

GENTA INC DE/  
Form 10-K  
March 10, 2006

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

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

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

**For the Fiscal Year Ended December 31, 2005**

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

Commission File Number 0-19635

**GENTA INCORPORATED**

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

**Delaware**

(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**

**Series G Participating Cumulative Preferred Stock Purchase Rights**

(Title of Class)

Indicate by check mark if a registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ý

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

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

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (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 equity held by non-affiliates of the registrant was \$111,605,441 as of June 30, 2005 (the last business day of the registrant's most recently completed second fiscal quarter). For purposes of determining this number, 777,333 shares of common stock held by affiliates as of June 30, 2005 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 10, 2006, the registrant had 114,549,543 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, 2006 pursuant to Regulation 14A are incorporated by reference in Items 10 through 13 of Part III of this Annual Report on Form 10-K.

**Genta Incorporated**  
**Table of Contents**

|                 |   |    |
|-----------------|---|----|
| <b>Part I</b>   |   |    |
| Item 1.         | <u>Business</u>   | 4  |
| Item 1A.        | <u>Risk Factors</u>   | 17 |
| Item 1B.        | <u>Unresolved Staff Comments</u>  | 29 |
| Item 2.         | <u>Properties</u>   | 29 |
| Item 3.         | <u>Legal Proceedings</u>  | 29 |
| Item 4.         | <u>Submission of Matters to a Vote of Security Holders</u>  | 29 |
| <b>Part II</b>  |   |    |
| Item 5.         | <u>Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> | 30 |
| Item 6.         | <u>Selected Consolidated Financial Data</u>   | 31 |
| Item 7.         | <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                        | 32 |
| Item 7A.        | <u>Quantitative and Qualitative Disclosure about Market Risk</u>  | 41 |
| Item 8.         | <u>Financial Statements and Supplemental Data</u>   | 42 |
| Item 9.         | <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>                         | 64 |
| Item 9A.        | <u>Controls and Procedures</u>  | 64 |
| Item 9B.        | <u>Other Information</u>  | 66 |
| <b>Part III</b> |   |    |
| Item 10.        | <u>Directors and Executive Officers of the Registrant (1)</u>   | 66 |
| Item 11.        | <u>Executive Compensation (1)</u>   | 66 |
| Item 12.        | <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters (1)</u>           | 66 |
| Item 13.        | <u>Certain Relationships and Related Transactions (1)</u>   | 66 |
| Item 14.        | <u>Principal Accounting Fees and Services (1)</u>   | 66 |
| <b>Part IV</b>  |   |    |
| Item 15.        | <u>Exhibits and Financial Statement Schedules</u>   | 67 |
|                 | <u>Signatures</u>   | 70 |
|                 | <u>Certifications</u>   | 77 |

(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, 2006 pursuant to Regulation 14A of the General Rules and Regulations under the Securities Exchange Act of 1934, as amended.

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 obtain necessary regulatory approval for Genasense® from the U.S. Food and Drug Administration ( FDA ) or European Medicines Agency ( EMEA );
- o the safety and efficacy of the Company's products;
- o the commencement and completion of clinical trials;
- o the Company's ability to develop, manufacture and sell its products;
- o the adequacy of the Company's capital resources and the Company's ability to obtain sufficient financing to maintain the Company's planned operations;
- o the adequacy of the Company's patents and proprietary rights;
- o the impact of litigation that has been brought against the Company and its officers and directors;
- 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.

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

## PART I

### Item 1. Business

#### Overview

Genta Incorporated ( Genta or the Company ) was incorporated in Delaware on February 4, 1988. Genta is a biopharmaceutical company engaged in pharmaceutical (drug) research and development, its sole reportable segment. The Company is dedicated to the identification, development and commercialization of novel drugs for the treatment of cancer and related diseases. The Company's research portfolio consists of two major programs: DNA/RNA Medicines and Small Molecules .

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

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

In September 2003, Genta announced results of its randomized trial in patients with advanced melanoma and the Company initiated submission of a New Drug Application ( NDA ) to the U.S. Food and Drug Administration ( FDA ) for the use of Genasense® plus chemotherapy in patients with this disease. In May 2004, the application failed to gain a majority vote for marketing approval from FDA's Oncology Drug Advisory Committee ( ODAC ). As a consequence, Genta withdrew the NDA, which allows the Company to potentially resubmit the application. In February 2005, the Company completed 24 months of minimum follow-up for patients that had been specified in the clinical protocol. The data collected during this extended follow-up period were sufficiently encouraging that the Company elected to re-evaluate submission of the application for regulatory approval. On January 3, 2006, Genta announced that it had completed a Marketing Authorization Application ( MAA ) to the European Medicines Agency ( EMEA ) that seeks approval for use of Genasense® plus dacarbazine for the treatment of patients with advanced melanoma who have not previously received chemotherapy. This centralized licensing procedure provides a single marketing authorization that is valid in all 25 member-states of the European Community. While review of the application is coordinated by the EMEA, Spain and France have been appointed as rapporteur and co-rapporteur countries, respectively. On February 1, 2006, the Company announced that it had received notice from the EMEA that its MAA had been validated for review, which signaled the start of formal scientific assessment. While the timeline is subject to considerable imprecision, the Company currently expects to receive an opinion regarding approvability of its application by the EMEA's Committee on Human Medicinal Products ( CHMP ) in the second half of 2006.

In November 2004, the Company announced that its second randomized trial, which was conducted in patients with advanced multiple myeloma, failed to meet endpoints that would be sufficient for regulatory approval.

In December 2004, the Company presented results from its third randomized trial, which was conducted in patients with relapsed or refractory CLL. In this trial, 241 patients who had relapsed or had not responded to prior therapy were treated with standard chemotherapy using fludarabine and cyclophosphamide ( Flu/Cy ) and were randomly assigned to receive Genasense® or no additional treatment. Initial results showed that the trial achieved its primary endpoint: the proportion of patients who achieved a complete or nodular partial response ( CR/nPR ) was improved with the addition of Genasense® to Flu/Cy chemotherapy (17% vs. 7%; P=0.025). The response required independent confirmation by an external clinical reviewer who was blinded to treatment assignment and who reviewed clinical, laboratory and radiologic data. A second independent reviewer evaluated bone marrow biopsies. Agreement between the clinical and bone marrow reviews was required in order to determine response in this study. A clinical trial result is statistically significant if it is unlikely to have occurred by chance. The statistical significance of clinical trial results is determined by a widely used statistical method that establishes the P-value of the results. A P-value of 0.05 or less for clinical trial results is generally considered by regulatory authorities as indicating statistically significant results for evidence of effectiveness.

The CLL trial also showed that the duration of CR/nPR was improved for patients treated with Genasense® plus chemotherapy. To date, six of the eight patients (75%) who achieved CR/nPR with chemotherapy alone have relapsed compared with five of twenty patients (25%) in the Genasense® treatment group. The median duration of CR/nPR was 22 months in the chemotherapy-alone group; the median has not been reached in the Genasense® group (P=0.03). All CR/nPR responses have been durable (i.e., exceeding six months duration). Additional analysis showed that patients who achieved CR/nPR also experienced clinical benefit, especially with respect to improvement of disease-related symptoms. Several secondary endpoints were not improved by the addition of Genasense®. For example, no difference was observed in overall response rate (i.e., the percentage of patients who achieved CR/nPR plus partial response ( PR ), or in time-to-disease progression. Overall survival will be formally evaluated in mid-2006 after all patients have completed a minimum of two years of follow-up. Adverse events (irrespective of relation to study drugs) during treatment or within 30 days from last dose of treatment that resulted in death occurred in nine patients treated with Genasense® plus chemotherapy compared with five patients treated with chemotherapy alone. The percentage of patients who experienced serious adverse events was increased in the Genasense® arm; however, the percentages of patients who discontinued treatment due to adverse events were equal in the treatment arms. The incidence of certain serious adverse reactions, including but not limited to nausea, fever and catheter-related complications, was increased in patients treated with Genasense®.

On December 28, 2005, the Company completed submission of an NDA to the FDA that sought accelerated approval for the use of Genasense® in combination with fludarabine plus cyclophosphamide for the treatment of patients with relapsed or refractory CLL who have previously received fludarabine. Genasense® has received Fast Track designation by the FDA in CLL, meaning that the indication represents an unmet medical need. Genasense® has also been granted designation as an Orphan Drug by the FDA. On March 1, 2006, the Company announced that the NDA had been accepted for review by the FDA with a target action date of October 28, 2006. However, acceptance of this NDA does not necessarily lead to FDA approval. Following its review of all the Company's information concerning Genasense®, the FDA may refuse to approve altogether, or may ask for more data to be obtained, so that approval can be reconsidered. Either of these two decisions by the FDA would have a material adverse effect on our business. One requirement for Accelerated Approval is that the Company will be required to conduct a confirmatory trial. The Company has formulated a design for such a trial and has submitted a proposal to the FDA for review as a Special Protocol Assessment ( SPA ). The submitted proposal incorporated initial comments received from the FDA. Final comments on the submission are expected during the first half of 2006. Formal initiation of the trial will depend upon resolution of trial design issues with the FDA, among other factors. Although Fast Track designation, Orphan Drug designation and Accelerated Approval provisions are beneficial, we cannot assure you that the NDA will be approved. In particular, the FDA may not be satisfied that achievement of the primary endpoint used in the Company's recent clinical trial, which was increased proportion of complete responses/nodular partial responses compared to patients treated with standard chemotherapy, is a sufficient basis for approval. Further, increased symptom-free time may not be considered to be sufficient demonstration of clinical benefit.

In December 2005, the Company also announced preliminary clinical results regarding the use of Genasense® in combination with fludarabine plus rituximab (Rituxan®; Genentech/IDEC) in patients with CLL. Two clinical studies have explored the use of Genasense® plus rituximab, with and without cytotoxic chemotherapy, in patients with non-Hodgkin's lymphoma ( NHL ). The goals of these Phase 1 and 2 studies have primarily been to evaluate safety and tolerability of Genasense® when used in combination with rituximab, along with obtaining preliminary evidence of activity.

The Company has commenced discussions with several companies regarding partnership for the further development and global commercialization of Genasense®. Those discussions are currently ongoing.

The Company has two additional programs in its DNA/RNA Medicines program. The first is an antisense drug (G4460, previously known as LR3001), which is directed against an oncogene called c-myc. G4460 was briefly tested in a preliminary clinical trial several years ago. The Company licensed rights to G4460 and associated technology from Temple University and

we currently anticipate that a Phase 1 clinical trial of the compound will be initiated at the University of Pennsylvania during 2006. The Company also has licensed rights to a drug called the CRE-BP Decoy, from the National Institutes of Health ( NIH ). This compound remains in the laboratory testing stage and the Company cannot currently project when, if ever, the CRE-BP decoy may enter clinical testing.

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

The Company seeks to acquire additional drugs in these two programs and possibly other areas that will enhance the value of its pipeline to shareholders.

### **Summary of Business and Research and Development Programs**

Our goal is to establish Genta as a biopharmaceutical leader and preferred partner in the oncology market and as direct marketers of our products in the United States. Our key strategies in this regard are:

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

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

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

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

### **Research and Development Programs**

#### **DNA/RNA Medicines**

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

## **Antisense Technology**

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

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

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

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

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

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

### ***Bcl-2 as an Inhibitor of Programmed Cell Death***

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

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

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



## **Genasense®**

Genasense® has been designed to block the production of Bcl-2. Current science suggests that Bcl-2 is a fundamental although not sole - cause of the inherent resistance of cancer cells to most types of existing anticancer treatments, such as chemotherapy, radiation or monoclonal antibodies. Blocking Bcl-2, therefore, may enable cancer treatments to be more effective. While Genasense® has displayed some anticancer activity when used by itself, we believe the drug can be optimally used as a means of amplifying the effectiveness of other cancer therapies, most of which function by triggering apoptosis, which as noted is relatively blocked in cancer cells due to over-production of Bcl-2.

## **Overview of Preclinical and Clinical studies of Genasense®**

### **Preclinical Studies**

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

### **Clinical Studies**

Genasense® has been in clinical trials since 1995. We currently have efficacy and safety data on over 1,500 patients in Phase 1, Phase 2 and Phase 3 clinical trials that have been conducted in the U.S., Europe, South America and Australia. These studies have included patients with a wide variety of tumor types, including advanced melanoma, several types of acute and chronic leukemia, non-Hodgkin's lymphoma ( NHL ), multiple myeloma and cancers of the prostate, colon, lung, breast and other tumor types. Since 2001, Genta and the NCI have jointly approved the initiation of approximately twenty clinical trials. In addition to making Genasense® available to more physicians and patients, these trials enable the evaluation of Genasense® in certain diseases (and in combination with other chemotherapy drugs) that would otherwise be outside our initial development priorities. The overall results of clinical trials performed to date suggest that Genasense® can be administered to cancer patients with acceptable side-effects and that such treatment may reduce the level of Bcl-2 protein in cancer cells. The Company believes the clinical safety and efficacy results in patients with advanced melanoma and relapsed or refractory CLL have been sufficiently promising to warrant marketing approval in these indications. Accordingly, the Company currently has marketing applications pending in Europe (for melanoma) and the U.S. (for CLL).

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

| Indication                                 | Status   |
|--|--|
| Malignant Melanoma                         | Phase 3 completed; a Marketing Authorization Application (MAA) to the EMEA completed |
| Chronic Lymphocytic Leukemia               | Phase 3 completed; results of trial met primary endpoint; NDA submitted to the FDA   |
| Multiple Myeloma                           | Phase 3 completed; trial did not meet primary endpoint                               |
| Acute Myelocytic Leukemia                  | Phase 3 (randomized)   |
| Non-Small-Cell Lung Cancer                 | Phase 2 (randomized), fully enrolled   |
| Prostate Cancer                            | Phase 2 (randomized), fully enrolled   |
| Small-Cell Lung Cancer                     | Phase 2 (randomized), fully enrolled   |
| Breast Cancer                              | Phase 1-2  |
| Colorectal Cancer                          | Phase 1-2  |
| Non-Hodgkin s lymphoma                     | Phase 1-2 and Phase 2  |
| Kidney Cancer                              | Phase 2  |
| Pancreatic Cancer (and other solid tumors) | Phase 1-2  |
| Waldenstrom s macroglobulinemia            | Phase 1-2  |
| Hepatocellular Carcinoma                   | Phase 1-2  |
| Childhood Solid Tumors                     | Phase 1  |

Highlights of the randomized trials sponsored directly by the Company are as follows:

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

In late 2003, we filed an NDA for Genasense® to be used in combination with dacarbazine for the treatment of patients with advanced melanoma who had not previously received chemotherapy. On May 3, 2004, a majority of the ODAC members voted that while the increased number of clinical responses were indicative of clinical activity, the evidence presented did not provide substantial evidence of effectiveness to outweigh the increased toxicity of administering Genasense®. On May 13, 2004, the Company announced that it was withdrawing its NDA. Subsequent to the withdrawal in the U.S., Genta continued to track data from patients enrolled in its Phase 3 trial and to analyze its results.

Data that emerged from extended follow-up of patients who entered into this trial were analyzed in 2005 and were informally reviewed with certain regulatory authorities. Encouraged by the study results, on January 3, 2006, the Company announced that it had completed an MAA to the EMEA for use of Genasense® plus dacarbazine for the treatment of patients with advanced melanoma who have not previously received chemotherapy. On February 1, 2006, the Company announced that it had received notice from the EMEA that its MAA had been validated for review by the Agency, which signals the start of formal scientific assessment.

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

In December 2004, the Company presented results from its third randomized trial, which was conducted in patients with relapsed or refractory CLL. In this trial, 241 patients who had relapsed or had not responded to prior therapy were treated with standard chemotherapy using fludarabine and cyclophosphamide ( Flu/Cy ). After stratifying patients using conventional criteria, they were randomly assigned to receive Genasense® or no additional treatment. Initial results showed that the trial achieved its primary endpoint: the proportion of patients who achieved a complete or nodular partial response ( CR/nPR ) was significantly improved with the addition of Genasense® to Flu/Cy chemotherapy (17% vs. 7%; P=0.025). The response required independent confirmation by an external clinical reviewer who was blinded to treatment

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

assignment and who reviewed clinical, laboratory and radiologic data. A second independent reviewer evaluated bone marrow biopsies. Agreement between the clinical and bone marrow reviews was required in order to determine response in this study.

The CLL trial also showed that the duration of CR/nPR was improved for patients treated with Genasense® plus chemotherapy. To date, six of the eight patients (75%) who achieved CR/nPR with chemotherapy alone have relapsed compared with five of twenty patients (25%) in the Genasense® treatment group. The median duration of CR/nPR was 22 months in the chemotherapy-alone group; the median has not been reached in the Genasense® group (P=0.03). All CR/nPR responses have been durable (i.e., exceeding six months duration). Additional analysis showed that patients who achieved CR/nPR also experienced clinical benefit, especially with respect to improvement of disease-related symptoms. Several secondary endpoints were not improved by the addition of Genasense®. For example, no difference was observed in overall response rate (i.e., the percentage of patients who achieved CR/nPR plus partial response [ PR ]), or in time-to-disease progression. Overall survival will be formally evaluated in mid-2006 after all patients have completed a minimum of two years of follow-up. Adverse events (irrespective of relation to study drugs) during treatment or within 30 days from last dose of treatment that resulted in death occurred in nine patients treated with Genasense® plus chemotherapy compared with five patients treated with chemotherapy alone. The percentage of patients who experienced serious adverse events was increased in the Genasense® arm; however, the percentages of patients who discontinued treatment due to adverse events were equal in the treatment arms. The incidence of certain serious adverse reactions, including but not limited to nausea, fever and catheter-related complications, was increased in patients treated with Genasense®.

