor Carrier Act of 1980 and amends the provisions of SFAS No. 13 to require that certain lease modifications be treated as sale leaseback transactions. The provisions of SFAS No. 145 related to classification of debt extinguishment are effective for fiscal years beginning after May 15, 2002. Commencing January 1, 2003, the Company will classify debt extinguishment costs within income from operations. The provisions of SFAS No. 145 related to lease modifications are effective for transactions occurring after May 15, 2002. The Company does not expect the provisions of SFAS No. 145 related to lease modifications to have a material impact on its financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 nullifies Emerging Issues Task Force ("EITF") No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain

Edgar Filing: GENTA INC DE/ - Form 10-K

Costs Incurred in a Restructuring). The principal difference between SFAS No. 146 and EITF No. 94-3 relates to its requirements for recognition of a liability for a cost associated with an exit or disposal activity. SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF No. 94-3, a liability for an exit cost was recognized at the date of an entity's commitment to an exit plan. SFAS No. 146 is effective for exit and disposal activities that are initiated after December 31, 2002. The Company does not expect the provisions of SFAS No. 146 to have a material impact on its financial position or results of operations.

In November 2002, FASB Interpretation, ("FIN") 45, "Guarantor's Accounting And Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others," was approved by the FASB. FIN 45 clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The initial recognition and initial measurement provisions of this interpretation are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The interpretation also requires enhanced and additional disclosures of guarantees in financial statements ending after December 15, 2002. In the normal course of business, the Company does not issue guarantees, accordingly this interpretation has not effect on the financial statements.

38

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):

	Amortized costs -----	Unrealized gains -----	Unrealized losses -----	Estimated fair value -----
December 31, 2002				
Corporate debt securities	\$80,991 =====	\$ 42 =====	\$ (17) =====	\$81,016 =====
December 31, 2001				
Corporate debt securities	\$16,054 =====	\$ 23 =====	\$ (89) =====	\$15,988 =====

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

	December 31,	
	2002	2001
Due in one year or less	\$55,979	\$15,988
Due after one year	25,037	--
	\$81,016 =====	\$15,988 =====

Edgar Filing: GENTA INC DE/ - Form 10-K

The estimated fair value of each marketable security has been compared to its cost, and therefore, an unrealized gain of approximately \$0.025 million has been recognized in accumulated other comprehensive income at December 31, 2002.

4. Accounts Receivable

Included in accounts receivable and netted against operating expenses in the consolidated statement of operations at December 31, 2002, is \$14.554 million in net expense reimbursements due from Aventis for various third-party costs, internal costs of scientific and technical personnel ("Full-time Equivalents" or "FTE's") and Genasense(TM) drug supply costs for the three month period ended December 31, 2002. Information with respect to this cost reimbursement is presented below (\$ thousands):

Reimbursement to Genta:	December 31, 2002

Third-party costs	\$10,936
Drug supply costs	2,254
FTE's	1,364

Amount due Genta	\$14,554
	=====

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 19). The principal of the note plus accrued interest was due as follows: \$0.700 million on June 30, 2000 and \$0.500 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 \$0.138 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 \$0.2 million non-interest bearing note due upon final resolution of certain environmental issues related to JBL and forgive all accrued interest (Note 19). The transaction resulted in a non-recurring charge of \$1.0 million for the quarter ended March 31, 2001. As of March 21, 2003, the Company is awaiting final acceptance by the EPA of the Company's settlement offer before the remaining note receivable will be repaid by JBL.

39

6. Prepaid Expenses and Other Current Assets

Included in prepaid expenses and other current assets at December 31, 2002, is \$0.834 million for prepaid insurance expenses for various corporate insurance policies, of which \$0.723 million is for directors and officers liability. After an initial deposit was paid by the Company related to the insurance policies, the remaining balance was financed and will be repaid in eight equal installments. At December 31, 2002 the remaining balance to be paid was \$0.490 million.

The remaining amount in prepaid expenses and other current assets is primarily interest due on short-term investments.

7. Property and Equipment

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

Edgar Filing: GENTA INC DE/ - Form 10-K

	Estimated Useful Lives	December 31,	
		2002	2001
Computer equipment	3	\$1,734	\$ 599
Software	3	1,237	256
Furniture and fixtures	5	920	764
Leasehold improvements	5	613	523
Equipment	5	80	74
		-----	-----
		4,584	2,216
Less accumulated depreciation and amortization		(1,328)	(368)
		-----	-----
		\$3,256	\$1,848
		=====	=====

8. 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 \$0.502 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 only \$0.033 million in net earnings of the joint venture allocated to Genta and we are currently seeking to terminate our involvement with the joint venture.

In 1999, the Company wrote-off its liability in this joint venture and recorded a gain of approximately \$2.3 million. Financial statements of the joint venture for the year ended December 31, 2002 and 2001 were not available.

9. Intangibles

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

	December 31,	
	2002	2001
Patent and patent applications	\$ 3,905	\$ 3,905
Other amortizable costs	87	87
	-----	-----
	3,992	3,992
Less accumulated amortization	(2,552)	(1,872)
	-----	-----
	\$ 1,440	\$ 2,120
	=====	=====

Future amortization expense related to intangibles at December 31, 2002 are as follows (\$ thousands):

Edgar Filing: GENTA INC DE/ - Form 10-K

	Amortization Expense

2003	\$ 577
2004	577
2005	286
2006	--
2007	--
Thereafter	--

Total	\$ 1,440
	=====

40

10. 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. 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.