On December 28, 2005, the Company completed submission of an NDA to the FDA that seeks accelerated approval for the use of Genasense® in combination with fludarabine plus cyclophosphamide for the treatment of patients with relapsed or refractory CLL who have previously received fludarabine. Genasense® has received Fast Track designation by the FDA in CLL, meaning that the indication represents an unmet medical need. Genasense® has also been granted designation as an Orphan Drug by the FDA. On March 1, 2006, the Company announced that the NDA had been accepted for review by the FDA with a target action date of October 28, 2006. However, acceptance of this NDA does not necessarily lead to FDA approval. Following its review of all the Company's information concerning Genasense®, the FDA may refuse to approve altogether, or may ask for more data to be obtained, so that approval can be reconsidered. Either of these two decisions by the FDA would have a material adverse effect on our business. One requirement for Accelerated Approval is that the Company will be required to conduct a confirmatory trial. The Company has formulated a design for such a trial and has submitted a proposal to the FDA for review as a Special Protocol Assessment ( SPA ). The submitted proposal incorporated initial comments received from the FDA. Final comments on the submission are expected during the first half of 2006. Formal initiation of the trial will depend upon resolution of trial design issues with the FDA, among other factors. Although Fast Track designation, Orphan Drug designation and Accelerated Approval provisions are beneficial, we cannot assure you that the NDA will be approved. In particular, the FDA may not be satisfied that achievement of the primary endpoint used in the Company's recent clinical trial being an increased proportion of complete responses/nodular partial responses compared to patients treated with standard chemotherapy is sufficient basis for approval. Further, increased symptom-free time may not be considered to be sufficient demonstration of clinical benefit.

In December 2005, the Company also announced preliminary clinical results regarding the use of Genasense® in combination with fludarabine plus rituximab (Rituxan®; Genentech/IDEC) in patients with CLL. Two clinical studies have explored the use of Genasense® plus rituximab, with and without cytotoxic chemotherapy, in patients with NHL. The goals of these Phase 1-2 studies have primarily been to evaluate safety and tolerability of Genasense® when used in combination with rituximab, along with obtaining preliminary evidence of activity.

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

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

---

*Other Trials*

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

A large U.S. cooperative oncology group, the Cancer and Leukemia Group B ( CALGB ) is running a Phase 3 trial in patients with acute myelocytic leukemia ( AML ) over the age of 60 who have not previously received chemotherapy. All patients in this trial receive standard chemotherapy with daunorubicin and cytarabine and they are randomly assigned to receive additional treatment with Genasense® or no other treatment. This trial is currently projected to enroll up to approximately 500 patients. In January 2006, the CALGB informed our collaborators in NCI that it expected to complete enrollment in this trial during 2006. While the primary endpoint of the AML trial is overall survival, a variety of secondary endpoints (such as complete remission ( CR ) rate and remission duration) will be sequentially examined during the analysis of this trial. The Company believes that if the CR results are significantly superior for patients treated with Genasense®, results from this trial may prove sufficient for filing marketing applications in this indication on a global basis. The initial CR data may become available as early as 2007. However, the Company has no control over the conduct or analysis of this trial and thus no reliance can be placed upon these timelines at this time.

During June 2004, Genta completed enrollment in a randomized Phase 2 trial of Genasense® plus docetaxel in patients with non-small cell lung cancer. Patients who met a variety of eligibility criteria and who had failed front-line platinum-containing chemotherapy were eligible. Patients were randomly assigned to receive a standard dose of docetaxel with or without Genasense®. A total of 298 patients were enrolled into this study. The primary endpoint of the study was to increase overall survival in patients treated with Genasense® plus chemotherapy compared with patients treated with chemotherapy alone. Key secondary endpoints include comparisons of progression-free survival and objective response. A minimum follow-up period prior to analysis was specified in this trial, which concluded in December 2005. Depending upon our ability to defend the global marketing applications that are already pending, the Company currently projects that it will be able to analyze and release initial results from this trial during 2006. However, since this trial will not, by itself, suffice for regulatory approval, the priority for analysis of this trial will be subordinate to other logistical considerations within the Company.

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

During the fourth quarter of 2004, the CALGB completed enrollment in a randomized trial of Genasense® in patients with small cell lung cancer. The trial evaluated patients with extensive disease who had not previously received chemotherapy. The trial included approximately 65 patients who were randomly assigned to receive Genasense® plus chemotherapy with carboplatin and etoposide or chemotherapy alone. The primary endpoint of the trial was to determine the proportion of patients who survived at least twelve months from the date of randomization. The minimum follow-up period concluded in October 2005. While data from this trial may be available in 2006, the Company has no control over the conduct or analysis of this trial, and thus no reliance can be placed upon these timelines at this time.

In January 2006, the EORTC completed enrollment into a randomized study of Genasense® in patients with hormone-refractory prostate cancer who had not previously received chemotherapy. In this study, all patients received standard chemotherapy with docetaxel and were randomly assigned to receive Genasense® or no other treatment. The Company was recently informed that enrollment into this trial was completed with the accrual of 118 patients. The primary endpoint of this study was to compare response rates, as measured by a decrease of prostate specific antigen ( PSA ). While data from this trial may be available in 2006, the Company has no control over the conduct or analysis of this trial, and thus no reliance can be placed upon these timelines at this time.

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

For additional background information on the drug application process and clinical trials, see [Government Regulation](#) .

---

**Ganite®**

***Ganite® as a Treatment for Cancer-Related Hypercalcemia***

On October 6, 2003, we began marketing Ganite® for the treatment of cancer-related hypercalcemia. Ganite® is our first drug to receive marketing approval. The principal patent covering the use of Ganite® for its approved indication, including potential extensions under Hatch-Waxman provisions in the U.S., expired in April 2005.

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

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

In May 2004, the Company eliminated its sales force and significantly reduced its marketing support for Ganite®. Since then, the Company has continued only minimal marketing support of the product.

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

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

**Other Pipeline Products and Technology Platforms**

**Oral Gallium**

For several years, we have been attempting to develop novel formulations of gallium-containing compounds that can be taken orally. Such formulations might be useful for diseases in which long-term low-dose therapy is deemed desirable, such as bone metastases, Paget's disease and osteoporosis. Such patients are commonly afflicted by bone pain and susceptibility to fractures. To date, a suitable oral formulation available for clinical development has not yet been identified.

## **Decoys**

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

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

## **c-myb Antisense**

In December 2004, Genta acquired worldwide rights from Temple University to intellectual property and technology and a novel antisense compound (G4460, previously known as LR3001) that targets c-myb, a central gene that regulates the growth of cancer cells. G4460 has been tested in two Phase 1 clinical trials at the University of Pennsylvania in patients with drug-resistant myeloid leukemia. To date, clinical investigations have been supported by grants from the NIH, including the Rapid Access to Investigational Drugs ( RAID ) program. Genta has submitted a request for designation of G4460 as an Orphan Drug for the treatment of chronic myelocytic leukemia (CML) to the FDA and notice of this designation was received in February 2005. The Company currently anticipates that a Phase 1 clinical trial of G4460 will be initiated during 2006 at the University of Pennsylvania and that sufficient inventory currently exists to complete the Phase 1 program. Following completion of Phase 1, the Company will decide whether or not to take G4460 into Phase 2 clinical trials. Based on the biology of c-myb, potential target diseases for G4460 include CML, neuroblastoma and cancer of the breast and colon, among other conditions.

## **Antisense and RNAi Research and Discovery**

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

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

## **Patents and Proprietary Technology**

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

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

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

Included among Genta's intellectual property rights are certain rights licensed from the NIH covering phosphorothioate oligonucleotides. We also acquired from the University of Pennsylvania exclusive rights to antisense oligonucleotides directed against the Bcl-2 mRNA, as well as methods of their use for the treatment of cancer. The claims of the University of Pennsylvania patents cover our proprietary antisense oligonucleotide molecules, which target the Bcl-2 mRNA, including Genasense® and methods employing them. Other related U.S. and corresponding foreign patent applications are still pending.

The principal patent covering the use of Ganite® for its approved indication, including extensions under Hatch-Waxman provisions, expired in April 2005.

The patent positions of biopharmaceutical and biotechnology firms, including Genta, can be uncertain and can involve complex legal and factual questions. Consequently, even though we are currently pursuing our patent applications with the United States and foreign patent offices, we do not know whether any of our applications will result in the issuance of any patents, or if any issued patents will provide significant proprietary protection, or even if successful that these patents will not be circumvented or invalidated. Even if issued, patents may be circumvented or challenged and invalidated in the courts. Because some applications in the United States are kept in secrecy until an actual patent issues, we cannot be certain that others have not filed patent applications directed at inventions covered by our pending patent applications, or that we were the first to file patent applications for such inventions. Thus, we may become involved in interference proceedings declared by the U.S. Patent and Trademark Office (or comparable foreign office or process) in connection with one or more of our patents or patent applications to determine priority of invention, which could result in substantial costs to us, as well as an adverse decision as to priority of invention of the patent or patent application involved.

Competitors or potential competitors may have filed applications for, or have received patents and may obtain additional patents and proprietary rights relating to, compounds or processes competitive with those of ours. Accordingly, there can be no assurances that our patent applications will result in issued patents or that, if issued, the patents will afford protection against competitors with similar technology. We cannot provide assurance that any patents issued to Genta will not be infringed or circumvented by others, nor can there be any assurance that we will obtain necessary patents or technologies or the rights to use such technologies. In addition, there may be patents which are unknown to us and which may block our ability to make, use or sell our product. We may be forced to defend ourselves against charges of infringement or we may need to obtain expensive licenses to continue our business. See the Risk Factor entitled "We may be unable to obtain or enforce patents, other proprietary rights and licenses to protect our business; we could become involved in litigation relating to our patents or licenses that could cause us to incur additional costs and delay or prevent our introduction of new drugs to market," on page 22.

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

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

## **Research and Development**

In addition to our current focus in the areas described above, we continually evaluate our programs in light of the latest market information and conditions, the availability of third party funding, technological advances, financial liquidity and other factors. As a result of such evaluations, we change our product development plans from time to time and anticipate that we will continue to do so. We recorded research and development expenses of \$20.9 million, \$71.5 million and \$83.1 million during the years ended December 31, 2005, 2004 and 2003, respectively.



## **Sales and Marketing**

Either alone or in partnerships with other companies, we intend to be a direct marketer or co-marketer of our pharmaceutical products by building a sales and marketing infrastructure in the United States to launch and fully realize the commercial potential of our products if approved by the FDA. In January 2006, the Company announced that it had appointed W. Lloyd Sanders as Vice-President of Sales and Marketing. Most recently, Mr. Sanders was Vice President, Oncology Sales, at sanofi-aventis Group. For international product sales, we intend to distribute our products through collaborations with third parties.

## **Manufacturing and Raw Materials**

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

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

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

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

## **Human Resources**

As of December 31, 2005, Genta had 59 employees, 15 of whom hold doctoral degrees. As of that date, there were 43 employees engaged in research, development and other technical activities and 16 in administration. None of Genta's employees are represented by a union. Most of the management and professional employees of Genta have had prior experience and positions with pharmaceutical and biotechnology companies. Genta believes it maintains satisfactory relations with its employees and has not experienced interruptions of operations due to labor disagreements.

## **Government Regulation**

Regulation by governmental authorities in the United States and foreign countries is a significant factor in our ongoing research and product development activities and in the manufacture and marketing of our proposed products. All of our therapeutic products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical testing and pre-market approval procedures by the FDA and similar authorities in foreign countries. Various federal, and in some cases, state statutes and regulations also govern or affect the development, testing, manufacturing, safety, labeling, storage, recordkeeping and marketing of such products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable federal and, in some cases, state statutes and regulations, require substantial expenditures. Any failure by Genta, our collaborators or our licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the marketing of our products and our ability to receive products or royalty revenue.

The activities required before a new pharmaceutical agent may be marketed in the United States begin with preclinical testing. Preclinical tests include laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of the product and its formulations. The results of these studies must be submitted to the FDA as part of an IND. An IND becomes effective within 30 days of filing with the FDA unless the FDA imposes a clinical hold on the IND. In addition, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence, as the case may be, without prior FDA authorization and then only under terms authorized by the FDA.

Clinical trials are generally categorized into four phases.

Phase 1 trials are initial safety trials on a new medicine in which investigators attempt to establish the dose range tolerated by a small group of patients using single or multiple doses, and to determine the pattern of drug distribution and metabolism.

Phase 2 trials are clinical trials to evaluate efficacy and safety in patients afflicted with a specific disease. Typically, Phase 2 trials in oncology comprise 14 to 50 patients. Objectives may focus on dose-response, type of patient, frequency of dosing or any of a number of other issues involved in safety and efficacy.

In the case of products for life-threatening diseases, the initial human testing is generally done in patients rather than in healthy volunteers. Since these patients are already afflicted with the target disease, it is possible that such studies may provide results traditionally obtained in Phase 2 trials.

Phase 3 trials are usually multi-center, comparative studies that involve larger populations. These trials are generally intended to be pivotal in importance for the approval of a new drug. In oncology, Phase 3 trials typically involve 100 to 1,000 patients for whom the medicine is eventually intended. Trials are also conducted in special groups of patients or under special conditions dictated by the nature of the particular medicine and/or disease. Phase 3 trials often provide much of the information needed for the package insert and labeling of the medicine. A trial is fully enrolled when it has a sufficient number of patients to provide enough data for the statistical proof of efficacy and safety required by the FDA and others. After a sufficient period of follow-up has elapsed to satisfactorily evaluate safety and efficacy, the trials' results can then be analyzed. Those results are then commonly reported at a scientific meeting, in a medical journal and to the public.

Depending upon the nature of the trial results, a company may then elect to discuss the results with regulatory authorities such as the FDA. If the company believes the data may warrant consideration for marketing approval of the drug, the results of the preclinical and clinical testing, together with chemistry, manufacturing and control information, are then submitted to the FDA for a pharmaceutical product in the form of an NDA. In responding to an NDA, biologics license application or premarket approval application, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not satisfy its regulatory approval criteria. There can be no assurance that the approvals that are being sought or may be sought by Genta in the future will be granted on a timely basis, if at all, or if granted will cover all the clinical indications for which we are seeking approval or will not contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use. Phase 3b trials are conducted after submission of a NDA, but before the product's approval for market launch. Phase 3b trials may supplement or complete earlier trials, or they may seek different kinds of information, such as quality of life or marketing. Phase 3b is the period between submission for approval and receipt of marketing authorization.

After a medicine is marketed, Phase 4 trials provide additional details about the product's safety and efficacy.

In circumstances where a company intends to develop and introduce a novel formulation of an active drug ingredient already approved by the FDA, clinical and preclinical testing requirements may not be as extensive. Limited additional data about the safety and/or effectiveness of the proposed new drug formulation, along with chemistry and manufacturing information and public information about the active ingredient, may be satisfactory for product approval. Consequently, the new product formulation may receive marketing approval more rapidly than a traditional full new drug application, although no assurance can be given that a product will be granted such treatment by the FDA.

Under European Union regulatory systems, we may submit requests for marketing authorizations either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

We and our third-party manufacturers are also subject to various foreign, federal, state and local laws and regulations relating to health and safety, laboratory and manufacturing practices, the experimental use of animals and the use, manufacture, storage, handling and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research and development work and manufacturing processes. We currently incur costs to comply with laws and regulations and these costs may become more significant.

## **Competition**

In many cases, our products under development will be competing with existing therapies for market share. In addition, a number of companies are pursuing the development of antisense technology and controlled-release formulation technology and the development of pharmaceuticals utilizing such technologies. We compete with fully integrated pharmaceutical companies that have substantially more experience, financial and other resources and superior expertise in research and development, manufacturing, testing, obtaining regulatory approvals, marketing and distribution. Smaller companies may also prove to be significant competitors, particularly through their collaborative arrangements with large pharmaceutical companies or academic institutions. Furthermore, academic institutions, governmental agencies and other public and private research organizations have conducted and will continue to conduct research, seek patent protection and establish arrangements for commercializing products. Such products may compete directly with any products that may be offered by us.

Our competition will be determined in part by the potential indications for which our products are developed and ultimately approved by regulatory authorities. For certain of our potential products, an important factor in competition may be the timing of market introduction of our or our competitors' products. Accordingly, the relative speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are expected to be important competitive factors. We expect that competition among products approved for sale will be based, among other things, on product efficacy, safety, reliability, availability, price, patent position and sales, marketing and distribution capabilities. The development by others of new treatment methods could render our products under development non-competitive or obsolete.

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

## **Item 1A. Risk Factors**

*You should carefully consider the following risks and all of the other information set forth in this Form 10K before deciding to invest in shares of our common stock. The risks described below are not the only ones facing our Company. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.*

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

---

## Risks Related to Our Business

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

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

- o our ability to demonstrate clinically that our products are useful and safe in particular indications;
- 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.

We cannot assure you that Genasense® will receive FDA or EMEA approval. Our financial condition and results of operations have been and will continue to be significantly affected by FDA and EMEA action with respect to Genasense®. Any adverse events with respect to FDA and/or EMEA approvals could negatively impact our ability to obtain additional funding or identify potential partners.

For example, on January 3, 2006, we announced that we had completed a Marketing Authorization Application, or MAA, to the EMEA that seeks approval for use of Genasense® plus dacarbazine for the treatment of patients with advanced melanoma who have not previously received chemotherapy. On February 1, 2006, we announced that we had received notice from the EMEA that our MAA was validated for review by the EMEA. We anticipate receiving consolidated questions from the EMEA approximately 120 days from the date of the MAA's validation. The centralized licensing procedure provides a single marketing authorization that is valid in all 25-member states of the European Community. Review of the application is coordinated by the EMEA, and Spain and France have been appointed as rapporteur and co-rapporteur countries, respectively.

On December 28, 2005, we completed submission of an NDA to the FDA that sought accelerated approval for the use of Genasense® in combination with fludarabine plus cyclophosphamide for the treatment of patients with relapsed or refractory CLL who have previously received fludarabine. Genasense® has received Fast Track designation by the FDA in CLL, meaning that the indication represents an unmet medical need. Genasense® has also been granted designation as an Orphan Drug by the FDA. On March 1, 2006, we announced that the NDA had been accepted for review by the FDA with a target action date of October 28, 2006. However, acceptance of this NDA does not necessarily lead to FDA approval. After reviewing in May 2005 a summary of our preliminary clinical data that were released in November 2004 from our CLL trial, the FDA expressed concern that simply achieving statistical significance in the primary endpoint (complete plus nodular partial responses [CR/nPR]) may not be likely to convey or predict clinical benefit, particularly absent improvement in time-to-progression. Subsequent to preparation of the preliminary data summary, the Company compiled additional information to support its claims of clinical benefit. First, the proportion of patients who relapsed from CR/nPR increased substantially over time from 25% to 75% in the patient group treated with chemotherapy alone. By contrast, the comparable increase in the Genasense® group was 16% to 25%, which indicated a lower risk of relapse. Second, the preliminary clinical data indicated that the median duration of CR/nPR had not been reached in either treatment group. Further follow-up showed that CR/nPRs achieved with the addition of Genasense® to chemotherapy were significantly longer when compared with those responses achieved with chemotherapy alone. For example, the median CR/nPR duration in the chemotherapy alone group was reached at

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

22 months, whereas the median has still not been reached in the Genasense® group [P=0.03]. Third, the Company had prospectively collected data regarding specific parameters of disease-related morbidity, including but not limited to symptoms. Subsequent analysis of these data showed that patients in the Genasense® treatment group who achieved CR/nPR also attained substantial improvement in these disease parameters. The NDA that was submitted by the Company in December 2005, which includes these data, was subsequently accepted for review by the FDA in February 2006.