11. Accrued Expenses

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

	December 31,	
	-----	-----
	2002	2001
	-----	-----
Accrued expenses relating to clinical trials	\$ 910	\$ 792
Accrued compensation	1,826	822
Accrued interest	384	--
Other accrued costs	1,620	695
	-----	-----
	\$4,740	\$2,309
	=====	=====

12. Collaborative Agreement

In April 2002, the Company entered into a development and commercialization agreement ("Collaborative Agreement") with Aventis Pharmaceuticals Inc. ("Aventis"). Under the terms of the Collaborative Agreement, the Company and Aventis will jointly develop and commercialize Genasense(TM) in the U.S. ("the Alliance"), and Aventis will have exclusive development and marketing rights to the compound in all countries outside of the U.S. The Company will retain responsibility for global manufacturing and for regulatory filings within the U.S., while Aventis will assume all regulatory responsibilities outside the U.S. Joint management teams, including representatives from both Genta and Aventis, will oversee the Alliance. Collectively, this Collaborative Agreement could provide up to \$476.9 million in cash, equity and convertible debt proceeds to the Company. In addition, under

Edgar Filing: GENTA INC DE/ - Form 10-K

the Collaborative Agreement, Genta is entitled to royalties on any worldwide sales of Genasense(TM), from which Genta is required to pay third-party pass-through royalties to the University of Pennsylvania ("UPenn") and The National Institutes of Health ("NIH") based on net worldwide sales. Furthermore, under the Collaborative Agreement, Aventis will pay 75% of U.S. NDA-directed development costs incurred by either Genta or Aventis subsequent to the execution of the Collaborative Agreement, and 100% of all other development, marketing, and sales costs incurred within the U.S. and elsewhere as subject to the Collaborative Agreement. An analysis of expenses reimbursed under the Collaborative Agreement follows (\$ thousands):

	Three Months Ended December 31,			Twelve Months Ended December 31,		
	2002	2001	2000	2002	2001	2000
Research and development expenses, gross	\$ 40,760	\$ 15,569	\$ 2,916	\$ 86,645	\$ 39,355	\$ 6,830
Less expense reimbursement	(14,434)	--	--	(27,746)	--	--
Research and development expenses, net	\$ 26,326	\$ 15,569	\$ 2,916	\$ 58,899	\$ 39,355	\$ 6,830
General and administrative expenses, gross	\$ 4,816	\$ 2,633	\$ 596	\$ 20,052	\$ 8,215	\$ 3,323
Less expense reimbursement	(120)	--	--	(705)	--	--
General and administrative expenses, net	\$ 4,696	\$ 2,633	\$ 596	\$ 19,347	\$ 8,215	\$ 3,323

41

As of December 31, 2002, the Company has received a total of \$131.9 million in initial and near-term funding, which included a \$10.0 million licensing fee and \$40.0 million in development funding (Note 13), \$10.0 million in convertible debt proceeds (Note 14), and \$71.9 million pursuant to an at-market equity investment in the Company's common stock priced at \$10.792 per share. The remaining amounts that could be received under the Collaborative Agreement, \$280.0 million in cash and \$65.0 million in convertible note proceeds, are contingent upon the achievement of certain research and development milestones. In connection with this \$131.9 million, the Company paid approximately \$1.5 million for financial advisory services and an aggregate of \$3.5 million in one-time pass-through payments to UPenn and the NIH. Neither UPenn nor the NIH is entitled to any portion of future research and development milestone payments that Genta may receive.

13. Deferred Revenues

As of December 31, 2002, the Company had recorded \$46.591 million, net of amortization in deferred revenues relating to the initial \$10.0 million licensing fee and \$40.0 million development funding received from Aventis under the Collaborative Agreement (Note 12), of which \$5.237 million is included in current liabilities and \$41.354 million is classified as long-term deferred revenues, which will be recognized on a straight-line basis over the estimated

Edgar Filing: GENTA INC DE/ - Form 10-K

useful life of the related first-to-expire patent of 115 months, in accordance with SAB 101. Any subsequent milestone payments that may be received from Aventis will also be recognized over the then, remaining estimated useful life of the related first-to-expire patent.

14. Convertible Debt

At December 31, 2002, the Company had \$10.0 million in convertible debt that was issued in connection with the Collaborative Agreement (Note 12). The Company received \$10.0 million in debt proceeds from Aventis, and issued a \$10.0 million convertible promissory note to Aventis ("Aventis Note"). Interest accrues at the rate of 5.63% per annum until April 26, 2009 (the "Maturity Date") and compounds annually on each anniversary date of the Aventis Note through the Maturity Date. The Company may redeem the Aventis Note for cash in whole or in part (together with any accrued and unpaid interest with respect to such principal amount) in amounts of not less than \$0.5 million (and in \$0.1 million increments thereafter). In addition, the Company may convert the Aventis Note on or prior to the Maturity Date in whole or in part (together with any accrued and unpaid interest with respect to such principal amount) in amounts of not less than \$5.0 million (and in \$1.0 million increments thereafter), into fully paid and non-assessable shares of common stock (calculated as to the nearest 1/1000 of a share). As of any date, the number of shares of common stock into which the Aventis Note may be converted shall be determined by a formula based on the then market value of the common stock (the "Conversion Price"), subject to a minimum Conversion Price of \$8.00 per share.

As of December 31, 2002, the Company has accrued interest of \$0.384 million on the Aventis Note.

15. Income Taxes

The Company's tax provision is comprised of \$0.184 million of current state taxes related to the New Jersey Alternate Minimum Assessment (AMA) Tax. Significant components of the Company's deferred tax assets as of December 31, 2002 and 2001 and related valuation reserves are presented below (\$ thousands):

	December 31,	
	2002	2001
Deferred tax assets:		
Deferred compensation	\$ 6,152	\$ 5,292
Net operating loss carryforwards	68,407	53,414
Research and development credits	52,630	5,554
Purchased technology and license fees	4,850	4,519
Depreciation, net	--	18
Deferred revenue	20,500	--
New Jersey Alternate Minimum Assessment (AMA) Tax ..	184	--
Other, net	212	246
	152,935	69,043
Valuation allowance for deferred tax assets	(152,775)	(68,999)
	160	44
Net deferred tax assets		

Edgar Filing: GENTA INC DE/ - Form 10-K

Deferred tax liabilities:		
Patent expenses	--	(44)
Depreciation, net	(160)	--
	-----	-----
	(160)	(44)
	-----	-----
Net deferred tax assets (liabilities)	\$ --	\$ --
	=====	=====

A full valuation allowance has been provided at December 31, 2002 and 2001 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, 2002, the Company has federal and state net operating loss carryforwards of approximately \$171.0 million and \$95.0 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 \$52.6 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 Company's future annual utilization of their net operating loss carryforwards and research and development tax credits will be limited due ownership changes which occurred previously.

16. Operating Leases

At December 31, 2002 and 2001, the Company maintained \$0.507 million and \$0.365 million, respectively, in restricted cash balances with a financial institution related to lease obligations on its corporate facilities and leased fleet vehicles. Such restricted cash balances collateralize letters of credit issued by the financial institution in favor of the Company's landlord with respect to corporate facilities and GE Capital with respect to leased fleet vehicles.

Future minimum obligations under operating leases at December 31, 2002 are as follows (\$ thousands):

	Operating Leases	

2003	\$ 2,199	
2004	2,478	
2005	2,476	
2006	2,585	
2007	2,613	
Thereafter	5,581	

Total	\$17,932	
	=====	

Edgar Filing: GENTA INC DE/ - Form 10-K

17. 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 \$0.363 million was included as a charge to non-cash equity related compensation in the amounts of \$0.215 million and \$0.148 million in 2000 and 1999, respectively. The Company obtained Board approval in February 2003 for the issuance of the 50,000 shares to the University, which will be issued in March 2003.

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 at Baltimore to treat prostate cancer. As consideration for the acquisition, the Company paid \$0.132 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 1.0 million shares of common stock, 90% of which will not become exercisable until the successful conclusion of certain development milestones, ranging from the initial clinical patient trial through the submission of an application for marketing authorization. As of December 31, 2002, the above-mentioned milestones have not been met.

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, 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 \$0.125 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 95.0 million shares from 65.0 million. 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 related party of Genta, in which the Company acquired all assets, rights and technology to a portfolio of gallium containing compounds, known as Ganite(TM), in exchange for common stock valued at \$0.084 million. These compounds are used to treat cancer-related hypercalcemia.

In May 2000, the Company entered into a worldwide licensing arrangement

Edgar Filing: GENTA INC DE/ - Form 10-K

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 proceeds of approximately \$13.7 million, net of placement costs of \$0.916 million. 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 \$0.867 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.

44

In November 2000, the Company sold 4.285 million shares of common stock through a private placement and received proceeds of approximately \$26.8 million, net of placement costs of \$1.633 million. 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.

In November 2001, the Company sold 2.5 million shares of common stock through a private placement and received proceeds of approximately \$32.2 million, net of placement agent commissions of \$0.420 million and related expenses.

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

In May 2002, the Company sold 6.665 million shares of common stock to Aventis in connection with the Collaborative Agreement (Note 12) and received proceeds of \$71.0 million, net of investment banking fees of \$0.899 million and related expenses.

Treasury Stock

In June 2002, the Company commenced a stock repurchase program, whereby up to 5.0 million shares of its common stock may be repurchased by the Company at prices deemed desirable by the Company. The Company uses the cost method to account for treasury stock. Since initiating the stock repurchase program, the Company has repurchased a total of 392,700 shares at an average cost of \$6.3807 per share.

Preferred Stock

The Company has authorized 5.0 million shares of preferred stock and has issued and outstanding 260,500 shares of Series A Convertible Preferred Stock as of December 31, 2002. In 1999, the Board of Directors of the Company and certain

Edgar Filing: GENTA INC DE/ - Form 10-K

holders of common stock, Series A and D preferred stock approved, in accordance with Delaware law, an amendment to the Company's Restated Certificate of Incorporation to remove the "Fundamental Change" redemption right. The Company has formally amended its Restated Certificate of Incorporation after the expiration of the 20-day period provided for in Rule 14c-5 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Series A Preferred Stock

Each share of Series A Preferred Stock is immediately convertible, into shares of the Company's common stock, at a rate determined by dividing the aggregate liquidation preference of the Series A Preferred Stock by the conversion price. The conversion price is subject to adjustment for antidilution. As of December 31, 2002 and 2001, each share of Series A Preferred Stock was convertible into 6.8334 and 7.1573 shares of common stock, respectively.

In the event of a liquidation of the Company, the holders of the Series A Preferred Stock are entitled to a liquidation preference equal to \$50 per share, or \$13.025 million at December 31, 2002.

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,

45

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.

In May 1998, the Company requested, and subsequently received, consents (the "Letter Agreements") from the holders of a majority of the Series D 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 holders warrants to purchase an aggregate of up to 807,900 shares of common stock at \$0.94375 per share, 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. During 2002, the remaining

Edgar Filing: GENTA INC DE/ - Form 10-K

155,640 Class D Warrants expired and are no longer redeemable at \$0.10 per warrant. No dividends have been accrued after January 29, 2000 due to the mandatory conversion of the Series D Preferred Stock.

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 \$0.150 million in commissions upon the exercise of the warrants, which were exercised in September 2001, resulting in commissions expense of \$0.150 million.

46

Warrants

Summary information with respect to outstanding common stock warrants at December 31, 2002 is presented below:

	Exercise Price -----	Potential Warrant Exercise Proceeds -----	Co Equi -----
June 1997 Private Placement (Series D):			
Placement & Advisory Warrants:	\$0.86465 - \$1.10	\$ 3,037,995	3,3
Androgenics Warrants (August 1999):			
Vested December 31, 1999:	\$1.25	121,875	
Vest upon achievement of various milestones: ..	\$1.50 - \$2.50	1,787,500	9
December 1999 Private Placement (Common):			
Related Party Warrants:			
Common Stock:	\$3.30	1,060,739	3
Warrants:	\$5.31	426,711	
Funding Warrants:	\$4.69716	2,629,282	5
Penalty Warrants (May 2000):	\$4.69716	213,791	
September 2000 Private Placement (Common):			
Penalty Warrants:	\$6.75	91,550	
Placement Agent Warrants:	\$7.1500	310,117	
Placement Agent Warrants:	\$7.4250	289,330	
November 2000 Private Placement (Common):			

Edgar Filing: GENTA INC DE/ - Form 10-K

Placement Agent Warrants:	\$7.4250	429,336	---
		-----	---
		\$10,398,226	5,5
		=====	===

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. The Placement Warrants and the Advisory Warrants expire on June 29, 2007.

On August 30 1999, the Company acquired Androgenics Technologies, Inc. ("Androgenics"), a wholly owned entity of a related party shareholder. As consideration for the acquisition, the Company paid \$0.132 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 1.0 million shares of common stock, 90% of which will not become exercisable until the successful conclusion of certain development milestones, ranging from the initial clinical patient trial through the submission of an application for marketing authorization. The acquisition was accounted for as a transfer of interest between companies under common control. The cash and warrants were issued in exchange for 100% of the shares of Androgenics and licensed technology and the assumption of a research and development agreement with the University of Maryland at Baltimore. The 1.0 million warrants were accounted for as a deemed distribution based on their fair value of \$0.441 million. At December 31, 2002, none of the above-mentioned milestones have been met and these warrants expire in August 2004.