Following its review of all our information concerning Genasense®, the FDA may refuse to approve altogether, or may ask for more data to be obtained, so that approval can be reconsidered. Any of these decisions by the FDA would have a material adverse effect on our business. One requirement for Accelerated Approval is that we will be required to conduct a confirmatory trial. We have formulated a design for such a trial and have submitted a proposal to the FDA for review as a Special Protocol Assessment, or SPA. The submitted proposal incorporated initial comments received from the FDA. Final comments on the submission are expected during the first half of 2006. Formal initiation of the trial will depend upon resolution of trial design issues with the FDA, among other factors. Although Fast Track designation, Orphan Drug designation and Accelerated Approval provisions are beneficial, we cannot assure you that the NDA will be approved. In particular, the FDA may not be satisfied that achievement of the primary endpoint used in our recent clinical trial, which was an increased proportion of complete responses/nodular partial responses compared to patients treated with standard chemotherapy, is a sufficient basis for approval. Further, increased symptom-free time may not be considered to be sufficient demonstration of clinical benefit.

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

***Recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern.***

Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statement for the year ended December 31, 2005 with respect to this uncertainty. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of the common shares of our stock and we may have a more difficult time obtaining financing.

We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

***Our business will suffer if we fail to obtain timely funding. We may be unable to raise additional capital when needed and may not continue as a going concern.***

Our operations to date have required significant cash expenditures. As a result of Aventis' termination of the Collaborative Agreement, after May 8, 2005, we became solely responsible for all Genasense® related costs. Our future capital requirements will depend on the results of our research and development activities, preclinical studies and clinical trials, competitive and technological advances, and regulatory activities of the FDA and other regulatory authorities. In order to commercialize our products, we will need to raise additional funds. On August 11, 2005, we sold 19.1 million shares of common stock at a price of \$0.92 per share, raising \$16.0 million, net of fees and expenses. In addition, on March 6, 2006, we executed definitive subscription agreements with institutional investors to sell 19 million shares of our common stock at a price of \$2.15 per share raising approximately \$37.8 million, net of estimated fees and expenses. Assuming the completion of this financing, management believes that at the projected rate of spending, including building our sales and marketing team and capabilities, we should have sufficient cash funds to maintain our present operations into the first quarter of 2007. We will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing. We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. Future collaborations or similar arrangements may require us to license valuable intellectual property to, or to share substantial economic benefits with, our collaborators. If we raise additional capital by issuing additional equity or securities convertible into equity, our stockholders may experience dilution and our share price may decline. Any debt financing may result in restrictions on our spending.

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

- 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 and commercialize ourselves;
- o attempt to sell our company;
- o cease operations; or
- o declare bankruptcy.

***We intend to be a direct marketer of some products in the United States. This effort will consume large amounts of our resources and management time and we may not be successful in our efforts.***

Currently we do not have a sales force. Our sales force was eliminated in 2004 following our decision to withdraw the NDA for Genasense® for the treatment of advanced melanoma. We intend to build a sales force throughout the second and third quarters of 2006. In January 2006, we announced that we had appointed W. Lloyd Sanders as Vice-President of Sales and Marketing. Most recently, Mr. Sanders was Vice President, Oncology Sales, at sanofi-aventis Group. If we are unable to build a sales force capable of marketing our products, our sales will be adversely affected, and the commercial success of our products will be limited.

***On May 10, 2005, we announced that we and Aventis Pharmaceuticals Inc., part of sanofi-aventis Group, or Aventis, had signed an agreement to terminate their development and commercialization collaboration for Genasense®. We lost a significant source of funding for Genasense® as a result of this termination.***

In April 2002, we entered into a series of agreements relating to the development and commercialization of Genasense®, to which we refer collectively as the Collaborative Agreement, with Aventis and its affiliates. On November 8, 2004, we received from Aventis a notice of termination of the Collaborative Agreement. On May 10, 2005, we announced that we had signed an agreement with Aventis to terminate our development and commercialization collaboration for Genasense®. The termination agreement provided for no future financial obligations by either party. Aventis also returned its then current inventory of Genasense® drug supply to us. In addition, we assumed responsibility for the randomized clinical trial of Genasense® in combination with docetaxel (Taxotere®; sanofi-aventis) in patients with hormone-refractory prostate cancer, which recently completed accrual. Among other provisions, the Standstill and Voting Agreement and Registration Rights Agreement that were established pursuant to the Aventis investment in our common stock in 2002 did not terminate at this time.

***We are seeking a new partner for the development and commercialization of Genasense®, and if we are unable to do so, we may not have sufficient resources to fully develop and commercialize Genasense®.***

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

***We have relied on and continue to rely on our contractual collaborative arrangements with research institutions and corporate partners for development and commercialization of our products. Our business could suffer if we are not able to enter into suitable arrangements, maintain existing relationships, or if our collaborative arrangements are not successful in developing and commercializing products.***

We have entered into collaborative relationships relating to the conduct of clinical research and other research activities in order to augment our internal research capabilities and to obtain access to specialized knowledge and expertise. Our business strategy depends in part on our continued ability to develop and maintain relationships with leading academic and research institutions and with independent researchers. The competition for these relationships is intense, and we can give no assurances that we will be able to develop and maintain these relationships on acceptable terms.





We also seek strategic alliances with corporate partners, primarily pharmaceutical and biotechnology companies, to help us develop and commercialize drugs. Various problems can arise in strategic alliances. A partner responsible for conducting clinical trials and obtaining regulatory approval may fail to develop a marketable drug. A partner may decide to pursue an alternative strategy or focus its efforts on alliances or other arrangements with third parties. A partner that has been granted marketing rights for a certain drug within a geographic area may fail to market the drug successfully. Consequently, strategic alliances that we may enter into may not be scientifically or commercially successful. In this regard, in April 2002, we entered into a series of agreements relating to the development and commercialization of Genasense® with Aventis and its affiliates. On November 8, 2004, we received from Aventis a notice of termination of the Collaborative Agreement. On May 10, 2005, we announced that we and Aventis had signed an agreement to terminate our development and commercialization collaboration for Genasense® as described above.

We cannot control the resources that any collaborator may devote to our products. Any of our present or future collaborators may not perform their obligations as expected. These collaborators may breach or terminate their agreements with us, for instance upon changes in control or management of the collaborator, or they may otherwise fail to conduct their collaborative activities successfully and in a timely manner.

In addition, our collaborators may elect not to develop products arising out of our collaborative arrangements or to devote sufficient resources to the development, regulatory approval, manufacture, marketing or sale of these products. If any of these events occur, we may not be able to develop our products or commercialize our products.

An important part of our strategy involves conducting multiple product development programs. We may pursue opportunities in fields that conflict with those of our collaborators. In addition, disagreements with our collaborators could develop over rights to our intellectual property. The resolution of such conflicts and disagreements may require us to relinquish rights to our intellectual property that we believe we are entitled to. In addition, any disagreement or conflict with our collaborators could reduce our ability to obtain future collaboration agreements and negatively impact our relationship with existing collaborators. Such a conflict or disagreement could also lead to delays in collaborative research, development, regulatory approval or commercialization of various products or could require or result in litigation or arbitration, which would be time consuming and expensive, divert the attention of our management and could have a significant negative impact on our business, financial condition and results of operations.

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

We have never been profitable. We have incurred substantial annual operating losses associated with ongoing research and development activities, preclinical testing, clinical trials, regulatory submissions and manufacturing activities. From the period since our inception to December 31, 2005, we have incurred a cumulative net loss of \$358.2 million. We may never achieve revenue sufficient for us to attain profitability. Achieving profitability is unlikely unless Genasense® receives approval from the FDA for commercial sale in one or more indications.

***Our business depends heavily on a small number of products.***

We currently market and sell one product, Ganite® and the principal patent covering its use for the approved indication expired in April 2005. We do not expect to expand our marketed product portfolio significantly in the short term unless Genasense® receives marketing approval. If Genasense® is not approved, if approval is significantly delayed, or if in the event of approval, the product is commercially unsuccessful, we do not expect significant sales of other products to offset this loss of potential revenue.

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

---

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

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

- o obtain U.S. and foreign patent or other proprietary protection for our technologies, products and processes;
- 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 they involve complex legal and factual questions. As a result, our ability to obtain and enforce patents that protect our drugs is highly uncertain. If we are unable to obtain and enforce patents and licenses to protect our drugs, our business, results of operations and financial condition could be adversely affected.

We hold numerous U.S., foreign and international patents covering various aspects of our technology, which include novel compositions of matter, methods of large-scale synthesis and methods of controlling gene expression and methods of treating disease. In the future, however, we may not be successful in obtaining additional patents despite pending or future applications. Moreover, our current and future patents may not be sufficient to protect us against competitors who use similar technology. Additionally, our patents, the patents of our business partners and the patents for which we have obtained licensing rights may be challenged, narrowed, invalidated or circumvented. Furthermore, rights granted under our patents may not be broad enough to cover commercially valuable drugs or processes and therefore may not provide us with sufficient competitive advantage with respect thereto.

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

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

We also may be required to participate in interference proceedings declared by the U.S. Patent and Trademark Office in opposition or similar proceedings before foreign patent offices and in International Trade Commission proceedings aimed at preventing the importation of drugs that would compete unfairly with our drugs. These types of proceedings could cause us to incur considerable costs.

The principal patent covering the use of Ganite® for its approved indication expired, including Hatch-Waxman extensions, in April 2005.

We have licensed a portfolio of U.S. patents and applications from the University of Pennsylvania and the NIH relating to Genasense® and its backbone chemistry that expire between 2008 and 2015. Corresponding patent applications have been filed in Canada, Europe and Japan. The claims of these patents cover our proprietary antisense oligonucleotide molecules which target the Bcl-2 mRNA and methods employing them. We also hold several U.S. patent applications relating to methods of using Genasense® that expire in 2020, with approximately 45 corresponding foreign patent applications.

---

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

Most of our resources have been dedicated to the research and development of potential antisense pharmaceutical products such as Genasense®, based upon oligonucleotide technology. While we have demonstrated the activity of antisense oligonucleotide technology in model systems in vitro and in animals, Genasense® is our only antisense product to have been tested in humans. Several of our other technologies that serve as a possible basis for pharmaceutical products are only in preclinical testing. Results obtained in preclinical 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.

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

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

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

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

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

We cannot assure you that our ongoing preclinical studies and clinical trials will produce successful results in order to support regulatory approval of Genasense® in any territory or for any indication. Failure to obtain approval, or a substantial delay in approval of Genasense® for these or any other indications would have a material adverse effect on our results of operations and financial condition.

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

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

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

- 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;
- 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.***

The FDA and comparable regulatory agencies in foreign countries (such as the EMEA) impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve lengthy and detailed preclinical and clinical testing and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more depending upon the type, complexity and novelty of the product. We cannot apply for FDA approval to market any of our products under development until preclinical and clinical trials on the product are successfully completed. Several factors could prevent successful completion or cause significant delays of these trials, including an inability to enroll the required number of patients or failure to demonstrate adequately that the product is safe and effective for use in humans. If safety concerns develop, the FDA could stop our trials before completion. We may not market or sell any product for which we have not obtained regulatory approval. In May 2004, the application failed to gain a majority vote for marketing approval from ODAC. As a consequence, we withdrew the NDA, which allows us to potentially resubmit the application.

We cannot assure you that the FDA, the EMEA or other regulatory agencies will ever approve the use of our products that are under development. If the patient populations for which our products are approved are not sufficiently broad, or if approval is accompanied by unanticipated labeling restrictions, the commercial success of our products could be limited and our business, results of operations and financial condition could consequently be materially adversely affected.

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

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



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

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

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

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

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

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

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 an adequate supply of materials at an acceptable price and quality, we could be materially adversely affected.

---

***If third-party payors do not provide coverage and reimbursement for use of our products, we may not be able to successfully commercialize our products.***

Our ability to commercialize drugs successfully will depend in part on the extent to which various third-party payors are willing to reimburse patients for the costs of our drugs and related treatments. These third-party payors include government authorities, private health insurers and other organizations, such as health maintenance organizations. Third-party payors often challenge the prices charged for medical products and services. Accordingly, if less costly drugs are available, third-party payors may not authorize or may limit reimbursement for our drugs, even if they are safer or more effective than the alternatives. In addition, the federal government and private insurers have changed and continue to consider ways to change the manner in which health care products and services are provided and paid for in the United States. In particular, these third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products. In the future, it is possible that the government may institute price controls and further limits on Medicare and Medicaid spending. These controls and limits could affect the payments we collect from sales of our products. Internationally, medical reimbursement systems vary significantly, with some countries requiring application for, and approval of, government or third-party reimbursement. In addition, some medical centers in foreign countries have fixed budgets, regardless of levels of patient care. Even if we succeed in bringing therapeutic products to market, uncertainties regarding future health care policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in quantities, or at prices, that will enable us to achieve profitability.

***Our business exposes us to potential product liability that may have a negative effect on our financial performance and our business generally.***

The administration of drugs to humans, whether in clinical trials or commercially, exposes us to potential product and professional liability risks, which are inherent in the testing, production, marketing and sale of human therapeutic products. Product liability claims can be expensive to defend and may result in large judgments or settlements against us, which could have a negative effect on our financial performance and materially and adversely affect our business. We maintain product liability insurance (subject to various deductibles), but our insurance coverage may not be sufficient to cover claims. Furthermore, we cannot be certain that we will always be able to maintain or increase our insurance coverage at an affordable price. Even if a product liability claim is not successful, the adverse publicity and time and expense of defending such a claim may interfere with or adversely affect our business and financial performance.

***We may incur a variety of costs to engage in future acquisitions of companies, products or technologies, and the anticipated benefits of those acquisitions may never be realized.***

As a part of our business strategy, we may make acquisitions of, or significant investments in, complementary companies, products or technologies, although no significant acquisition or investments are currently pending. Any future acquisitions would be accompanied by risks such as:

- o difficulties in assimilating the operations and personnel of acquired companies;
- o diversion of our management's attention from ongoing business concerns;
- o our potential inability to maximize our financial and strategic position through the successful incorporation of acquired technology and rights into our products and services;
- o additional expense associated with amortization of acquired assets;
- o maintenance of uniform standards, controls, procedures and policies; and
- o impairment of existing relationships with employees, suppliers and customers as a result of the integration of new management personnel.

We cannot guarantee that we will be able to successfully integrate any business, products, technologies or personnel that we might acquire in the future, and our failure to do so could harm our business.

***We face substantial competition from other companies and research institutions that are developing similar products, and we may not be able to compete successfully.***

In many cases, our products under development will be competing with existing therapies for market share. In addition, a number of companies are pursuing the development of antisense technology and controlled-release formulation technology and the development of pharmaceuticals utilizing such technologies. We compete with fully integrated pharmaceutical companies that have more substantial experience, financial and other resources and superior expertise in research and development, manufacturing, testing, obtaining regulatory approvals, marketing and distribution. Smaller companies may also prove to be significant competitors, particularly through their collaborative arrangements with large pharmaceutical companies or academic institutions. Furthermore, academic institutions, governmental agencies and other public and private research organizations have conducted and will continue to conduct research, seek patent protection and establish arrangements for commercializing products. Such products may compete directly with any products that may be offered by us.

Our competition will be determined in part by the potential indications for which our products are developed and ultimately approved by regulatory authorities. For certain of our potential products, an important factor in competition may be the timing of market introduction of our or our competitors' products. Accordingly, the relative speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are expected to be important competitive factors. We expect that competition among products approved for sale will be based, among other things, on product efficacy, safety, reliability, availability, price, patent position and sales, marketing and distribution capabilities. The development by others of new treatment methods could render our products under development non-competitive or obsolete.

Our competitive position also depends upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often-substantial period between technological conception and commercial sales. We cannot assure you that we will be successful in this regard.

***We are dependent on our key executives and scientists, and the loss of key personnel or the failure to attract additional qualified personnel could harm our business.***

Our business is highly dependent on our key executives and scientific staff. The loss of key personnel or the failure to recruit necessary additional or replacement personnel will likely impede the achievement of our development objectives. There is intense competition for qualified personnel in the pharmaceutical and biotechnology industries, and there can be no assurances that we will be able to attract and retain the qualified personnel necessary for the development of our business.

#### **Risks Related to Outstanding Litigation**

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

In 2004, numerous complaints were filed in the United States District Court for the District of New Jersey against us and certain of our principal officers on behalf of purported classes of our shareholders who purchased our securities during several class periods. The complaints have been consolidated into a single action and allege that we and certain of our principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of malignant melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action complaint in the various actions seeks monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. On September 30, 2005, the court granted in part and denied in part our motion to dismiss the plaintiffs' complaint. The court dismissed plaintiffs' claim that the defendants engaged in a scheme or artifice to defraud plaintiffs, but allowed plaintiffs' claims to proceed with respect to their allegations that defendants issued false and misleading public statements about Genasense®. The parties commenced nonbinding mediation in March 2006. If mediation is unsuccessful, the case is expected to proceed to discovery.

In addition, two separate shareholder derivative actions have been filed against our directors and certain of our officers in New Jersey State and Federal courts. The Federal shareholder derivative action was consolidated with the securities action. The Federal derivative plaintiffs have not yet filed a consolidated amended complaint asserting their claims. Instead, the Federal shareholder derivative action has been stayed,



pending developments in the Federal securities action.

Based on facts substantially similar to those asserted in the shareholder class actions, the state derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and committed other violations of New Jersey law. On February 9, 2006, the Superior Court of New Jersey dismissed the plaintiffs' derivative complaint in the New Jersey State case based in part on plaintiffs' failure to make a pre-suit demand on our Board of Directors and in part based on plaintiffs' failure to state a cause of action. Plaintiffs served a motion for reconsideration on February 27, 2006.

We believe these litigations are without merit and will continue to vigorously defend against these suits.

#### **Risks Related to Our Common Stock**

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

Provisions in our restated certificate of incorporation and bylaws may discourage third parties from seeking to obtain control of us and, therefore, could prevent our stockholders from receiving a premium for their shares. Our restated certificate of incorporation gives our board of directors the power to issue shares of preferred stock without approval of the holders of common stock. Any preferred stock that is issued in the future could have voting rights, including voting rights that could be superior to that of our common stock. The affirmative vote of 66-2/3% of our voting stock is required to approve certain transactions and to take certain stockholder actions, including the amendment of certain provisions of our certificate of incorporation. Our bylaws contain provisions that regulate how stockholders may present proposals or nominate directors for election at annual meetings of stockholders.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which contains restrictions on stockholder action to acquire control of us.

On September 16, 2005, we announced that its Board of Directors approved a Stockholder Rights Plan and declared a dividend of one preferred stock purchase right ( Right ) for each share of our common stock held of record as of the close of business on September 27, 2005. In addition, Rights shall be issued in respect of all shares of common stock issued after such date, including the shares issued hereunder, pursuant to the Plan. The Rights contain provisions to protect stockholders in the event of an unsolicited attempt to acquire us, including an accumulation of shares in the open market, a partial or two-tier tender offer that does not treat all stockholders equally and other activities that the Board believes are not in the best interests of shareholders. The Rights may discourage a takeover and prevent our stockholders from receiving a premium for their shares.

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

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

***Our stock price is volatile.***

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

- o the results of preclinical 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;

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

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

At December 31, 2005, we had 114.5 million shares of common stock outstanding, 11.0 million additional shares reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants and 5.1 million additional shares of common stock authorized for issuance and remaining to be granted under our stock option plans. Future sales of shares of our 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 our common stock. Moreover, the perception that sales of substantial amounts of our common stock might occur could adversely affect the market price of our common stock.

**Item 1B. *Unresolved Staff Comments***

None

**Item 2. *Properties***

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

**Item 3. *Legal Proceedings***

In 2004, numerous complaints were filed in the United States District Court for the District of New Jersey against Genta and certain of its principal officers on behalf of purported classes of the Company's shareholders who purchased its securities during several class periods. The complaints have been consolidated into a single action and allege that the Company and certain of its principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of malignant melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action complaint in the various actions seeks monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. On September 30, 2005, the court granted in part and denied in part the Company's motion to dismiss the plaintiffs' complaint. The court dismissed plaintiffs' claim that the defendants engaged in a scheme or artifice to defraud plaintiffs, but allowed plaintiffs' claims to proceed with respect to their allegations that defendants issued false and misleading public statements about Genasense®. The parties have commenced nonbinding mediation in March 2006. If mediation is unsuccessful, the case is expected to proceed to discovery.

In addition, two separate shareholder derivative actions have been filed against the directors and certain officers of Genta in New Jersey State and Federal courts. The Federal shareholder derivative action was consolidated with the securities action. The Federal derivative plaintiffs have not yet filed a consolidated amended complaint asserting their claims. Instead, the Federal shareholder derivative action has been stayed, pending developments in the Federal securities action.

Based on facts substantially similar to those asserted in the shareholder class actions, the State derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and committed other violations of New Jersey law. On February 9, 2006, the Superior Court of New Jersey dismissed the plaintiffs' derivative complaint in the New Jersey State case based in part on plaintiffs' failure to make a pre-suit demand on Genta's Board of Directors and in part based on plaintiffs' failure to state a cause of action. Plaintiffs served a motion for reconsideration on February 27, 2006.

The Company believes these litigations are without merit and will continue to vigorously defend against these suits.

**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, 2005.

**PART II****Item 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***(a) Market Information*

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

|                | <u>High</u> | <u>Low</u> |
|----------------|-------------|------------|
| <b>2005</b>    |             |            |
| First Quarter  | \$ 1.83     | \$ 1.10    |
| Second Quarter | 1.50        | 0.75       |
| Third Quarter  | 1.98        | 1.00       |
| Fourth Quarter | 1.75        | 1.18       |
| <b>2004</b>    |             |            |
| First Quarter  | \$ 14.25    | \$ 9.25    |
| Second Quarter | 16.65       | 2.06       |
| Third Quarter  | 3.20        | 1.35       |
| Fourth Quarter | 3.03        | 1.18       |

In August 2005, the Company raised \$16.0 million, net of issuance costs, from the issuance of common stock pursuant to our shelf registration statement. The net proceeds from the sale of the common stock will be used for general corporate purposes.

*(b) Holders*

There were 609 holders of record of the Company's common stock as of March 9, 2006. We estimate that there are approximately 40,000 beneficial owners of our common stock.

*(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.

**Item 6. Selected Consolidated Financial Data**

| (In thousands, except share data)                             | Years Ended December 31, |                    |                    |                    |                    |
|---|--------------------------|--------------------|--------------------|--------------------|--------------------|
|   | 2005                     | 2004               | 2003               | 2002               | 2001               |
| <b>Consolidated Statements of Operations Data:</b>            |                          |                    |                    |                    |                    |
| Revenues:   |                          |                    |                    |                    |                    |
| License fees and royalties                                    | \$ 5,241                 | \$ 3,022           | \$ 1,045           | \$ 756             | \$ 146             |
| Development funding   | 20,988                   | 12,105             | 4,194              | 2,803              | --                 |
| Product sales - net   | 356                      | (512)              | 1,420              | --                 | --                 |
| <b>Total revenues</b>   | <b>26,585</b>            | <b>14,615</b>      | <b>6,659</b>       | <b>3,559</b>       | <b>146</b>         |
| Cost of goods sold  |                          |                    |                    |                    |                    |
| Cost of goods sold  | 73                       | 170                | 404                | --                 | --                 |
| Provision for excess inventory                                | (21)                     | 1,350              | --                 | --                 | --                 |
| <b>Total cost of goods sold</b>                               | <b>52</b>                | <b>1,520</b>       | <b>404</b>         | <b>--</b>          | <b>--</b>          |
| Operating expenses:   |                          |                    |                    |                    |                    |
| Research and development                                      | 20,902                   | 71,494             | 83,084             | 87,162             | 39,925             |
| Selling, general and administrative                           | 16,100                   | 28,576             | 29,831             | 20,551             | 9,719              |
| Loss on disposition of property and equipment                 | 4                        | 1,254              | 3                  | 13                 | 19                 |
| <b>Total operating expenses - gross</b>                       | <b>37,006</b>            | <b>101,324</b>     | <b>112,918</b>     | <b>107,726</b>     | <b>49,663</b>      |
| Aventis reimbursement   | (6,090)                  | (43,292)           | (55,891)           | (28,451)           | --                 |
| <b>Total operating expenses - net</b>                         | <b>30,916</b>            | <b>58,032</b>      | <b>57,027</b>      | <b>79,275</b>      | <b>49,663</b>      |
| Gain on forgiveness of debt                                   | 1,297                    | 11,495             | --                 | --                 | --                 |
| Other income/(expense)  | 502                      | (147)              | 669                | 1,372              | 2,804              |
| <b>Loss before income taxes</b>                               | <b>(2,584)</b>           | <b>(33,589)</b>    | <b>(50,103)</b>    | <b>(74,344)</b>    | <b>(46,713)</b>    |
| Income tax benefit/(expense)                                  | 381                      | 904                | (6)                | (184)              | --                 |
| <b>Net loss applicable to common shares</b>                   | <b>\$ (2,203)</b>        | <b>\$ (32,685)</b> | <b>\$ (50,109)</b> | <b>\$ (74,528)</b> | <b>\$ (46,713)</b> |
| <b>Net loss per basic and diluted share</b>                   | <b>\$ (0.02)</b>         | <b>\$ (0.41)</b>   | <b>\$ (0.67)</b>   | <b>\$ (1.05)</b>   | <b>\$ (0.84)</b>   |
| Shares used in computing net loss per basic and diluted share | 102,883                  | 79,798             | 75,093             | 70,656             | 55,829             |

|  | As of December 31, |           |           |            |           |
|--|--------------------|-----------|-----------|------------|-----------|
|  | 2005               | 2004      | 2003      | 2002       | 2001      |
| <b>Consolidated Balance Sheet Data:</b>          |                    |           |           |            |           |
| Cash, cash equivalents and marketable securities | \$ 21,282          | \$ 42,247 | \$ 82,929 | \$ 113,716 | \$ 54,086 |
| Working capital                                  | 11,703             | (4,269)   | 81,252    | 91,586     | 42,709    |
| Total assets                                     | 27,386             | 50,532    | 114,675   | 136,419    | 60,630    |
| Total stockholders' equity                       | 15,697             | 1,752     | 12,254    | 46,703     | 48,310    |

---

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

Since its inception in February 1988, Genta has devoted its principal efforts toward drug discovery and research and development. Genta's strategy is to build a product and technology portfolio primarily focused on its cancer-related products. Genta has been unprofitable to date and expects to incur substantial operating losses due to continued requirements for ongoing and planned research and development activities, preclinical and clinical testing, manufacturing activities, regulatory activities and establishment of a sales and marketing organization. From our inception to December 31, 2005, we have incurred a cumulative net loss of \$358.2 million. Management expects that such losses will continue at least until its lead product, Genasense® (oblimersen sodium) Injection, receives approval from the U.S. Food and Drug Administration (FDA) for commercial sale in one or more indications. Achievement of profitability for the Company is dependent on the timing of Genasense® regulatory approvals in the U.S. and outside the U.S.

The Company had \$21.3 million of cash and cash equivalents and marketable securities on hand at December 31, 2005. The Company's recurring losses from operations and negative cash flows from operations raise substantial doubt about Genta's ability to continue as a going concern and as a result, Genta's independent registered public accounting firm included an explanatory paragraph in its report on Genta's consolidated financial statements for the year ended December 31, 2005 with respect to this uncertainty.

In addition, on March 6, 2006, the Company executed definitive subscription agreements with institutional investors to issue and sell 19 million shares of our common stock at a price of \$2.15 per share raising approximately \$37.8 million, net of estimated fees and expenses. The closing of this financing is expected to close on or about March 13, 2006, subject to the satisfaction of customary closing condition. Assuming the completion of this financing, management believes that at the projected rate of spending, including building our sales and marketing team and capabilities, we should have sufficient cash funds to maintain our present operations into the first quarter of 2007.

The Company has commenced discussions with several companies regarding partnership for the further development and global commercialization of Genasense®. Those discussions are currently ongoing.

Additional alternatives available to the Company to subsequently sustain its operations include other collaborative agreements, equity financing and other financing arrangements with potential corporate partners and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available on favorable terms, if at all. The Company will need substantial additional funds before it can expect to realize significant product revenue.

Our financial results in 2005 have been and will continue to be significantly affected by FDA action with respect to Genasense®. In late 2003, we filed our first NDA with the FDA for Genasense® as a treatment combined with chemotherapy for patients with advanced malignant melanoma. In May 2004, the application failed to gain a majority vote for marketing approval from ODAC. As a consequence, Genta withdrew the NDA, which allows the Company to potentially resubmit the application. However, we continued long-term follow-up of patients who were enrolled in the advanced malignant melanoma trial. On May 16, 2005, we announced updated data from our Phase 3 trial of Genasense® in patients with advanced malignant melanoma at the American Society of Clinical Oncology meeting. The updated data continued to show statistical significance for overall response, complete response and progression free survival. Statistical significance was also achieved for durable response (P=0.02). We commissioned a new, independent review of the X-rays that documented the major responses, which confirmed the originally reported responses with high concordance. Overall survival by intent to treat analysis had improved from the time of the FDA filing but did not yield a statistically significant improvement at a significance level (i.e., P less than 0.05). The P value at the time of the FDA filing was 0.18, whereas the P value with the most recent analysis was 0.077. Our analysis also identified a statistically significant treatment interaction effect for blood levels of an enzyme known as LDH, which was one of three prospectively specified stratification factors in this trial. When this effect was analyzed by treatment arm, survival (and all other efficacy endpoints) was significantly superior for patients who had received Genasense® (P=0.018) who did not have an elevation in LDH at study entry (n=508).

On January 3, 2006, the Company announced that it had completed an MAA to the EMEA, which seeks approval for use of Genasense® plus dacarbazine for the treatment of patients with advanced melanoma who have not previously received chemotherapy. On February 1, 2006, the Company announced that it had received notice from the EMEA that its MAA had been validated for review by the Agency, which signals the start of formal scientific assessment. As part of this process, Genta anticipates receiving scientific questions from EMEA in June 2006 and then expects to make a formal response thereafter.

In December 2004, the Company presented results from its third randomized trial, which was conducted in patients with relapsed or refractory CLL. In this trial, 241 patients who had relapsed or had not responded to prior therapy were treated with standard chemotherapy using fludarabine and cyclophosphamide ( Flu/Cy ). After stratifying patients using conventional criteria, they were randomly assigned to receive Genasense or no additional treatment. Initial results showed that the trial achieved its primary endpoint: the proportion of patients who achieved a complete or nodular partial response ( CR/nPR ) was significantly improved with the addition of Genasense to Flu/Cy chemotherapy (17% vs. 7%; P=0.025). The response required independent confirmation by an external clinical reviewer who was blinded to treatment assignment and who reviewed clinical, laboratory and radiologic data. A second independent reviewer evaluated bone marrow biopsies. Agreement between the clinical and bone marrow reviews was required in order to determine response in this study.

The CLL trial also showed that the duration of CR/nPR was significantly superior for patients treated with Genasense plus chemotherapy. To date, six of the eight patients (75%) who achieved CR/nPR with chemotherapy alone have relapsed compared with five of twenty patients (25%) in the Genasense® treatment group. The median duration of CR/nPR was 22 months in the chemotherapy-alone group; the median has not been reached in the Genasense® group (P=0.03). All CR/nPR responses have been durable (i.e., exceeding six months duration). Additional analysis showed that patients who achieved CR/nPR also experienced substantial clinical benefit, especially with respect to improvement of disease-related symptoms. Several secondary endpoints were not improved by the addition of Genasense. For example, no difference was observed in overall response rate (i.e., the percentage of patients who achieved CR/nPR plus partial response ( PR ), or in time-to-disease progression. Overall survival will be formally evaluated in mid-2006 after all patients have completed a minimum of two years of follow-up. Adverse events (irrespective of relation to study drugs) during treatment or within 30 days from last dose of treatment that resulted in death occurred in nine patients treated with Genasense® plus chemotherapy compared with five patients treated with chemotherapy alone. The percentage of patients who experienced serious adverse events was increased in the Genasense® arm; however, the percentages of patients who discontinued treatment due to adverse events were equal in the treatment arms. The incidence of certain serious adverse reactions, including but not limited to nausea, fever and catheter-related complications, was increased in patients treated with Genasense®.

On December 28, 2005, the Company completed submission of an NDA to the FDA that seeks accelerated approval for the use of Genasense® in combination with fludarabine plus cyclophosphamide for the treatment of patients with relapsed or refractory CLL who have previously received fludarabine. Genasense® has received Fast Track designation by the FDA in CLL, meaning that the indication represents an unmet medical need. Genasense has also been granted designation as an Orphan Drug by the FDA. On March 1, 2005, the Company announced that the NDA had been accepted for review by the FDA and set a target action date of October 28, 2006. However, acceptance of this NDA does not necessarily lead to FDA approval. Following its review of all the Company's information concerning Genasense®, the FDA may refuse to approve altogether, or may ask for more data to be obtained, so that approval can be reconsidered. Either of these two decisions by the FDA would have a material adverse effect on our business. One of the requirements for Accelerated Approval is that the Company will be required to conduct a confirmatory trial. The Company has formulated a design for such a trial and has submitted a proposal to the FDA for review as a Special Protocol Assessment ( SPA ). The submitted proposal incorporated initial comments received from the FDA. Final comments on the submission are expected during the first half of 2006. Formal initiation of the trial will depend upon resolution of trial design issues with the FDA, among other factors. Although Fast Track designation, Orphan Drug designation and Accelerated Approval provisions are beneficial, we cannot assure you that the NDA will be approved. In particular, the FDA may not be satisfied that achievement of the primary endpoint used in the Company's recent clinical trial being an increased proportion of complete responses/nodular partial responses compared to patients treated with standard chemotherapy is sufficient basis for approval. Further, increased symptom-free time may not be considered to be sufficient demonstration of clinical benefit.

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



In addition, the Company is conducting (under its own sponsorship or in conjunction with various cooperative groups) randomized trials in non-small cell lung cancer ( NSCLC ), small cell lung cancer ( SCLC ), acute myeloid leukemia ( AML ) and hormone refractory prostate cancer ( HRPC ). We are also conducting a number of non-randomized clinical trials in patients with various types of cancer, either under our own sponsorship or in collaboration with the National Cancer Institute ( NCI ).

In April 2002, we entered into a series of agreements with Aventis regarding the development and commercialization of Genasense®. On November 8, 2004, the Company received from Aventis notice of termination of the agreements between Genta and Aventis. On May 10, 2005, the Company announced that Genta and Aventis had signed an agreement to finalize the termination of their development and commercialization collaboration for Genasense®. The termination agreement provided for no future financial obligations by either party and the retirement of the Line of Credit established by Aventis to Genta. Aventis returned its current inventory of Genasense® drug supply to Genta. In addition, Genta assumed responsibility for the randomized clinical trial of Genasense® in combination with docetaxel (Taxotere®; sanofi-aventis) in patients with hormone-refractory prostate cancer, which is currently ongoing in Europe. Among other provisions, the Standstill and Voting Agreement and Registration Rights Agreement that were established pursuant to the Aventis investment in Genta common stock in 2002 were not terminated at that time.