On November 5, 1999, the Company issued 550,000 Bridge Warrants to the Aries Funds in full settlement of the Company's obligation under a 1997 note and warrant purchase agreement. The settlement of this obligation was accounted for as a capital distribution, since the Aries Funds are a shareholder of the Company. Accordingly, these warrants were accounted for at their fair value of \$1.8 million and included in accrued dividends at December 31, 1999. In September 2001, these warrants were exercised for \$0.204 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 \$0.867 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

Edgar Filing: GENTA INC DE/ - Form 10-K

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, 2002, an aggregate of 16,662,202 shares of common stock were reserved for the conversion of preferred stock and the exercise of outstanding options and warrants.

18. 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.

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 January 1, 2000	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
Granted	--	--
Exercised	--	--
Canceled	--	--
	-----	-----
Balance at December 31, 2002	4,388	\$22.41
	=====	=====

At December 31, 2002, 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.

Edgar Filing: GENTA INC DE/ - Form 10-K

1998 Plan

Pursuant to the Company's 1998 Stock Plan as amended (the "1998 Plan"), 15.6 million shares have been provided for the grant of stock options to employees, directors, consultants and advisors of the Company. In March 2002, the Board of Directors approved an amendment to increase the total number of shares of common stock authorized for issuance under the 1998 Plan to 15.6 million shares from 12.1 million. In June 2002, shareholders approved this amendment at the annual meeting of stockholders. Options may be designated as incentive stock options or non-statutory stock options; however, incentive stock options may be granted only to employees of the Company. Options under the 1998 Plan have a term of up to 10 years and must be granted at not less than the fair market value, or 85% of fair market value for non-statutory options, on the date of the grant. Common stock sold and options granted pursuant to the 1998 Plan generally vest over a period of four years.

Grants to Employees and Directors - 1998 Plan

During 1999, 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 \$0.471 million, \$0.417 million, and \$0.519 million as non-cash equity related compensation expense in 2002, 2001, and 2000, respectively. In 2000, the Company recorded additional deferred compensation of \$0.064 million for the remeasurement of the new CEO's options, of which \$0.013 million, \$0.013 million and \$0.027 million was amortized as non-cash equity related compensation expense in 2002, 2001 and 2000, respectively.

During 2000, the Company granted to a 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 \$0.032 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 \$0.934 million attributable to the intrinsic value of these options, and amortized \$0.234 million and \$0.293 million as non-cash equity related compensation expense in 2002 and 2001.

The Company's employees were granted 1,274,400, 1,392,300 and 558,362 stock options with exercise prices equal to fair market value on the date of grant in 2002, 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 had 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 \$0.529 million and \$1.175 million of deferred compensation relative to these JBL options in 2000 and 1999, respectively, and amortized

Edgar Filing: GENTA INC DE/ - Form 10-K

\$0.948 million and \$0.756 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 \$0.033 million and \$0.136 million in deferred compensation in 2000 and 1999, respectively, of which \$0.069 million and \$0.100 million was amortized as non-cash equity related compensation expense in 2000 and 1999, respectively.

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 \$0.297 million and \$0.257 million was amortized as non-cash equity related compensation expense in 2002 and 2001, respectively.

49

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 January 1, 2000	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
Granted	1,274,400	11.88
Exercised	(871,632)	2.12
Canceled	(198,400)	11.88
	-----	-----
Balance at December 31, 2002	8,499,612	\$ 4.89
	=====	=====

At December 31, 2002, options to purchase 5,493,987 shares of common stock were exercisable at a weighted average exercise price of approximately \$3.21 per share and 3,359,706 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"), 3.3 million shares have been provided for the grant of stock options to non-employee members of the Board of Directors. In March 2002, the Board of Directors approved an amendment to increase the total number of shares of common stock authorized for issuance under the Directors'

Edgar Filing: GENTA INC DE/ - Form 10-K

Plan to 3.3 million shares from 2.9 million and an amendment to change the amount and the time when stock options are granted under the Directors' Plan. In June 2002, shareholders approved both amendments at the annual meeting of stockholders. Options under the Directors' Plan have a term of up to ten years and must be granted at not less than the fair market value on the date of grant. As amended and approved, each director shall be granted 20,000 options at the first Board of Directors meeting they attend in person. Each option granted shall become exercisable in full on the date of grant.

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 \$0.366 million, of which \$0.124 million and \$0.153 million was amortized as non-cash equity related compensation expense in 2000 and 1999, respectively.

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 compensation of \$0.052 million attributable to the intrinsic value of these options, of which \$0.001 million and \$0.051 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 174,667, 170,769 and 450,000 shares of common stock in 2002, 2001 and 2000, respectively, with an exercise price equal to the fair market value of the common stock on the date of grant.

50

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

1998 Directors' Plan -----	Shares Under Option -----	Weighted Average Exercise Price Per Share -----
Balance at January 1, 2000	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
Granted	174,667	11.29
Exercised	(475,000)	1.96
Canceled	(125,000)	8.77

Edgar Filing: GENTA INC DE/ - Form 10-K

Balance at December 31, 2002	864,336	\$ 7.41
	=====	=====

At December 31, 2002, options granted under the Directors' Plan to purchase 771,836 shares of common stock were exercisable at a weighted average exercise price of approximately \$6.86 per share and 1,457,813 shares of common stock were available for grant or sale under the Directors' Plan.

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 average grant date fair value of \$8.53 per share, and 50,000 were granted below fair market value with a weighted average grant date fair value of \$6.64 per share. In 2002, a total of 1,449,067 options were granted pursuant to the 1998 Plan and the 1998 Directors Plan at fair market value with a weighted average grant date fair value of \$11.81 per share. No options were granted below fair market value.