## Results of Operations

| (\$ thousands)   | Summary Operating Results<br>For the years ended December 31, |                        |          |                        |          |
|--|---|------------------------|----------|------------------------|----------|
|  | 2005  | Increase<br>(Decrease) | 2004     | Increase<br>(Decrease) | 2003     |
| Revenues:  |   |                        |          |                        |          |
| License fees and royalties   | \$ 5,241  | \$ 2,219               | \$ 3,022 | \$ 1,977               | \$ 1,045 |
| Development funding  | 20,988  | 8,883                  | 12,105   | 7,911                  | 4,194    |
| Product sales - net  | 356   | 868                    | (512)    | (1,932)                | 1,420    |
| Total revenues   | 26,585  | 11,970                 | 14,615   | 7,956                  | 6,659    |
| Cost of goods sold   | 73  | (97)                   | 170      | (234)                  | 404      |
| Provision for excess inventory   | (21)  | (1,371)                | 1,350    | 1,350                  | --       |
| Total cost of goods sold   | 52  | (1,468)                | 1,520    | 1,116                  | 404      |
| Operating expenses:  |   |                        |          |                        |          |
| Research and development (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of \$0, \$158 and \$209 for the twelve months ended December 31, 2005, 2004 and 2003, respectively )            | 20,902  | (50,592)               | 71,494   | (11,590)               | 83,084   |
| Selling, general and administrative (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of \$41, \$62 and \$227 for the twelve months ended December 31, 2005, 2004 and 2003, respectively ) | 16,100  | (12,476)               | 28,576   | (1,255)                | 29,831   |
| Loss on disposition of equipment   | 4   | (1,250)                | 1,254    | 1,251                  | 3        |
| Total operating expenses - gross   | 37,006  | (64,318)               | 101,324  | (11,594)               | 112,918  |
| Less: Aventis reimbursement  | (6,090)   | 37,202                 | (43,292) | 12,599                 | (55,891) |
| Total operating expenses - net   | 30,916  | (27,116)               | 58,032   | 1,005                  | 57,027   |
| Gain on forgiveness of debt  | 1,297   | (10,198)               | 11,495   | 11,495                 | --       |

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

|                              |                   |                  |                    |                  |                    |
|------------------------------|-------------------|------------------|--------------------|------------------|--------------------|
| Other income/(expense)       | <u>502</u>        | <u>649</u>       | <u>(147)</u>       | <u>(816)</u>     | <u>669</u>         |
| Loss before income taxes     | (2,584)           | 31,005           | (33,589)           | 16,514           | (50,103)           |
| Income tax benefit/(expense) | <u>381</u>        | <u>(523)</u>     | <u>904</u>         | <u>910</u>       | <u>(6)</u>         |
| Net loss                     | <u>\$ (2,203)</u> | <u>\$ 30,482</u> | <u>\$ (32,685)</u> | <u>\$ 17,424</u> | <u>\$ (50,109)</u> |

34

---

Total revenues

Total revenues, consisting of license fees, development funding and product sales were \$26.6 million in 2005 compared to \$14.6 million in 2004 and \$6.7 million in 2003. License fees and development funding revenues are generated by the initial \$10.0 million licensing fee and \$40.0 million development funding received from Aventis in 2002 under the Collaborative Agreement (see Note 4 to our financial statements). On November 8, 2004, Aventis gave notice to Genta that it was terminating its Collaborative Agreement with the Company regarding the development and commercialization of Genasense®. Under the terms of the Collaborative Agreement, Aventis continued to fund ongoing development activities through May 8, 2005. The Company had previously determined that, due to the nature of the ongoing development work related to the Collaborative Agreement, the end of the development phase and the fair-value of the undelivered elements were not determinable. Accordingly, we deferred recognition of the initial licensing fee and up-front development funding received from Aventis and recognized these payments on a straight-line basis over the original estimated useful life of the related first-to-expire patent of 115 months. As a result of the notice of termination of the Collaborative Agreement, the Company determined that the period over which the remaining deferred revenue should be recognized was through May 8, 2005. On November 9, 2004, we began to recognize the remaining deferred revenue over a six-month period, resulting in increased revenue of \$11.1 million during 2005 and \$9.9 million during 2004.

In 2003, the Company launched the commercial product Ganite® for the treatment of cancer-related hypercalcemia that is resistant to hydration, generating \$1.4 million in product sales. In 2004, the Company eliminated its sales force and significantly reduced its marketing support for Ganite®. In December 2004, a wholesaler contacted the Company to return a significant portion of its inventory of Ganite®. The Company agreed to the return of this product and recorded a provision for sales returns, as well as provided for potential returns from other wholesalers. Our provision for sales returns increased by \$1.2 million in 2004, resulting in net sales of (\$0.5) million for 2004. Sales of Ganite® during 2005 were \$0.4 million.

Cost of goods sold

During 2004, we recorded provisions for excess Ganite® inventory of \$1.4 million. Excluding the provision for excess inventory, cost of goods sold for 2005 decreased from the prior-year period, consistent with the decline in product sales.

Research and development expenses

Research and development expenses before reimbursement were \$20.9 million in 2005 compared to \$71.5 million in 2004 and \$83.1 million in 2003.

Approximately \$19.5 million or 93% of research and development expenses before reimbursement were incurred on the Genasense® project for the twelve months ended December 31, 2005. In the prior-year period, approximately \$66.8 million or 93% of research and development expenses before reimbursement were incurred on the Genasense® project. Included in the \$66.8 million was \$33.0 million related to the expensing of vialled Genasense® product and Genasense® bulk drug substance, much of which had been originally produced and acquired to be commercial inventory and other expenses related to the manufacturing and purchase of Genasense® bulk drug substance. Research and development expenses in 2005 also declined due to our decision in May 2004 to reduce staff and reduce most non-Genasense® related programs as well as a lower level of activity on clinical trials. Of the \$20.9 million in research and development expenses for the year ended December 31, 2005, \$6.1 million were reimbursable pursuant to our Collaborative Agreement with Aventis. With the Aventis notice of termination, payments otherwise due to Genta were applied against the balance of the Line of Credit until it was repaid in May 2005 (see Note 10 to our Financial Statements).

Research and development expenses in 2003 include a \$13.5 million write-off of acquired in-process research and development resulting from the August 2003 acquisition of Salus Therapeutics, Inc. In August 2004, Genta completed the closure of its research facility in Salt Lake City, which had originated from the acquisition of Salus Therapeutics, Inc. Excluding these items, research and development expenses declined \$31.1 million in 2004, primarily resulting from our decision in May 2004 to reduce staff and reduce most non-Genasense® related programs, as well as from the comparison to a prior-year period where expenses were significantly higher resulting from Genasense® Phase 3 clinical trials and NDA preparation activities.

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

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are not reasonably estimable. Results from clinical trials may not be favorable. Data from clinical trials are subject to varying interpretation and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines.

Selling, general and administrative expenses

Selling, general and administrative expenses were \$16.1 million in 2005 compared to \$28.6 million in 2004 and \$29.8 million in 2003. Lower expenses in 2005 reflect the impact of the May 2004 elimination of the sales force, reduction of other administrative positions and substantial reduction of marketing support for Ganite®. In addition, during 2004, we recorded \$1.0 million of legal expenses related to certain class action lawsuits (see Note 16 to our Financial Statements).

In 2004, selling, general and administrative expenses decreased by \$1.2 million compared to 2003 as a higher rate of spending in the first half of the year, in anticipation of approval and launch of Genasense®, was more than offset by the impact of the elimination of the sales force and other cost-cutting measures.

Loss on disposition of property and equipment

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

Aventis reimbursement

A breakdown of the various third-party, drug supply costs and internal costs of scientific and technical personnel, ( Full-Time Equivalents or FTE s ) that Aventis was required to reimburse under our Collaborative agreement with Aventis, follows:

|                            | <u>2005</u> | <u>2004</u> | <u>2003</u> |
|----------------------------|-------------|-------------|-------------|
| Reimbursement to Genta     |             |             |             |
| Third-party costs          | \$ 2,917    | \$ 19,284   | \$ 34,073   |
| Drug supply costs          | 1,807       | 20,061      | 16,326      |
| FTE s                      | 1,513       | 5,833       | 7,228       |
|                            | <hr/>       | <hr/>       | <hr/>       |
| Amount due to Genta        | \$ 6,237    | \$ 45,178   | \$ 57,627   |
| Reimbursement to Aventis   | 147         | 1,886       | 1,736       |
|                            | <hr/>       | <hr/>       | <hr/>       |
| Net reimbursement to Genta | \$ 6,090    | \$ 43,292   | \$ 55,891   |
|                            | <hr/>       | <hr/>       | <hr/>       |

Net expense reimbursement from Aventis of \$6.1 million for 2005 declined from \$43.3 million for 2004 due to the termination of the Collaborative Agreement in May 2005 and lower expenses incurred on the Genasense® project. In addition, in September 2004, the Company transferred \$15.5 million of vialled Genasense® drug product and Genasense® bulk drug substance to Aventis. This amount is included in Drug supply costs in the above table.

Once Aventis provided notice of termination of the Collaborative Agreement, all payments otherwise due from Aventis were applied against the balance on the Line of Credit until the Line of Credit was repaid in May 2005.

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

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

#### Gain on forgiveness of debt

Gain on forgiveness of debt of \$1.3 million in 2005 and \$11.5 million in 2004 is the result of the termination of the Collaborative Agreement with sanofi-aventis. In 2005, pursuant to the terms of the Collaborative Agreement, \$2.8 million of reimbursable costs accrued and owed to the Company by Aventis were applied against the Line of Credit with Aventis and the remaining balance of \$1.3 million was forgiven. In 2004, under the terms of the Collaborative Agreement, Aventis forgave the \$10.0 million of convertible debt issued to them in connection with the collaboration, along with \$1.5 million in accrued interest, resulting in a gain on extinguishment of debt of \$11.5 million.

#### Other income/(expense)

Net other income of \$0.5 million in 2005 favorably compared to net other expense of \$0.1 million for the prior year. This was the result of lower interest expense, due to the Company having no debt since May 2005, partially offset by lower interest income, resulting from lower investment balances. Net other expense of \$0.1 million in 2004 unfavorably compared to net other income of \$0.7 million in 2003, primarily due to lower average investment balances throughout 2004 as compared to 2003.

#### Income tax benefit/(expense)

New Jersey has enacted legislation permitting certain corporations located in the state to sell state tax loss carryforwards and state research and development credits. The Company sold portions of its New Jersey net operating losses in both 2005 and 2004 and received a payment of \$0.9 million in each year that is recognized as income tax benefit. In 2005, the benefit was offset by \$0.5 million of an accrued income tax expense that has arisen from a State of New Jersey tax audit for the years 2000 through 2004. The State has taken the position that amounts reimbursed to the Company by Aventis for co-development expenditures during the audit period are subject to New Jersey's Alternative Minimum Assessment. Although the Company and its outside tax accountants believe the State's position is unjustified, there is little case law on the matter and it is probable that the Company will be required to pay the liability in 2006.

If still available under New Jersey law, the Company will attempt to sell its tax loss carryforwards in 2006. We cannot be assured that the New Jersey program will continue in 2006, nor can we estimate what percentage of our saleable tax benefits New Jersey will permit us to sell, how much money will be received in connection with the sale, or if the Company will be able to find a buyer for its tax benefits.

#### Net loss

Genta incurred a net loss of \$2.2 million, or \$0.02 per share, for 2005, \$32.7 million, or \$0.41 per share, for 2004 and \$50.1 million, or \$0.67 per share, for 2003.

In 2005, the improvement in net loss and per share net loss to common shareholders was primarily due to accelerated recognition through May 2005 of the initial licensing fee and up-front development funding previously received from Aventis, lower research and development expenses, lower selling, general and administrative expenses, along with a gain on forgiveness of debt.

In 2004, the improvement in net loss and per share net loss to common shareholders was primarily due to accelerated recognition of the initial licensing fee and up-front development funding previously received from Aventis starting in the month of November and a gain on forgiveness of debt.

---

## Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123(R), Share-Based Payment. SFAS No. 123(R) is a revision of SFAS No. 123, Accounting for Stock-Based Compensation, supersedes Accounting Principles Board ( APB ) Opinion No. 25, Accounting for Stock Issued to Employees and amends SFAS No. 95, Statement of Cash Flows. In April 2005, the Securities and Exchange Commission approved a ruling that delayed the effective date of SFAS 123(R) for annual rather than interim periods that begin after June 15, 2005. Under the new standard, all share-based payments to employees, including grants of employee stock options will now be recognized in the income statement based on their fair values, as pro-forma disclosure is no longer an alternative. The amount of compensation cost will be measured based on the grant-date fair value of the equity instrument issued. The Company currently utilizes a standard option pricing model (i.e., Black-Scholes) to measure the fair value of stock options granted to employees. While SFAS 123(R) permits entities to continue to use such a model; the standard also permits the use of a more complex binomial, or lattice model. Based upon research done by the Company on the alternative models available to value option grants, and in conjunction with the type and number of stock options expected to be issued in the future, the Company has determined that it will continue to use the Black-Scholes model for option valuation as of the current time.

For the years ended December 31, 2005, 2004 and 2003, we accounted for share-based compensation arrangements in accordance with APB No. 25, and complied with the disclosure provisions of SFAS 123. SFAS 123(R) requires all public entities that used the fair-value method for either recognition or disclosure under SFAS 123 to apply the modified prospective transition method as of the required effective date. As a result, we adopted the provisions of SFAS 123(R) using this method, effective January 1, 2006. Under the modified prospective method, new awards will be valued and accounted for prospectively upon adoption. Outstanding prior awards that are unvested as of January 1, 2006 will be recognized as compensation cost over the remaining requisite service period. Prior periods will not be restated. The adoption of SFAS 123(R) is anticipated to increase our reported net loss and loss per share.

Management forecasts that the impact of adopting SFAS 123(R) for the twelve months ending December 31, 2006 will be between \$2.0 million and \$3.0 million, taking into account options granted in January 2006. This forecast is based on the Black-Scholes option-pricing model and includes estimates on the additional number of options to be granted during 2006, the price of our stock at the time of grants, the volatility of our stock price and the expected forfeiture rates. As such, our actual stock option expense may differ from this estimate.

## Critical Accounting Policies

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements. In preparing our financial statements in accordance with accounting principles generally accepted in the United States of America, management is required to make estimates and assumptions that, among other things, affect the reported amounts of assets and liabilities and reported amounts of revenues and expenses. These estimates are most significant in connection with our critical accounting policies, namely those of our accounting policies that are most important to the portrayal of our financial condition and results and require management's most difficult, subjective or complex judgments. These judgments often result from the need to make estimates about the effects of matters that are inherently uncertain. Actual results may differ from those estimates under different assumptions or conditions. The Company believes that the following represent its critical accounting policies:

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

Genta recognizes revenue from product sales when title to product and associated risk of loss has passed to the customer and we are reasonably assured of collecting payment for the sale. All revenue from product sales are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances. We allow return of our product for up to twelve months after product expiration. In December 2004, a wholesaler contacted the Company to return a significant portion of its inventory of Ganite®. The Company agreed to the return of this product and recorded a provision for sales returns, as well as provided for potential returns from other wholesalers. Our provision for sales returns increased by \$1.2 million in 2004. In January 2005, the wholesaler returned \$0.5 million of Ganite®. At December 31, 2005, the Company's remaining provision for sales returns was \$0.8 million.

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

### **Liquidity and Capital Resources**

At December 31, 2005, we had cash, cash equivalents and marketable securities totaling \$21.3 million, a decline of \$20.9 million from \$42.2 million at December 31, 2004. During 2005, cash flow used in operating activities was \$37.0 million compared with \$61.0 million in 2004. This decline reflects our smaller organization, focus on Genasense® and lower level of activity on clinical trials.

At December 31, 2005, Genta had no outstanding short-term debt compared with the outstanding balance of \$7.3 million on the Line of Credit with Aventis as of December 31, 2004.

The Company's recurring losses from operations and negative cash flows from operations raise substantial doubt about Genta's ability to continue as a going concern and as a result, Genta's independent registered public accounting firm included an explanatory paragraph in its report on Genta's consolidated financial statements for the year ended December 31, 2005 with respect to this uncertainty.

In addition, on March 6, 2006, the Company executed definitive subscription agreements with institutional investors to issue and sell 19 million shares of our common stock at a price of \$2.15 per share raising approximately \$37.8 million, net of estimated fees and expenses. Assuming the completion of this financing, management believes that at the projected rate of spending, including building our sales and marketing team and capabilities, we should have sufficient cash funds to maintain our present operations into the first quarter of 2007. The closing of this financing is expected to close on or about March 13, 2006, subject to the satisfaction of customary closing conditions.

The Company commenced discussions with several companies regarding partnership for the further development and global commercialization of Genasense®. Those discussions are currently ongoing.

Additional alternatives available to the Company to subsequently sustain its operations include other collaborative agreements, equity financing and other financing arrangements with potential corporate partners and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available on favorable terms, if at all. The Company will need substantial additional funds before it can expect to realize significant product revenue.

At December 31, 2004, we had cash, cash equivalents and marketable securities totaling \$42.2 million, a decline of \$40.7 million from \$82.9 million at December 31, 2003. During 2004, cash flow used in operating activities was \$61.2 million, primarily resulting from a net loss of \$32.7 million and non-cash reimbursements of research and development expenses of \$27.3 million. Partially offsetting this outflow, in December 2004, we raised \$21.6 million, net of issuance costs, from the issuance of common stock.

At December 31, 2004, the Company had \$7.3 million outstanding (compared to \$35.0 million as of December 31, 2003) on the Line of Credit from Aventis. During 2004, as a result of certain non-cash transactions, the Company reduced amounts owed under the Line of Credit by \$27.7 million. As a result of Aventis' purchase commitments to Genta, in September we supplied \$15.5 million of vialled Genasense® drug product and Genasense® bulk drug substance to Aventis. This amount is included in the Company's Consolidated Statement of Operations as Aventis reimbursement. The companies agreed to offset amounts owed under the Line of Credit by \$14.8 million and accrued interest on the Line of Credit by \$0.7 million. With the Aventis notice of termination, Genta could not borrow additional funds and the Line of Credit had to be repaid no later than May 8, 2005. All payments otherwise due to Genta were applied against the balance on the Line of Credit until the Line of Credit was repaid. In 2004, \$12.9 million of reimbursement due to Genta was applied to the balance of the Line of Credit.