An analysis of all options outstanding as of December 31, 2002 is presented below:

Range of Prices	Options Outstanding	Weighted Average Remaining Life in Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price
\$ 0.88 - \$ 0.94	769,000	5.96	\$ 0.92	769,000	\$ 0.92
\$ 2.41 - \$ 5.92	5,398,262	7.31	4.03	4,325,885	2.72
\$ 6.03 - \$ 9.92	1,898,283	8.85	7.89	904,510	7.65
\$10.00 - \$15.85	1,160,401	9.00	13.02	223,926	12.26
\$16.14 - \$25.00	142,390	7.17	18.87	46,890	18.53
	-----			-----	
	9,368,336			6,270,211	
	=====			=====	

Pro Forma Disclosure

As permitted under SFAS No. 123, the Company has elected to follow APB Opinion No. 25 and related interpretations in accounting for stock-based awards to employees. Pro-forma information regarding net income is required by SFAS No. 123. This information is required to be determined as if the Company had accounted for its stock-based awards to employees under the fair value method of that statement. The fair value of options during the years ended December 31, 2002, 2001, and 2000, as reported below has been estimated at the date of grant using the minimum value option pricing model with the following assumptions:

	Years Ended December 31,		
	2002	2001	2000
Risk-free interest rate	2.8%	4.0%	6.3%
Dividend yield	--	--	--
Expected life (years)	4.0	4.5	4.5

Edgar Filing: GENTA INC DE/ - Form 10-K

Volatility 65% 69% 74%

All of the options issued during 2002 were issued with an exercise price equal to market value on the date of grant. The weighted-average estimated fair value of employee stock options granted during 2002 was \$11.81 per share.

Employee Savings Plan

In January 2001, the Company initiated sponsorship of the Genta Incorporated Savings and Retirement Plan, a defined contribution plan under Section 401(K) of the Internal Revenue Code. The Company's matching contribution to the Plan was \$0.343 million and \$0.144 million for 2002 and 2001, respectively.

19. Commitments and Contingencies

Litigation and Potential Claims

JBL

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 \$0.065 million 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 was required.

JBL was notified 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 \$0.075 million during 1998. In 1999, the EPA estimated that the Company would be required to pay approximately \$0.063 million to settle their potential liability. In December 2001, Genta received a revised settlement proposal from the EPA in the amount of \$0.033 million, the terms of the settlement with the EPA containing standard contribution protection and release language and accordingly, reduced the previous accrual. In January 2002, the Company accepted the proposal and paid the \$0.033 million as an offer to settle this matter. There can be no assurance, however, that the EPA will not reject our settlement offer if there is not a sufficient number of PRP's settling with the EPA.

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

Edgar Filing: GENTA INC DE/ - Form 10-K

approximately US\$0.863 million at December 31, 2002) 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\$0.671 million at December 31, 2002) and subsequently notified us that Genta was liable as a guarantor on the note. At December 31, 2002, the Company has accrued a net liability of \$0.212 million related to the ANVAR Agreement, which management believes is adequate to provide for that contingency.

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

52

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\$0.374 million at September 30, 2002). 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\$0.284 million at September 30, 2002). The Company negotiated with Marseille Amenagement and agreed to settle this matter for EUR0.140 million or \$0.138 million, which was paid in September 2002. The settlement amount of \$0.138 million was recorded as a reduction to the Company's accrued net liability.

University of Pennsylvania

In October 2002, a licensing officer from the University of Pennsylvania ("UPenn") asserted a claim to a portion of the initial \$40.0 million development funding (Note 13) the Company received from Aventis pursuant to the Collaborative Agreement. The Company has disputed this claim and has filed a petition for binding arbitration for this matter, as provided in the original licensing agreement between the Company and UPenn. At the current time the Company cannot reasonably estimate the outcome of this claim; however, the Company does not believe that this claim will have a material adverse impact on the Company's financial results and liquidity. As such, the Company has not reserved any amount for royalty payments that could be due to UPenn as a result of binding arbitration.

Purchase Commitments

At December 31, 2002, the Company was obligated for \$27.5 million in drug substance purchases during 2003 per an agreement entered into with Avecia Biotechnology, Inc. ("Avecia") in December 2002 (the "Supply Agreement"). Pursuant to the Collaborative Agreement with Aventis (Note 13), the Company

Edgar Filing: GENTA INC DE/ - Form 10-K

anticipates that it will be reimbursed for at least 75% of these purchase commitments after the drug is shipped to the clinical sites. In addition, the Company has committed up to \$5.0 million of advance financing to the drug substance manufacturer, for facility expansion, which would be recovered with interest through future payments determined as a function of drug substance purchases to be made by Genta in the future. In 2003, the Company paid \$0.392 million in advance financing.

20. 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 \$0.147 million, and legal, accounting, tax and other miscellaneous costs of the sale approximating \$0.653 million.

In connection with the JBL Agreement (Note 18), the Company granted stock options during 1999 to acquire 450,000 shares of common stock, to 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, 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 \$0.948 million and \$0.757 million for the years ended December 31, 2000 and 1999, respectively.

53

21. Subsequent Events

In March 2003, the Company and Aventis signed an amendment to the Collaborative Agreement (Note 12), which establishes a line of credit, up to \$40.0 million, related to the development, manufacturing and commercialization of Genasese(TM).

22. Selected Quarterly Financial Data (Unaudited)

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

Edgar Filing: GENTA INC DE/ - Form 10-K

Net loss per common share:

Basic and diluted \$ (0.19) \$ (0.25) \$ (0.21) \$ (0.40)

2001

(\$ thousands, except per share data)

	Mar. 31	Jun. 30	Sep. 30	Dec. 31
	-----	-----	-----	-----
Revenues	\$ 70	\$ 12	\$ 23	\$ 41
Operating expenses (2)	7,028	11,129	11,210	18,203
Loss from continuing operations	(7,459)	(10,903)	(10,420)	(17,931)
Net loss	(7,459)	(10,903)	(10,420)	(17,931)
Loss per common share from continuing operations:				
Basic and diluted	\$ (0.15)	\$ (0.21)	\$ (0.19)	\$ (0.29)
Net loss per common share:				
Basic and diluted	\$ (0.15)	\$ (0.21)	\$ (0.19)	\$ (0.29)

(1) Excludes equity related compensation expense

(2) Excludes equity related compensation expense and Promega settlement expense (Note 5)

23. Supplemental disclosure of cash flows information and non-cash investing and financing activities

(\$ thousands)	Years Ended December 31,		
	2002	2001	2000
	----	----	----
Preferred stock dividend accrued	\$ --	\$ --	\$3,443
Common stock issued in payment of dividends on preferred stock	--	--	8,577
Common stock issued in payment of patent portfolios	--	--	2,484
Income receivable on securities to be sold		(3)	64
Market value change on short-term investments	91	(97)	31
Stock warrants issued to placement agent	--	--	867
Common stock to be issued in payment of future royalties	--	--	1,268
Common stock issued in payment of hiring bonus		50	--

Interest paid during the year ended December 31, 2000 was \$0.036 million. No interest was paid in the years ended December 31, 2002 and 2001.

PART III

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

Changes in Accountants

None.

Disagreements with Accountants

None.

Edgar Filing: GENTA INC DE/ - Form 10-K

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, 2003 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, 2003 pursuant to Regulation 14A.

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

The information required in this item is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 2003 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, 2003 pursuant to Regulation 14A.

Item 14. Controls and Procedures

Evaluation of disclosure controls and procedures. Genta's Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of the Company's "disclosure controls and procedures" (as defined in Exchange Act Rules 13a-14(c) and 15-d and 14(c)) as of a date (the "Evaluation Date") within 90 days of the filing of this annual report, have concluded that as of the Evaluation Date, our disclosure controls and procedures were adequate and designed to ensure that material information relating to the Company would be made known to them by others within the Company.

Changes in internal controls. There were no significant changes in our internal controls or, to our knowledge, in other factors that could significantly affect the Company's disclosure controls and procedures subsequent to the Evaluation Date.

PART IV

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

(a) Financial statements

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

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

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

Edgar Filing: GENTA INC DE/ - Form 10-K

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

On June 12, 2002, the Company filed a Current Report on Form 8-K disclosing a press release issued on June 11, 2002, regarding the Company's commencement of a stock repurchase program, whereby up to 5,000,000 shares of its common stock may be repurchased by the Company at prices deemed desirable by the Company.

On April 29, 2002, the Company filed a Current Report on Form 8-K disclosing a press release issued on April 29, 2002, regarding an agreement the Company entered into with Aventis Pharmaceuticals Inc. to jointly develop and commercialize Genasense(TM) (G3139), the Company's lead antisense compound.

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.

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

Exhibit Number -----	Description of Document -----
3(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 Company.
3(i).3(15)	Certificate of Amendment of Restated Certificate of Incorporation of the Company.
3(i).4(15)	Amended Certificate of Designations of Series D Convertible Preferred Stock of the Company.
3(i).5(15)	Certificate of Increase of Series D Convertible Preferred Stock of the Company.
3(i).6(13)	Certificate of Amendment of Restated Certificate of Incorporation of the Company.
3(i).7(13)	Certificate of Amendment of Restated Certificate of Incorporation of the Company.
3(i).8(15)	Certificate of Amendment of Restated Certificate of Incorporation of the Company.
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.
4.4(4)	Form of Unit Purchase Agreement dated as of September 23, 1993 by and between the Company and the Purchasers of the Series A Convertible Preferred Stock.
10.1(2)	Amended and Restated 1991 Stock Plan of Genta Incorporated.

Edgar Filing: GENTA INC DE/ - Form 10-K

- 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 directors and officers.
- 10.3(1) Preferred Stock Purchase Agreement dated September 30, 1991 and Amendment Agreement dated October 2, 1991.

56

- 10.4(1)** Development, License and Supply Agreement dated February 2, 1989 between the Company and Gen-Probe Incorporated.
- 10.5(3)** Common Stock Transfer Agreement dated as of December 15, 1992, between the Company and Dr. Jacques Gonella.
- 10.6(3) Consulting Agreement dated as of December 15, 1992, between the Company and Dr. Jacques Gonella.
- 10.7(3)** Common Stock Transfer Agreement dated as of December 15, 1992, between the Company and Jagotec AG.
- 10.8(3)** Collaboration Agreement dated as of January 22, 1993, between Jobewol Investments B.V. (now known as Genta Jago Technologies B.V.) and Gensia, Inc.
- 10.9(5) Form of Purchase Agreement between the Company and certain purchasers of Common Stock.
- 10.10(5) Common Stock Purchase Warrant dated May 8, 1995 between the Company and Index Securities S.A.
- 10.11(6)** Restated Joint Venture and Shareholders Agreement dated as of May 12, 1995 between the Company, Jagotec AG, Jago Holding AG, Jago Pharma AG and Genta Jago Technologies B.V.
- 10.12(6)** Limited Liability Company Agreement of Genta Jago Delaware LLC dated as of May 12, 1995 between GPM Generic Pharmaceuticals Manufacturing Inc. and the Company.
- 10.13(6)** Restated Transfer Restriction Agreement dated as of May 12, 1995 between the Company and Jagotec AG.
- 10.14(6)** Transfer Restriction Agreement dated as of May 12, 1995 between the Company, GPM Generic Pharmaceuticals Manufacturing Inc. and Jago Holding AG.
- 10.15(6)** Common Stock Transfer Agreement dated as of May 30, 1995 between the Company and Jago Finance Limited.
- 10.16(6)** Stockholders' Agreement dated as of May 30, 1995 between the Company, Jagotec AG, Dr. Jacques Gonella and Jago Finance Limited.
- 10.17(6)** Restated GEOMATRIX Research and Development Agreement dated as of May 12, 1995 between Jago Pharma AG, the Company, Genta Jago Delaware, L.L.C. and Genta Jago

Edgar Filing: GENTA INC DE/ - Form 10-K

Technologies B.V.

- 10.18(6)** Restated Services Agreement dated as of May 12, 1995 between Jago Pharma AG, the Company, Genta Jago Delaware, L.L.C. and Genta Jago Technologies B.V.
- 10.19(6)** Restated Working Capital Agreement dated as of May 12, 1995 and Amendment No. 1 to Restated Working Capital Agreement dated as of July 11, 1995 between the Company and Genta Jago Technologies B.V.
- 10.20(6)** Restated Promissory Note dated as of January 1, 1994 between Genta Jago Technologies B.V. and the Company.
- 10.21(6)** Restated License Agreement dated as of May 12, 1995 between Jagotec AG and the Company.
- 10.22(6)** Restated GEOMATRIX License Agreement dated as of May 12, 1995 between Jagotec AG and Genta Jago Technologies B.V.
- 10.23(6)** GEOMATRIX Manufacturing License Agreement dated as of May 12, 1995 between Jagotec AG and Genta Jago Technologies B.V.
- 10.24(6)** Restated GEOMATRIX Supply Agreement dated as of May 12, 1995 between Jago Pharma AG and Genta Jago Technologies B.V.