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

Our principal expenditures relate to our research and development activities, primarily focused on Genasense®, which include our ongoing and future clinical trials. We expect these expenditures to continue. The Company may seek collaborative agreements and other financing arrangements with potential corporate partners and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available on favorable terms, if at all. The Company will need substantial additional funds before it can expect to realize significant product revenue.

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

#### Contractual Obligations

Future contractual obligations at December 31, 2005 are as follows (\$ thousands):

|                             | <b>Total</b>     | <b>Less than<br/>1 year</b> | <b>1 - 3 years</b> | <b>3 - 5 years</b> | <b>More than 5<br/>years</b> |
|-----------------------------|------------------|-----------------------------|--------------------|--------------------|------------------------------|
| Operating lease obligations | \$ 11,056        | \$ 2,711                    | \$ 5,339           | \$ 3,005           | --                           |
| <b>Total</b>                | <b>\$ 11,056</b> | <b>\$ 2,711</b>             | <b>\$ 5,339</b>    | <b>\$ 3,005</b>    | <b>--</b>                    |

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

#### Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.



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

Our carrying values of cash, marketable securities, accounts payable, accrued expenses and debt are a reasonable approximation of their fair value. The estimated fair values of financial instruments have been determined by us using available market information and appropriate valuation methodologies (see Note 2 to our financial statements). We have not entered into and do not expect to enter into, financial instruments for trading or hedging purposes. We do not currently anticipate entering into interest rate swaps and/or similar instruments.

Genta's primary market risk exposure with regard to financial instruments is to changes in interest rates, which would impact interest income earned on such instruments. We have no material currency exchange or interest rate risk exposure as of December 31, 2005. Therefore there will be no ongoing exposure to material adverse effect on our business, financial condition or results of operation for sensitivity to changes in interest rates or to changes in currency exchange rates.

**Item 8. Financial Statements and Supplemental Data**

**Genta Incorporated  
Index to Financial Statements**

|  |    |
|--|----|
| Report of Independent Registered Public Accounting Firm  | 43 |
| Consolidated Balance Sheets at December 31, 2005 and 2004  | 44 |
| Consolidated Statements of Operations for the years ended December 31, 2005, 2004 and 2003           | 45 |
| Consolidated Statements of Stockholders' Equity for the years ended December 31, 2005, 2004 and 2003 | 46 |
| Consolidated Statements of Cash Flows for the years ended December 31, 2005, 2004 and 2003           | 48 |
| Notes to Consolidated Financial Statements   | 49 |

---

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
Genta Incorporated:

We have audited the accompanying consolidated balance sheets of Genta Incorporated and subsidiaries (the Company) as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Genta Incorporated and subsidiaries as of December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's recurring losses from operations and negative cash flows from operations raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2005, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 10, 2006 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey  
March 10, 2006

**GENTA INCORPORATED**  
**CONSOLIDATED BALANCE SHEETS**

(In thousands, except par value data)

| ASSETS  | December 31, |           |
|---|--------------|-----------|
|   | 2005         | 2004      |
| Current assets:   |              |           |
| Cash and cash equivalents   | \$ 9,314     | \$ 36,489 |
| Marketable securities (Note 3)  | 11,968       | 5,758     |
| Accounts receivable - net   | 59           | --        |
| Inventory (Note 5)  | 396          | 354       |
| Prepaid expenses and other current assets   | 1,655        | 1,910     |
|   | 23,392       | 44,511    |
| Total current assets  | 23,392       | 44,511    |
| Property and equipment, net (Note 6)  | 1,077        | 2,847     |
| Intangibles, net  | --           | 286       |
| Prepaid royalties (Note 7)  | 1,268        | 1,268     |
| Other assets  | 1,649        | 1,620     |
|   | 27,386       | 50,532    |
| Total assets  | \$ 27,386    | \$ 50,532 |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |              |           |
| Current liabilities:  |              |           |
| Accounts payable and accrued expenses (Note 8)  | \$ 10,960    | \$ 14,424 |
| Deferred revenues (Note 9)  | --           | 26,228    |
| Notes payable   | 729          | 816       |
| Short term debt (Note 10)   | --           | 7,312     |
|   | 11,689       | 48,780    |
| Total current liabilities   | 11,689       | 48,780    |
| Commitments and contingencies (Note 16)   |              |           |
| Stockholders' equity (Note 13):   |              |           |
| Preferred stock, 5,000 shares authorized  | --           | --        |
| Series A convertible preferred stock, \$.001 par value;<br>10 shares issued and outstanding, liquidation value of \$485<br>at December 31, 2005 and December 31, 2004, respectively | --           | --        |
| Series G participating cumulative preferred stock, \$.001 par value;<br>0 shares issued and outstanding at December 31, 2005<br>and December 31, 2004, respectively                 | --           | --        |
| Common stock, \$.001 par value; 150,000 shares authorized,<br>114,550 and 95,358 shares issued and outstanding at December 31, 2005<br>and December 31, 2004, respectively          | 115          | 95        |
| Additional paid-in capital  | 373,709      | 357,714   |
| Accumulated deficit   | (358,187)    | (355,984) |
| Deferred compensation   | --           | (41)      |
| Accumulated other comprehensive income/(loss)   | 60           | (32)      |
|   | 15,697       | 1,752     |
| Total stockholders' equity  | 15,697       | 1,752     |
| Total liabilities and stockholders' equity  | \$ 27,386    | \$ 50,532 |

See accompanying notes to consolidated financial statements.

**GENTA INCORPORATED**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

| (In thousands, except per share data)   | Years Ended December 31, |             |             |
|---|--------------------------|-------------|-------------|
|   | 2005                     | 2004        | 2003        |
| Revenues:   |                          |             |             |
| License fees and royalties (Note 9)   | \$ 5,241                 | \$ 3,022    | \$ 1,045    |
| Development funding (Note 9)  | 20,988                   | 12,105      | 4,194       |
| Product sales - net   | 356                      | (512)       | 1,420       |
|   | 26,585                   | 14,615      | 6,659       |
| Total revenues  |                          |             |             |
| Cost of goods sold  | 73                       | 170         | 404         |
| Provision for excess inventory  | (21)                     | 1,350       | --          |
|   | 52                       | 1,520       | 404         |
| Total cost of goods sold  |                          |             |             |
| Operating expenses:   |                          |             |             |
| Research and development (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of \$158 and \$209 for the years ended December 31, 2004 and 2003, respectively)                       | 20,902                   | 71,494      | 83,084      |
| Selling, general and administrative (including non-cash compensation expense related to certain stock options issued in 1999 and 2000 of \$41, \$62 and \$227 for the years ended December 31, 2005, 2004 and 2003, respectively) | 16,100                   | 28,576      | 29,831      |
| Loss on disposition of property and equipment   | 4                        | 1,254       | 3           |
|   | 37,006                   | 101,324     | 112,918     |
| Total operating expenses - gross  |                          |             |             |
| Aventis reimbursement (Note 4)  | (6,090)                  | (43,292)    | (55,891)    |
|   | 30,916                   | 58,032      | 57,027      |
| Total operating expenses - net  |                          |             |             |
| Gain on forgiveness of debt (Note 10)   | 1,297                    | 11,495      | --          |
| Other income/(expense)  | 502                      | (147)       | 669         |
|   | (2,584)                  | (33,589)    | (50,103)    |
| Loss before income taxes  |                          |             |             |
| Income tax benefit/(expense) (Note 11)  | 381                      | 904         | (6)         |
|   | \$ (2,203)               | \$ (32,685) | \$ (50,109) |
| Net loss  |                          |             |             |
| Net loss per basic and diluted share  | \$ (0.02)                | \$ (0.41)   | \$ (0.67)   |
| Shares used in computing net loss per basic and diluted share   | 102,883                  | 79,798      | 75,093      |

See accompanying notes to consolidated financial statements.

**GENTA INCORPORATED**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
For the Years Ended December 31, 2005, 2004 and 2003

|  | Convertible Preferred Stock |        | Common Stock |        | Treasury Stock |           | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) |              |               | Total Stockholders' Equity |
|--|-----------------------------|--------|--------------|--------|----------------|-----------|----------------------------|---|--------------|---------------|----------------------------|
|  | Shares                      | Amount | Shares       | Amount | Shares         | Amount    |                            | Deficit                                       | Compensation | Income (Loss) |                            |
| <b>(In thousands)</b>  |                             |        |              |        |                |           |                            |   |              |               |                            |
| Balance at January 1, 2003   | 261                         | --     | 74,168       | \$ 74  | (393)          | \$(2,506) | \$ 322,997                 | \$ (273,190)                                  | \$ (697)     | \$ 25         | \$ 46,703                  |
| Comprehensive loss:  |                             |        |              |        |                |           |                            |   |              |               |                            |
| Net Loss   | --                          | --     | --           | --     | --             | --        | --                         | (50,109)                                      | --           | --            | (50,109)                   |
| Unrealized investment loss   | --                          | --     | --           | --     | --             | --        | --                         | --  | --           | --            | --                         |
| Total comprehensive loss   | --                          | --     | --           | --     | --             | --        | --                         | --  | --           | --            | (50,109)                   |
| Issuance of common stock in connection with exercise of warrants and stock options           | --                          | --     | 1,172        | 1      | --             | --        | 2,542                      | --  | --           | --            | 2,543                      |
| Purchase of treasury stock   | --                          | --     | --           | --     | (51)           | (303)     | --                         | --  | --           | --            | (303)                      |
| Retirement of treasury stock   | --                          | --     | (444)        | --     | 444            | 2,809     | (2,809)                    | --  | --           | --            | --                         |
| Issuance of common stock in connection with acquisition of Salus Therapeutics, Inc           | --                          | --     | 1,031        | 1      | --             | --        | 12,983                     | --  | --           | --            | 12,984                     |
| Compensation expense related to certain stock options issued in 1999 and 2000                | --                          | --     | --           | --     | --             | --        | --                         | --  | 436          | --            | 436                        |
| Balance at December 31, 2003   | 261                         | \$ --  | 75,927       | \$ 76  | --             | \$ --     | \$ 335,713                 | \$ (323,299)                                  | \$ (261)     | \$ 25         | \$ 12,254                  |
| Comprehensive loss:  |                             |        |              |        |                |           |                            |   |              |               |                            |
| Net Loss   | --                          | --     | --           | --     | --             | --        | --                         | (32,685)                                      | --           | --            | (32,685)                   |
| Unrealized investment loss   | --                          | --     | --           | --     | --             | --        | --                         | --  | --           | (57)          | (57)                       |
| Total comprehensive loss   | --                          | --     | --           | --     | --             | --        | --                         | --  | --           | --            | (32,742)                   |
| Issuance of common stock in connection with Series A conversion                              | (251)                       | --     | 1,855        | 2      | --             | --        | (2)                        | --  | --           | --            | --                         |
| Issuance of common stock in connection with exercise of warrants and stock options           | --                          | --     | 2,576        | 2      | --             | --        | 478                        | --  | --           | --            | 480                        |
| Issuance of common stock in connection with direct placement, net of issuance costs of \$960 | --                          | --     | 15,000       | 15     | --             | --        | 21,525                     | --  | --           | --            | 21,540                     |
| Compensation expense related to certain stock options issued in 1999 and 2000                | --                          | --     | --           | --     | --             | --        | --                         | --  | 220          | --            | 220                        |

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

Balance at December 31, 2004

|       |    |    |        |    |    |    |    |    |    |         |    |           |    |      |    |      |    |       |
|-------|----|----|--------|----|----|----|----|----|----|---------|----|-----------|----|------|----|------|----|-------|
| 10    | \$ | -- | 95,358 | \$ | 95 | -- | \$ | -- | \$ | 357,714 | \$ | (355,984) | \$ | (41) | \$ | (32) | \$ | 1,752 |
| <hr/> |    |    |        |    |    |    |    |    |    |         |    |           |    |      |    |      |    |       |

**GENTA INCORPORATED**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**  
**For the Years Ended December 31, 2005, 2004 and 2003**

|   | Convertible Preferred Stock |        | Common Stock |        | Treasury Stock |        | Additional Paid-in Capital | Accumulated Deficit | Deferred Compensation | Accumulated Other Comprehensive Income (Loss) |           | Total Stockholders Equity |
|---|-----------------------------|--------|--------------|--------|----------------|--------|----------------------------|---------------------|-----------------------|---|-----------|---------------------------|
|   | Shares                      | Amount | Shares       | Amount | Shares         | Amount |                            |                     |                       | Capital                                       | Deficit   |                           |
| (In thousands)  |                             |        |              |        |                |        |                            |                     |                       |   |           |                           |
| Comprehensive loss:   |                             |        |              |        |                |        |                            |                     |                       |   |           |                           |
| Net Loss  | --                          | --     | --           | --     | --             | --     | --                         | (2,203)             | --                    | --  | --        | (2,203)                   |
| Unrealized investment income (loss)   | --                          | --     | --           | --     | --             | --     | --                         | --                  | --                    | --  | 92        | 92                        |
| Total comprehensive loss  | --                          | --     | --           | --     | --             | --     | --                         | --                  | --                    | --  | --        | (2,111)                   |
| Issuance of common stock, net of issuance costs of \$1,521                    | --                          | --     | 19,060       | 20     | --             | --     | 15,995                     | --                  | --                    | --  | --        | 16,015                    |
| Other conversions   | --                          | --     | 132          | --     | --             | --     | --                         | --                  | --                    | --  | --        | --                        |
| Compensation expense related to certain stock options issued in 1999 and 2000 | --                          | --     | --           | --     | --             | --     | --                         | --                  | 41                    | --  | --        | 41                        |
| Balance at December 31, 2005  | 10                          | \$ --  | 114,550      | \$ 115 | --             | \$ --  | \$ 373,709                 | \$ (358,187)        | \$ --                 | \$ 60   | \$ 15,697 |                           |



**GENTA INCORPORATED**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

| (In thousands)   | Years Ended December 31, |             |             |
|--|--------------------------|-------------|-------------|
|  | 2005                     | 2004        | 2003        |
| <b>Operating activities:</b>   |                          |             |             |
| Net loss   | \$ (2,203)               | \$ (32,685) | \$ (50,109) |
| Items reflected in net loss not requiring cash:  |                          |             |             |
| Depreciation and amortization  | 2,074                    | 3,003       | 2,383       |
| Loss on disposition of property and equipment  | 4                        | 1,254       | 3           |
| Non-cash reimbursement of research & development expense (Note 4 and Note 10)                                  | (6,090)                  | (27,328)    | --          |
| Amortization of deferred revenues (Note 9)   | (26,228)                 | (15,127)    | (5,237)     |
| Provision for sales returns  | --                       | 1,291       | 30          |
| Provision for excess inventory   | (21)                     | 1,350       | --          |
| Gain on forgiveness of debt (Note 10)  | (1,297)                  | (11,495)    | --          |
| Write-off of acquired in-process research and development (Note 2)   | --                       | --          | 13,465      |
| Compensation expense related to certain stock options issued in 1999 and 2000 (Note 14)                        | 41                       | 220         | 436         |
| Changes in operating assets and liabilities, net of effects of acquisition of Salus Therapeutics, Inc in 2003: |                          |             |             |
| Accounts receivable  | (59)                     | 15,509      | (2,131)     |
| Inventory (Note 5)   | (21)                     | (1,185)     | (518)       |
| Notes receivable   | --                       | 3,542       | (3,542)     |
| Prepaid expenses and other current assets  | 255                      | 574         | (817)       |
| Accounts payable and accrued expenses  | (3,389)                  | 58          | (17,404)    |
| Other assets   | (29)                     | (12)        | (7)         |
| Net cash used in operating activities  | (36,963)                 | (61,031)    | (63,448)    |
| <b>Investing activities:</b>   |                          |             |             |
| Purchase of marketable securities (Note 3)   | (21,839)                 | (7,281)     | (107,350)   |
| Maturities and sales of marketable securities (Note 3)   | 15,721                   | 59,241      | 130,590     |
| Deposits to restricted cash account  | --                       | (294)       | (1,029)     |
| Redemptions of restricted cash account   | --                       | 165         | 64          |
| Purchase of property and equipment   | (56)                     | (1,767)     | (3,293)     |
| Proceeds from sale of equipment  | 34                       | 157         | --          |
| Cash paid for acquisition of Salus, net of cash acquired (Note 2)  | --                       | --          | (579)       |
| Net cash (used in) provided by investing activities  | (6,140)                  | 50,221      | 18,403      |
| <b>Financing activities:</b>   |                          |             |             |
| Issuance of common stock, net (Note 13)  | 16,015                   | 21,598      | --          |
| Borrowings under long term debt  | --                       | --          | 35,000      |
| Borrowings under note payable  | 1,233                    | 1,431       | 998         |
| Repayments of note payable   | (1,320)                  | (1,363)     | (740)       |
| Purchase of treasury stock   | --                       | --          | (303)       |
| Issuance of common stock upon exercise of warrants and options (Note 13 & 14)                                  | --                       | 480         | 2,543       |
| Net cash provided by financing activities  | 15,928                   | 22,146      | 37,498      |
| Decrease (increase) in cash and cash equivalents   | (27,175)                 | 11,336      | (7,547)     |
| Cash and cash equivalents at beginning of year   | 36,489                   | 25,153      | 32,700      |
| Cash and cash equivalents at end of year   | \$ 9,314                 | \$ 36,489   | \$ 25,153   |

See accompanying notes to consolidated financial statements



---

**GENTA INCORPORATED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**For the years ended December 31, 2005, 2004 and 2003**

**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 the identification, development and commercialization of novel drugs for the treatment of cancer and related diseases.

The Company has had recurring annual operating losses since its inception. Management expects that such losses will continue at least until its lead product, Genasense® (oblimersen sodium) Injection, receives approval from the U.S. Food and Drug Administration ( FDA ) for commercial sale in one or more indications. Achievement of profitability for the Company is dependent on the timing of Genasense® regulatory approvals in the U.S. and outside the U.S. Any adverse events with respect to FDA and/or EMEA approvals could negatively impact our ability to obtain additional funding or identify potential partners.

The Company had \$21.3 million of cash, cash equivalents and marketable securities on hand at December 31, 2005.