57

- 10.25(7) Common Stock Purchase Warrant dated December 14, 1995 between the Company and Lease Management Services, Inc.
- 10.26(8) Common Stock Purchase Warrant for 375,123 shares of Common Stock issued to Lyon & Lyon.
- 10.27(8) Common Stock Purchase Warrant for 100,000 shares of Common Stock issued to Michael Arnouse.
- 10.28(9) Note and Warrant Purchase Agreement dated as of January 28, 1997 among the Company, The Aries Fund and The Aries Domestic Fund, L.P.
- 10.29(9) Letter Agreement dated January 28, 1997 from the Company to The Aries Fund and The Aries Domestic Fund, L.P.
- 10.30(9) Senior Secured Convertible Bridge Note of the Company dated January 28, 1997 for \$1.050 million issued to The Aries Domestic Fund, L.P.
- 10.31(9) Senior Secured Convertible Bridge Note of the Company dated January 28, 1997 for \$1.950 million issued to The Aries Trust.
- 10.32(9) Class A Bridge Warrant for the Purchase of 2,730,000 shares of Common Stock issued to The Aries Domestic Fund, L.P.
- 10.33(9) Class A Bridge Warrant for the Purchase of 5,070,000 shares of Common Stock issued to The Aries Trust.

Edgar Filing: GENTA INC DE/ - Form 10-K

- 10.34 (9) Class B Bridge Warrant for the Purchase of 4,270,000 shares of Common Stock issued to The Aries Domestic Fund, L.P.
- 10.35 (9) Class B Bridge Warrant for the Purchase of 7,930,000 shares of Common Stock issued to the Aries Trust.
- 10.36 (9) Security Agreement dated as of January 28, 1997 between the Company and Paramount Capital, Inc., as agent for the holders of the Company's Senior Secured Convertible Bridge Notes
- 10.37 (9) Letter Agreement dated January 28, 1997 among the Company, Paramount Capital, Inc., The Aries Domestic Fund, L.P. and The Aries Trust.
- 10.38 (10) Executive Compensation Agreement dated as of January 1, 1996 between the Company and Howard Sampson.
- 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 between Genta Jago and Gensia, Inc., dated January 23, 1993) to Brightstone Pharma, Inc., dated October 1, 1996 among Gensia, Inc., Genta Jago Technologies B.V., Brightstone Pharma, Inc., and SkyePharma PLC.
- 10.41 (10) ** Development and Marketing Agreement effective February 28, 1996 between Apothecon, Inc. and Genta Jago Technologies B.V.
- 10.42 (10) ** License Agreement effective February 28, 1996 between Apothecon, Inc. and Genta Jago Technologies B.V.
- 10.43 (10) ** Option, Development & Sub-License Agreement (the Company has requested confidential treatment for the name of this element) dated as of October 31, 1996 between Genta Jago Technologies B.V. and Krypton Ltd.
- 58
- 10.44 (10) ** Development and Sub-License Agreement (the Company has requested confidential treatment for the name of this element) dated as of October 31, 1996 between Genta Jago Technologies B.V. and Krypton Ltd.
- 10.45 (10) ** Development and Sub-License Agreement (the Company has requested confidential treatment for the name of this element) dated as of October 31, 1996 between Genta Jago Technologies B.V. and Krypton Ltd.
- 10.46 (10) ** Development and Sub-License Agreement/Diclofenac dated as of October 31, 1996 between Genta Jago Technologies B.V. and Krypton Ltd.
- 10.47 (10) ** Development and Sub-License Agreement/Naproxen dated as of October 31, 1996 between Genta Jago Technologies B.V. and

Edgar Filing: GENTA INC DE/ - Form 10-K

Krypton Ltd.

- 10.48(10)** Development and Sub-License Agreement/Verapamil dated as of October 31, 1996 between Genta Jago Technologies B.V. and Krypton Ltd.
- 10.49(10)** License Termination Agreement dated December 2, 1996 between the Company and Wilton Licensing AG and the Company.
- 10.50(10) Contract for Regional Aid for Innovation, effective July 1, 1993, between L'Agence Nationale de Valorisation de la Recherche, Genta Pharmaceuticals Europe S.A. and the Company.
- 10.51(11) Warrant for the Purchase of 32,500 shares of Common Stock of the Company, issued to The Aries Fund.
- 10.52(11) Warrant for the Purchase of 17,500 shares of Common Stock of the Company, issued to The Aries Domestic Fund, L.P.
- 10.53(11) Amended and Restated Amendment Agreement dated June 23, 1997 among the Company and The Aries Fund and The Aries Domestic Fund L.P.
- 10.54(11) Amended and Restated Senior Secured Convertible Bridge Note for \$1.050 million issued to The Aries Domestic Fund, L.P.
- 10.55(11) Amended and Restated Senior Secured Convertible Bridge Note for \$1.950 million issued to The Aries Trust.
- 10.56(11) New Class A Bridge Warrant for the Purchase of 350,000 shares of Common Stock issued to The Aries Domestic Fund, L.P.
- 10.57(11) New Class A Bridge Warrant for the Purchase of 650,000 shares of Common Stock issued to The Aries Trust.
- 10.58(11) New Class B Bridge Warrant for the Purchase of 350,000 shares of Common Stock issued to The Aries Domestic Fund, L.P.
- 10.59(11) New Class B Bridge Warrant for the Purchase of 650,000 shares of Common Stock issued to The Aries Trust.
- 10.60(11) Consulting Agreement dated as of August 27, 1997 by and between the Company and Paul O.P. Ts'o, Ph.D.
- 10.61(11) Consulting Agreement dated as of August 27, 1997 by and between the Company and Sharon B. Webster, Ph.D.
- 10.62(15) Warrant Agreement, dated as of May 20, 1997, among the Company, ChaseMellon Shareholder Services, 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 Thomas H. Adams, Ph.D. and the

Edgar Filing: GENTA INC DE/ - Form 10-K

Company.