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

On March 6, 2006, the Company executed definitive subscription agreements with institutional investors to issue and sell 19 million shares of the Company's common stock at a price of \$2.15 per share, raising approximately \$37.8 million, net of estimated fees and expenses. The closing of this financing is expected to close on or about March 13, 2006, subject to the satisfaction of customary closing condition.

The Company commenced discussions with several companies regarding partnership for the further development and global commercialization of Genasense®. Those discussions are currently ongoing.

Additional alternatives available to the Company to subsequently sustain its operations include other collaborative agreements, equity financing and other financing arrangements with potential corporate partners and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available on favorable terms, if at all. The Company will need substantial additional funds before it can expect to realize significant product revenue.

A significant source of funds during the last several years has been from the Company's collaboration with Aventis, a member of the sanofi-aventis Group ( Aventis ), regarding the development and commercialization of Genasense®. On November 8, 2004, the Company received from Aventis notice of termination of the agreements between Genta and Aventis. Pursuant to those agreements, Aventis continued to support the development of Genasense® for a six-month period. On May 10, 2005, the Company announced that Genta and Aventis had signed an agreement to finalize the termination of their development and commercialization collaboration for Genasense®. The termination agreement provided for no future financial obligations by either party.

The Company may also seek other collaborative agreements, equity financing and other financing arrangements with potential corporate partners and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available on favorable terms, if at all. The Company will need substantial additional funds before it can expect to realize significant product revenue.

If we are unable to raise additional funds, 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 and commercialize ourselves;
- o attempt to sell our company;

- o cease operations; or
- o declare bankruptcy.

---

## 2. Summary of Significant Accounting Policies

### *Basis of Presentation*

The consolidated financial statements are presented on the basis of accounting principles generally accepted in the United States of America. All professional accounting standards that are effective as of December 31, 2005 have been considered in preparing the consolidated financial statements. Such financial statements include the accounts of the Company and all majority-owned subsidiaries. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make certain estimates and assumptions that affect reported earnings, financial position and various disclosures. Actual results could differ from those estimates. Certain reclassifications have been made to prior-year amounts to conform to current-year presentation.

### *Revenue Recognition*

In April 2002, the Company entered into a development and commercialization agreement ( Collaborative Agreement ) with Aventis. On November 8, 2004 Aventis gave notice to Genta that it was terminating its Collaborative Agreement with the Company. Under the terms of the agreement, Aventis continued to fund ongoing development activities for a six-month period. The Company follows the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin ( SAB ) No. 104, Revenue Recognition and Emerging Issues Task Force ( EITF ) No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables.

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

The Company determined that, due to the nature of the ongoing development work related to its Collaborative Agreement with Aventis, the end of the development phase and the fair value of the undelivered elements were not determinable. Accordingly, the Company deferred recognition of the initial licensing fee and up-front development funding received from Aventis and recognized these payments on a straight-line basis over the original estimated useful life of the related first-to-expire patent of 115 months. As a result of the notice of termination of the agreement with Aventis, the Company determined that the remaining deferred revenue should be recognized over the six-month termination notice period from November 2004 to May 2005.

Genta recognizes revenue from product sales when title to product and associated risk of loss has passed to the customer and the Company is reasonably assured of collecting payment for the sale. All revenue from product sales are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances. The Company allows return of its product for up to twelve months after product expiration. In December 2004, a wholesaler contacted the Company to return a significant portion of its inventory of Ganite®. The Company agreed to the return of this product and recorded a provision for sales returns, as well as provided for potential returns from other wholesalers. Our provision for sales returns increased by \$1.2 million in 2004. In January 2005, the wholesaler returned \$0.5 million of Ganite®. At December 31, 2005, the Company's remaining provision for sales returns was \$0.8 million.

### *Research and Development*

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

*Cash, Cash Equivalents and Marketable Securities*

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

*Property and Equipment*

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

*Inventories*

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

*Income Taxes*

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

Management records valuation allowances against net deferred tax assets, if based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and when temporary differences become deductible. The Company considers, among other available information, uncertainties surrounding the recoverability of deferred tax assets, scheduled reversals of deferred tax liabilities, projected future taxable income and other matters in making this assessment. The Company reviewed its deferred tax assets and at both December 31, 2005 and December 31, 2004, recorded a valuation allowance to reduce these assets to zero to reflect that, more likely than not, they will not be realized.

*Stock Options*

The Company has two stock-based compensation plans (Note 14). The Company accounts for stock-based compensation arrangements in accordance with provisions of Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* and complies with the disclosure provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*. Under APB Opinion No. 25, compensation expense is based on the difference, if any, on the date of grant, between the fair value of the Company's stock and the exercise price of the option. The Company accounts for stock options issued to non-employees in accordance with the provisions of SFAS No. 123 and EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. The Company is amortizing deferred stock compensation using the graded vesting method, in accordance with Financial Accounting Standards Board Interpretation (FIN ) No. 28, over the vesting period of each respective option, which is generally four years.

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

| (\$ thousands, except per share data)  | Years Ended December 31, |             |             |
|--|--------------------------|-------------|-------------|
|  | 2005                     | 2004        | 2003        |
| Net loss applicable to common shares, as reported  | \$ (2,203)               | \$ (32,685) | \$ (50,109) |
| Add: Equity related employee compensation expense related to certain stock options issued in 1999 and 2000 included in reported net income, net of related tax effects | 41                       | 220         | 436         |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects                            | (6,206)                  | (7,236)     | (7,644)     |
| Pro forma net loss   | \$ (8,368)               | \$ (39,701) | \$ (57,317) |
| Net loss per share attributable to common shareholders:  |                          |             |             |
| As reported: Basic and diluted   | \$ (0.02)                | \$ (0.41)   | \$ (0.67)   |
| Pro forma: Basic and diluted   | \$ (0.08)                | \$ (0.50)   | \$ (0.76)   |

The fair value of options was estimated at the date of the grant using the Black-Scholes option-valuation model with the following weighted average assumptions:

|                         | Years Ended December 31, |       |       |
|-------------------------|--------------------------|-------|-------|
|                         | 2005                     | 2004  | 2003  |
| Risk-free interest rate | 4.4 %                    | 3.5 % | 3.3 % |
| Dividend yield          | --                       | --    | --    |
| Expected life (years)   | 6.3                      | 4.0   | 4.0   |
| Volatility              | 116 %                    | 98 %  | 58 %  |

In December 2004, the FASB issued SFAS No. 123(R), *Share-Based Payment*. SFAS No. 123(R) is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*, supersedes Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees* and amends SFAS No. 95. In April 2005, the Securities Exchange Commission approved a ruling that delayed the effective date of SFAS 123(R) for annual rather than interim periods that begin after June 15, 2005. Under the new standard, all share-based payments to employees, including grants of employee stock options will now be recognized in the income statement based on their fair values, as pro-forma disclosure is no longer an alternative. The amount of compensation cost will be measured based on the grant-date fair value of the equity instrument issued. The Company currently utilizes a standard option-pricing model (i.e., Black-Scholes) to measure the fair value of stock options granted to employees. While SFAS 123(R) permits entities to continue to use such a model, the standard also permits the use of a more complex binomial, or lattice model. Based upon research done by the Company on the alternative models available to value option grants, and in conjunction with the type and number of stock options expected to be issued in the future, the Company has determined that it will continue to use the Black-Scholes model for option valuation as of the current time.

For the years ended December 31, 2005, 2004 and 2003, the Company accounted for share-based compensation arrangements in accordance with APB No. 25, and complied with the disclosure provisions of SFAS 123. SFAS 123(R) requires all public entities that used the fair-value method for either recognition or disclosure under SFAS 123 to apply the modified prospective transition method as of the required effective date. As a result, the Company adopted the provisions of SFAS 123(R) using this method, effective January 1, 2006. Under the modified prospective method, new awards will be valued and accounted for prospectively upon adoption. Outstanding prior awards that are unvested as of January 1, 2006 will be recognized as compensation cost over the remaining requisite service period. Prior periods will not be restated. The adoption of SFAS 123(R) is anticipated to increase the Company's reported net loss and loss per share.

#### *Net Loss Per Common Share*

Net loss per common share for the twelve months ended December 31, 2005, 2004 and 2003, respectively, are based on the weighted average number of shares of common stock outstanding during the periods. Basic and diluted loss per share are identical for all periods presented as potentially dilutive securities, including options, warrants and convertible preferred stock, aggregating 11.0 million, 11.4 million and 18.0 million in 2005, 2004 and 2003, respectively, have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would be antidilutive.

### **3. Marketable Securities**

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

|                         | December 31, |          |
|-------------------------|--------------|----------|
|                         | 2005         | 2004     |
| Cost                    | \$ 11,908    | \$ 5,790 |
| Gross unrealized gains  | 60           | 10       |
| Gross unrealized losses | --           | (42)     |
| Fair value              | \$ 11,968    | \$ 5,758 |

The fair value of each marketable security has been compared to its cost and therefore, an unrealized gain of approximately \$60 thousand and a net unrealized loss of approximately \$32 thousand has been recognized in Accumulated other comprehensive income/(loss) at December 31, 2005 and December 31, 2004, respectively.

### **4. Collaborative Agreement**

In April 2002, we entered into a series of agreements with Aventis regarding the development and commercialization of Genasense®. On November 8, 2004, the Company received from Aventis notice of termination of the agreements between Genta and Aventis. On May 10, 2005, the Company announced that Genta and Aventis had signed an agreement to finalize the termination of their development and commercialization collaboration for Genasense®. The termination agreement provided for no future financial obligations by either party and the retirement of the Line of Credit established by Aventis to Genta. Aventis returned its current inventory of Genasense® drug supply to Genta. In addition, Genta assumed responsibility for the randomized clinical trial of Genasense® in combination with docetaxel (Taxotere®; sanofi-aventis) in patients with hormone-refractory prostate cancer, which is currently ongoing in Europe. Among other provisions, the Standstill and Voting Agreement and Registration Rights Agreement that were established pursuant to the Aventis investment in Genta common stock in 2002 did not terminate at that time.



Under the Collaborative Agreement Aventis paid 75% of the U.S. NDA-directed development costs incurred by either Genta or Aventis and 100% of all other development, marketing, and sales costs incurred within the U.S. and elsewhere through May 10, 2005. An analysis of expenses reimbursed under the Collaborative Agreement follows (\$ thousands):

|  | Twelve Months Ended<br>December 31, |                  |                  |
|--|-------------------------------------|------------------|------------------|
|  | 2005                                | 2004             | 2003             |
| Research and development expenses, gross | \$ 20,902                           | \$ 71,494        | \$ 83,084        |
| Less expense reimbursement               | (6,090)                             | (43,292)         | (55,891)         |
| Research and development expenses, net   | <u>\$ 14,812</u>                    | <u>\$ 28,202</u> | <u>\$ 27,193</u> |

### 5. Inventory

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

|                 | December 31,  |               |
|-----------------|---------------|---------------|
|                 | 2005          | 2004          |
| Raw materials   | \$ 191        | \$ 333        |
| Work in process | --            | --            |
| Finished goods  | 205           | 21            |
|                 | <u>\$ 396</u> | <u>\$ 354</u> |

On May 10, 2005, the Company announced that Genta and Aventis had signed an agreement to finalize the termination of their development and commercialization collaboration for Genasense®. The termination agreement provided for no future financial obligations by either party and Aventis returned its current inventory of Genasense® drug supply to Genta. With this returned drug supply, the Company has substantial quantities of Genasense® which are recorded at no cost. Such inventory would be available for the commercial launch of this product, should Genasense® be approved.

### 6. Property and Equipment, Net

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

|  | Estimated<br>Useful Lives | December 31,    |                 |
|--|---------------------------|-----------------|-----------------|
|  |                           | 2005            | 2004            |
| Computer equipment                             | 3                         | \$ 2,871        | \$ 2,860        |
| Software                                       | 3                         | 3,349           | 3,349           |
| Furniture and fixtures                         | 5                         | 936             | 936             |
| Leasehold improvements                         | Life of lease             | 410             | 443             |
| Equipment                                      | 5                         | 182             | 166             |
|  |                           | <u>7,748</u>    | <u>7,754</u>    |
| Less accumulated depreciation and amortization |                           | (6,671)         | (4,907)         |
|  |                           | <u>\$ 1,077</u> | <u>\$ 2,847</u> |

**7. Prepaid Royalties**

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

**8. Accounts Payable and Accrued Expenses**

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

|                           | December 31, |           |
|---------------------------|--------------|-----------|
|                           | 2005         | 2004      |
| Accounts payable          | \$ 4,665     | \$ 5,683  |
| Accrued compensation      | 1,467        | 1,957     |
| Reserve for sales returns | 765          | 1,261     |
| Other accrued expenses    | 4,063        | 5,523     |
|                           | \$ 10,960    | \$ 14,424 |

**9. Deferred Revenues**

As of December 31, 2004, the Company had recorded \$26.2 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. On November 8, 2004, Aventis gave notice to Genta that it was terminating the Collaborative Agreement. Under the terms of the agreement, Aventis continued to fund ongoing development activities through May 8, 2005. As a result of the notice of termination of the agreements with Aventis, the Company determined that the period over which the remaining deferred revenue should be recognized was through May 8, 2005.

**10. Short Term Debt**

Revolving debt was issued in connection with an amendment, dated March 14, 2003, to the Aventis Collaboration Agreement that established a Line of Credit related to the development, manufacturing and commercialization of Genasense® ( Line of Credit ). The Line of Credit was considered an advance against both past and future costs and the borrowing base was adjusted on a monthly basis. With the Aventis notice of termination, Genta could not borrow additional funds and the Line of Credit had to be repaid at the end of the termination period. All payments otherwise due to Genta were applied against the balance on the Line of Credit until the Line of Credit was repaid. On May 10, 2005, the Company announced that Genta and Aventis had finalized a termination agreement, providing for no future financial obligations by either party and the remaining balance on the Line of Credit was forgiven, resulting in a gain on forgiveness of debt of \$1.3 million.

**11. Income Taxes**

Significant components of the Company's deferred tax assets as of December 31, 2005 and 2004 and related valuation reserves are presented below (\$ thousands):

|  | December 31, |           |
|--|--------------|-----------|
|  | 2005         | 2004      |
| <b>Deferred tax assets:</b>  |              |           |
| Deferred compensation  | \$ 772       | \$ 754    |
| Net operating loss carryforwards                                     | 106,898      | 74,138    |
| Research and development credit and Orphan Drug credit carryforwards | 34,384       | 96,009    |
| Purchased technology and license fees                                | 4,850        | 4,850     |
| Depreciation, net  | 304          | --        |
| Deferred revenue - current   | --           | 11,540    |
| New Jersey Alternative Minimum Assessment (AMA) Tax                  | 738          | 182       |
| New Jersey research and development credits                          | 4,707        | 7,558     |
| Provision for excess inventory                                       | 717          | 2,656     |
| Reserve for product returns  | 337          | 568       |
| Accrued liabilities  | 1,465        | --        |
| Other, net   | 231          | 266       |
|  | <hr/>        | <hr/>     |
| Total deferred tax assets  | 155,403      | 198,521   |
| Valuation allowance for deferred tax assets                          | (155,403)    | (198,505) |
|  | <hr/>        | <hr/>     |
| Net deferred tax assets  | --           | 16        |
| <b>Deferred tax liabilities:</b>                                     |              |           |
| Depreciation, net  | --           | (16)      |
|  | <hr/>        | <hr/>     |
| Net deferred tax liabilities   | \$ --        | \$ --     |
|  | <hr/>        | <hr/>     |

A full valuation allowance has been provided at December 31, 2005 and 2004, respectively, to reserve for deferred tax assets, as it appears more likely than not that net deferred tax assets will not be realized. During 2005, the Company reviewed its historical calculation for its Orphan Drug credit. Due to ambiguities in the tax regulations relating to items included in the calculation, the Company has revised the amount of Orphan Drug credit, resulting in a reduction of \$61.0 million in the amount of Orphan Drug credit available for carryforward and also resulting in an increase of \$21.3 million in the amount of deferred tax assets generated by available net operating loss carryforwards.

New Jersey has enacted legislation permitting certain corporations located in the state to sell state tax loss carryforwards and state research and development credits. The Company sold portions of its New Jersey net operating losses in both 2005 and 2004 and received a payment of \$0.9 million in each year that is recognized as income tax benefit. In 2005 the benefit was offset by \$0.5 million of an accrued income tax expense that has arisen from a State of New Jersey tax audit for the years 2000 thru 2004. The State has taken the position that amounts reimbursed to the Company by Aventis for co-development expenditures during the audit period are subject to New Jersey's Alternative Minimum Assessment. Although the Company and its outside tax accountants believe the State's position is unjustified, there is little case law on the matter and it is probable that the Company will be required to pay the liability in 2006.

If still available under New Jersey law, the Company will attempt to sell its tax loss carryforwards in 2006. We cannot be assured that the New Jersey program will continue in 2006, nor can we estimate what percentage of our saleable tax benefits New Jersey will permit us to sell, how much money will be received in connection with the sale, or if the Company will be able to find a buyer for its tax benefits.

At December 31, 2005, the Company has federal and state net operating loss carryforwards of approximately \$256.9 million and \$188.8 million, respectively. The federal tax loss carryforward began expiring in 2003. The Company also has Research and development credits and Orphan Drug credits totaling \$34.4 million, which began expiring in 2003.

## 12. Operating Leases

At December 31, 2005 and December 31, 2004, the Company maintained \$1.6 million in restricted cash balances, included in Other assets, with financial institutions related to lease obligations on its corporate facilities. Such restricted cash balances collateralize letters of credit issued by the financial institutions in favor of the Company's landlord with respect to corporate facilities.

Future minimum obligations under operating leases at December 31, 2005 are as follows (\$ thousands):

|            | <b>Operating<br/>Leases</b> |
|------------|-----------------------------|
| 2006       | \$ 2,711                    |
| 2007       | 2,724                       |
| 2008       | 2,615                       |
| 2009       | 2,576                       |
| 2010       | 429                         |
| Thereafter | --                          |
|            | <b>\$ 11,055</b>            |

Annual rent expense incurred by the Company in 2005, 2004 and 2003 was \$2.4 million, \$2.5 million and \$2.2 million, respectively.

## 13. Stockholders' Equity

### *Common Stock*

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

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

In August 2005, the Company issued 19.1 million shares of its common stock and received net proceeds of approximately \$16.0 million.