- 10.64(12) Consulting Agreement dated May 5, 1998 between the Company and Thomas H. Adams, Ph.D.
- 10.65(14) Asset Purchase Agreement, dated as of March 19, 1999, among JBL Acquisition Corp., JBL Scientific Incorporated and the Company.
- 10.66(14) Agreement of Sublease dated March 31, 1999 between Interneuron Pharmaceuticals, Inc. and the Company
- 10.67(15) Warrant Agreement, dated as of December 23, 1999, among the Company, ChaseMellon Shareholder 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 G. Kasses, Ph.D.
- 10.69(15) Amendment No. 1 to Stock Option Agreement, dated as of December 1, 1999, to the Stock Option Agreement, dated as of May 28, 1998, between the Company and Kenneth G. Kasses, Ph.D.
- 10.70(15) Employment Letter Agreement, dated as of October 28, 1999, from the Company to Raymond P. Warrell, Jr., M.D.
- 10.71(15) Stock Option Agreement, dated as of October 28, 1999, between the Company and Raymond P. Warrell, 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 sale of common stock to Franklin Small-Mid Cap Growth Fund, Franklin Biotechnology Discovery Fund, and SF Capital Partners Ltd., and the November 30, 2001 sale of common stock to SF Capital Partners Ltd.
- 10.74(16) Employment Letter Agreement, dated as of March 27, 2001, from the Company to Loretta M. Itri, M.D.
- 10.75(16) Employment Letter Agreement, dated as of July 24, 2001, from the Company to Alfred J. Fernandez
- 10.76(16) Agreement of Lease dated June 28, 2000 between The Connell Company and the Company
- 10.77(16) Agreement of Sublease dated August 13, 2001 between Expanets, Inc. and the Company
- 10.78(17)** U.S. Commercialization Agreement dated April 26, 2002, by and between Genta Incorporated and Aventis Pharmaceuticals Inc.
- 10.79(17)** Ex-U.S. Commercialization Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited
- 10.80(17)** Global Supply Agreement, dated April 26, 2002, by and among Genta Incorporated, Aventis Pharmaceuticals Inc. and Garliston Limited

Edgar Filing: GENTA INC DE/ - Form 10-K

- 10.81(17)** Securities Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited
- 10.82(17) Standstill and Voting Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited
- 10.83(17) Registration Rights Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited

60

- 10.84(17) Convertible Note Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited
- 10.85(17)** 5.63% Convertible Promissory Note, due April 26, 2009
- 10.86(17)** Subordination Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited
- 10.87(17) Amendment of Lease, dated June 19, 2002 between The Connell Company and the Company
- 10.88(18)* Manufacture and Supply Agreement, dated December 20, 2002, between Genta Incorporated and Avecia Biotechnology Inc.
- 22.1(10) Subsidiaries of the Registrant.
- 23.1(16) Consent of Deloitte & Touche LLP, Independent Auditors, dated March 29, 2002
- 23.2(18) Consent of Deloitte & Touche LLP, Independent Auditors, dated March 31, 2003
- 99.1(18) Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
- 99.2(18) Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

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

** 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.

Edgar Filing: GENTA INC DE/ - Form 10-K

- (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 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, the Company's Annual Report on Form 10-K (Amendment No. 1) for the year ended December 31, 1996, Commission File No. 0-19635.

61

- (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) Exhibits 10.73, 10.74, 10.75, 10.76, 10.77 and 23.1 are incorporated herein by reference to Exhibits 10.73, 10.74, 10.75, 10.76, 10.77 and 23.1 respectively, to the Company's Annual Report on Form 10-K for the year

Edgar Filing: GENTA INC DE/ - Form 10-K

ended December 31, 2001, Commission File No. 0-19635.

- (17) Exhibits 10.78, 10.79, 10.80, 10.81, 10.82, 10.83, 10.84, 10.85, 10.86 and 10.87 are incorporated herein by reference to Exhibits 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635.
- (18) Filed herewith.

62

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 31st day of March 2003.

Genta Incorporated

/s/ RAYMOND P. WARRELL, JR., M.D.

 Raymond P. Warrell, Jr., M.D.
 Chairman, President, Chief Executive
 Officer and Principal Executive Officer

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

Signature -----	Capacity -----	Date ----
/s/ RAYMOND P. WARRELL, JR., M.D. ----- Raymond P. Warrell, Jr., M.D.	Chairman, President, Chief Executive Officer and Principal Executive Officer	March 31, 2003
/s/ WILLIAM P. KEANE ----- William P. Keane	Principal Financial and Accounting Officer, Vice President	March 31, 2003
/s/ BETSY MCCAUGHEY ----- Betsy McCaughey, Ph.D.	Director	March 31, 2003
/s/ JEROME GROOPMAN, M.D. ----- Jerome Groopman, M.D.	Director	March 31, 2003
/s/ DANIEL D. VON HOFF, M.D. ----- Daniel D. Von Hoff, M.D.	Director	March 31, 2003
/s/ HARLAN J. WAKOFF -----	Director	March 31, 2003

Edgar Filing: GENTA INC DE/ - Form 10-K

Harlan J. Wakoff

/s/ DOUGLAS G. WATSON

Director

March 31, 2008

Douglas G. Watson

/s/ MICHAEL S. WEISS

Director

March 31, 2008

Michael S. Weiss

/s/ PATRICK J. ZENNER

Director

March 31, 2008

Patrick J. Zenner

63

Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Raymond P. Warrell, Jr., M.D., certify that:

1. I have reviewed this annual report on Form 10-K of Genta Incorporated;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly represent in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

Edgar Filing: GENTA INC DE/ - Form 10-K

- a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

/s/ RAYMOND P. WARRELL, JR., M.D.

Name: Raymond P. Warrell, Jr., M.D.
Title: Chief Executive Officer

64

Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, William P. Keane, certify that:

1. I have reviewed this annual report on Form 10-K of Genta Incorporated;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly represent in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date");

Edgar Filing: GENTA INC DE/ - Form 10-K

and

- c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
- d) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - e) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

/s/ WILLIAM P. KEANE

Name: William P. Keane
Title: Chief Financial Officer