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

*Series A Preferred Stock*

Each share of Series A Preferred Stock is immediately convertible into shares of the Company's common stock, at a rate determined by dividing the aggregate liquidation preference of the Series A Preferred Stock by the conversion price. The conversion price is subject to adjustment for antidilution. As of December 31, 2005 and 2004, each share of Series A Preferred Stock was convertible into 9.8067 and 8.4274 shares of common stock, respectively. At December 31, 2005 and December 31, 2004, the Company had 9,700 shares of Series A Convertible Preferred Stock issued and outstanding.

In the event of a liquidation of the Company, the holders of the Series A Preferred Stock are entitled to a liquidation preference equal to \$50 per share, or \$0.5 million at December 31, 2005.

*Series G Preferred Stock*

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

*Warrants*

Summary information with respect to outstanding common stock warrants at December 31, 2005 is presented below:

| <u>Outstanding Warrants</u> | <u>Exercise Price</u> | <u>Potential<br/>Warrant<br/>Exercise<br/>Proceeds</u> | <u>Common<br/>Equivalents</u> | <u>Expiration Date</u> |
|-----------------------------|-----------------------|--|-------------------------------|------------------------|
| June 1997                   | \$ 0.86               | \$ 22,320  | 25,954                        | December 2007          |
| August 1999 Androgenics     | \$ 1.25               | 100,000  | 80,000                        | August 2006            |
| December 1999               | \$2.67-\$4.08         | 602,724  | 190,306                       | June 2007              |
|                             |                       | <u>\$ 725,044</u>                                      | <u>296,260</u>                |                        |

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

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

In December 1999, in connection with a private equity placement, a series of warrants were issued. The remaining outstanding warrants are exercisable and can be converted into a total of approximately 190 thousand common shares.

*Common Stock Reserved*

At December 31, 2005, the Company had 114.5 million shares of common stock outstanding, 11.0 million additional shares reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants and 5.1 million additional shares of common stock authorized for issuance and remaining to be granted under the Company's stock option plans.

**14. Employee Benefit Plans***1998 Plan*

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

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

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

The Company's employees were granted 1,484,300, 1,442,000 and 2,468,300 stock options with exercise prices equal to the fair value on the date of grant in 2005, 2004 and 2003, respectively. Summary information with respect to the Company's 1998 Stock Plan is as follows:

| 1998 Plan                           | Shares<br>Under<br>Option | Weighted<br>Average<br>Exercise<br>Price<br>Per Share |
|-------------------------------------|---------------------------|---|
| <b>Balance at December 31, 2002</b> | 8,499,612                 | \$ 4.89   |
| Granted                             | 2,468,300                 | 9.85  |
| Exercised                           | (834,400)                 | 1.87  |
| Canceled                            | (262,425)                 | 10.75   |
| <b>Balance at December 31, 2003</b> | 9,871,087                 | \$ 6.23   |
| Granted                             | 1,442,000                 | 7.56  |
| Exercised                           | (79,775)                  | 2.76  |
| Canceled                            | (1,239,492)               | 9.97  |
| <b>Balance at December 31, 2004</b> | 9,993,820                 | \$ 5.99   |
| Granted                             | 1,484,300                 | 1.36  |
| Exercised                           | --                        | --  |
| Canceled                            | (2,059,808)               | 7.00  |
| <b>Balance at December 31, 2005</b> | 9,418,312                 | \$ 5.04   |

At December 31, 2005, options to purchase 6,366,798 shares of common stock were exercisable at a weighted average exercise price of approximately \$4.23 per share and 4,446,831 shares of common stock were available for grant or sale under the Plan.

*1998 Non-Employee Directors Plan*

Pursuant to the Company's Non-Employee Directors 1998 Stock Plan as amended, (the Directors Plan) 3.8 million shares have been provided for the grant of stock options to non-employee members of the Board of Directors. Options under the Directors Plan have a term of up to ten years and must be granted at not less than the fair market value on the date of grant. As amended and approved, each director is granted 24,000 options upon election to the Board of Directors. Each option granted shall become exercisable over a three-year period. In addition, annually, each director receives 20,000 options at the first Board of Directors meeting they attend. Each option granted shall become exercisable in full on the date of grant.

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

The Company's directors were granted stock options to purchase a total of 193,000, 160,000 and 184,000 shares of common stock in 2005, 2004 and 2003, respectively, with an exercise price equal to the fair market value of the common stock on the date of grant.

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

| <b>1998 Directors Plan</b>          | <b>Shares Under<br/>Option</b> | <b>Weighted<br/>Average<br/>Exercise Price<br/>Per Share</b> |
|-------------------------------------|--------------------------------|--|
| <b>Balance at December 31, 2002</b> | 864,336                        | \$ 7.41  |
| Granted                             | 184,000                        | 7.98   |
| Exercised                           | (100,000)                      | 8.66   |
| Canceled                            | (20,000)                       | 13.66  |
| <b>Balance at December 31, 2003</b> | 928,336                        | \$ 7.26  |
| Granted                             | 160,000                        | 8.16   |
| Exercised                           | (4,500)                        | 6.86   |
| Canceled                            | (59,500)                       | 10.33  |
| <b>Balance at December 31, 2004</b> | 1,024,336                      | \$ 7.17  |
| Granted                             | 193,000                        | 1.15   |
| Exercised                           | --                             | --   |
| Canceled                            | (59,000)                       | 5.25   |
| <b>Balance at December 31, 2005</b> | 1,158,336                      | \$ 6.26  |

At December 31, 2005, options granted under the Directors Plan to purchase 1,110,335 shares of common stock were exercisable at a weighted average exercise price of approximately \$6.48 per share and 688,877 shares of common stock were available for grant or sale under the Directors Plan.

In 2005, a combined total of 1,677,300 options were granted pursuant to the 1998 Plan and the 1998 Directors Plan at fair market value with a weighted average grant date fair value of \$1.33 per share. In 2004, a combined total of 1,602,000 options were granted pursuant to the 1998 Plan and 1998 Directors Plan at fair market value with a weighted average grant date fair value of \$7.62 per share. In 2003, a combined total of 2,656,300 options were granted pursuant to the 1998 Plan and 1998 Directors Plan at fair market value with a weighted average grant date fair value of \$9.72 per share. No options were granted below fair market value in 2005, 2004 or 2003.

An analysis of all options outstanding as of December 31, 2005 is presented below:

| Range of Prices   | Options Outstanding | Weighted Average Remaining Life in Years | Weighted Average Exercise Price | Options Exercisable | Weighted Average Exercise Price of Options Exercisable |
|-------------------|---------------------|--|---------------------------------|---------------------|--|
| \$0.90 - \$2.88   | 6,490,362           | 5.0                                      | \$ 2.37                         | 5,288,112           | \$ 2.58  |
| \$5.63 - \$7.97   | 1,452,332           | 5.9                                      | \$ 7.17                         | 1,156,857           | \$ 7.14  |
| \$8.02 - \$9.92   | 1,182,351           | 7.0                                      | \$ 9.67                         | 170,175             | \$ 8.57  |
| \$10.00 - \$12.78 | 928,400             | 7.6                                      | \$ 11.00                        | 368,525             | \$ 10.58   |
| \$13.02 - \$18.25 | 523,203             | 6.1                                      | \$ 13.92                        | 493,464             | \$ 13.95   |
|                   | <u>10,576,648</u>   | <u>5.6</u>                               | <u>\$ 5.17</u>                  | <u>7,477,133</u>    | <u>\$ 4.56</u>   |

#### 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 \$0.4 million, \$0.7 million and \$0.6 million for 2005, 2004 and 2003, respectively.

#### 15. Comprehensive Loss

An analysis of comprehensive loss is presented below:

| (\$ in thousands)  | Years Ended<br>December 31, |                    |
|--|-----------------------------|--------------------|
|  | 2005                        | 2004               |
| Net loss   | \$ (2,203)                  | \$ (32,685)        |
| Change in market value on available-for-sale marketable securities | 60                          | (32)               |
| Total comprehensive loss   | <u>\$ (2,143)</u>           | <u>\$ (32,717)</u> |

#### 16. Commitments and Contingencies

##### Litigation and Potential Claims

In 2004, numerous complaints were filed in the United States District Court for the District of New Jersey against Genta and certain of its principal officers on behalf of purported classes of the Company's shareholders who purchased its securities during several class periods. The complaints have been consolidated into a single action and allege that the Company and certain of its principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of malignant melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action complaint in the various actions seeks monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. On September 30, 2005, the court granted in part and denied in part the Company's motion to dismiss the plaintiffs' complaint. The court dismissed plaintiffs' claim that the defendants engaged in a scheme or artifice to defraud plaintiffs, but allowed plaintiffs' claims to proceed with respect to their allegations that defendants issued false and misleading public statements about Genasense®. The parties have agreed to nonbinding mediation, which is expected to begin in March 2006.



In addition, two separate shareholder derivative actions have been filed against the directors and certain officers of Genta in New Jersey State and Federal courts. The Federal shareholder derivative action was consolidated with the securities action. The Federal derivative plaintiffs have not yet filed a consolidated amended complaint asserting their claims. Instead, the Federal shareholder derivative action has been stayed, pending developments in the Federal securities action.

Based on facts substantially similar to those asserted in the shareholder class actions, the State derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and committed other violations of New Jersey law. On February 9, 2006, the Superior Court of New Jersey dismissed the plaintiffs' derivative complaint in the New Jersey State case based in part on plaintiffs failure to make a pre-suit demand on Genta's Board of Directors and in part based on plaintiffs' failure to state a cause of action. Plaintiffs served a motion for reconsideration on February 27, 2006.

The Company believes these litigations are without merit and will continue to vigorously defend against these suits.

### Contractual Obligations

Future contractual obligations at December 31, 2005 are as follows (\$ thousands):

|                             | Total     | Less than<br>1 year | 1 - 3 years | 3 - 5 years | More than<br>5 years |
|-----------------------------|-----------|---------------------|-------------|-------------|----------------------|
| Operating lease obligations | \$ 11,055 | \$ 2,711            | \$ 5,339    | \$ 3,005    | \$ 0                 |
| Total                       | \$ 11,055 | \$ 2,711            | \$ 5,339    | \$ 3,005    | \$ 0                 |

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

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

As a result of the Aventis notice of termination, all payments otherwise due to Genta were contractually applied against the balance of the Line of Credit until the Line of Credit was repaid. During 2005 and 2004, \$6.0 million and \$12.9 million of reimbursement due to Genta respectively was applied to the balance of the Line of Credit. In addition, the Company recorded a gain on the forgiveness of debt of \$1.3 million.

During 2004, as a result of certain non-cash transactions, the Company reduced amounts owed under the Line of Credit by \$27.7 million. In September 2004, the Company supplied \$15.5 million of vialled Genasense® drug product and Genasense® bulk drug substance to Aventis. This amount is included in the Company's 2004 Consolidated Statement of Operations as Aventis reimbursement. The companies agreed to offset amounts owed under the Line of Credit by \$14.8 million and accrued interest on the Line of Credit by \$0.7 million.

During 2004, based on negotiations between the Company and Avecia, amounts owed to Genta under a Note receivable from Avecia were offset against amounts payable to Avecia, resulting in a non-cash reduction to Note receivable and Accounts payable and accrued expenses of approximately \$4.2 million.

No interest was paid for the twelve months ended December 31, 2005, 2004, and 2003, respectively.

**18. Selected Quarterly Financial Data (Unaudited)**

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

| 2005                                  | Quarter Ended |          |           |           |
|---------------------------------------|---------------|----------|-----------|-----------|
|                                       | Mar. 31       | Jun. 30  | Sep. 30   | Dec. 31   |
| (\$ thousands, except per share data) |               |          |           |           |
| Revenues                              | \$ 18,514     | \$ 7,887 | \$ 87     | \$ 97     |
| Operating expenses-net                | 4,604         | 7,348    | 8,114     | 10,850    |
| Net income (loss)                     | 14,025        | 1,919    | (7,904)   | (10,243)  |
| Net income (loss) per common share:   |               |          |           |           |
| Basic and diluted *                   | \$ 0.15       | \$ 0.02  | \$ (0.07) | \$ (0.09) |

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

For the quarters ended March 31, 2005 and June 30, 2005, the Company reported income of \$14.0 million or \$0.15 per share and \$1.9 million or \$0.02 per share, respectively. The Aventis notice of termination, resulted in the acceleration of the recognition of previously deferred revenue over a six-month period beginning November 9, 2004. As a result, revenue and income recognized in the quarter ended March 31, 2005 and June 30, 2005 increased \$17.1 million and \$6.5 million, respectively, over their prior-year comparison periods.

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

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

**19. Subsequent Event**

On March 6, 2006, the Company executed definitive agreements with institutional investors to sell 19 million shares of the Company's common stock at a price of \$2.15 per share, raising approximately \$37.8 million, net of estimated fees and expenses.

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

None.

**Item 9A. Controls and Procedures**

**Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures**

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

**Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control - Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2005. Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included herein.

**Changes in Internal Control Over Financial Reporting**

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

---

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
Genta Incorporated:

We have audited management's assessment, included in Item 9A Controls and Procedures Management's Report on Internal Control Over Financial Reporting, that Genta Incorporated and subsidiaries (the Company) maintained effective internal control over financial reporting as of December 31, 2005 based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2005 of the Company and our report dated March 10, 2006 expressed an unqualified opinion on those financial statements and included an explanatory paragraph relating to the Company's ability to continue as a going concern.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey  
March 10, 2006

**Item 9B. Other Information**

On March 6, 2006, the Company entered into definitive subscription agreements (the *Subscription Agreements*) with certain institutional investors pursuant to which the Company agreed to issue and sell an aggregate of 19,000,000 shares of its common stock at \$2.15 per share, through a registered direct offering, for aggregate gross proceeds of approximately \$40,850,000, before deducting estimated fees and expenses associated with the offering (the *Offering*). In conjunction with such *Subscription Agreements*, on March 10, 2006, the Company entered into a Confirmation to Purchase (the *Confirmation*) with those certain institutional investors, whereby such investors acknowledged the opportunity to review the Company's Annual Report on Form 10-K and indicated their willingness to proceed with the *Offering*, which was scheduled to close on or about Friday, March 10, 2006 and is currently anticipated to close on or about Monday, March 13, 2006.

On March 6, 2006, in connection with the *Offering*, the Company executed a placement agent agreement (the *Placement Agent Agreement*) by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC. In conjunction with the *Placement Agent Agreement*, on March 10, 2006, the Company entered into an amendment to the *Placement Agent Agreement* (the *Amendment*) whereby the parties agreed to postpone the closing of the *Offering* until Monday, March 13, 2006, subject to the satisfaction of certain customary closing conditions.

**PART III**

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

The information required in this item is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 2006 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, 2006 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, 2006 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, 2006 pursuant to Regulation 14A.

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

The information required in this item is incorporated by reference from the Company's definitive proxy statement to be filed not later than April 30, 2006 pursuant to Regulation 14A.

## PART IV

## Item 15. Exhibits and Financial Statement Schedules.

| Exhibit<br>Number | Description of Document  |
|-------------------|--|
| 1.1               | Engagement Letter, dated December 6, 2004 between the Company and Rodman & Renshaw, LLC (incorporated by reference to the Company's Current Report on 8-K filed December 16, 2004, Commission File No. 0-19635)  |
| 3.1.a             | Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1995, Commission File No. 0-19635)   |
| 3.1.b             | Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i) to the Company's Current Report on Form 8-K filed on February 28, 1997, Commission File No. 0-19635)                             |
| 3.1.c             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)                   |
| 3.1.d             | Amended Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)         |
| 3.1.e             | Certificate of Increase of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).5 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)                     |
| 3.1.f             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)                   |
| 3.1.g             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)                   |
| 3.1.h             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).8 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)                   |
| 3.1.i             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.i to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)  |
| 3.1.j             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.j to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)  |
| 3.1.k             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.k to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, Commission File No. 0-19635)                  |
| 3.1.l             | Certificated of Designation of Series G Participating Cumulative Preferred Stock of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on September 21, 2005, Commission File No. 0-19635)                |
| 3.2               | Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, Commission File No. 0-19635)  |
| 4.1               | Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)   |
| 4.2               | Rights Agreement, dated September 20, 2005, between the Company and Mellion Investor Services LLC, as Rights Agent (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on September 21, 2005, Commission No. 01-19635) |
| 10.1              | Amended and Restated 1991 Stock Plan of Genta Incorporated (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8, Reg. No. 333-101022)  |
| 10.2              | Non-Employee Directors' 1998 Stock Option Plan, as amended and restated (incorporated by reference to Exhibit 99.B to the Company's Definitive Proxy Statement on Schedule 14A filed on April 30, 2004, Commission File No. 0-19635)                           |

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

- 10.3 1998 Stock Incentive Plan, as amended and restated, effective March 19, 2004 (incorporated by reference to Exhibit 99.A to the Company's Definitive Proxy Statement on Schedule 14A filed on April 30, 2004, Commission File No. 0-19635)
- 10.4 Form of Indemnification Agreement entered into between the Company and its directors and officers (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1, Commission File No. 0-19635)

| Exhibit Number | Description of Document   |
|----------------|---|
| 10.5*          | Development, License and Supply Agreement dated February 2, 1989 between the Company and Gen-Probe Incorporated (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1, Commission File No. 0-19635)   |
| 10.6           | Asset Purchase Agreement, dated as of March 19, 1999, among JBL Acquisition Corp., JBL Scientific Incorporated and the Company (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report filed on Form 10-Q for the quarter ended March 31, 1999, Commission File No. 0-19635)   |
| 10.7           | Warrant Agreement, dated as of December 23, 1999, among the Company, ChaseMellon Shareholder Services, L.L.C., as warrant agent, and Paramount Capital, Inc. (incorporated by reference to Exhibit 10.67 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)   |
| 10.8           | Employment Letter Agreement, dated as of October 28, 1999, from the Company to Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.70 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)   |
| 10.9           | Stock Option Agreement, dated as of October 28, 1999, between the Company and Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.71 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)  |
| 10.10          | Letter Agreement, dated March 4, 1999, from SkyePharma Plc to the Company (incorporated by reference to Exhibit 10.72 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)  |
| 10.11          | Subscription Agreement executed in connection with the November 26, 2001 sale of common stock to Franklin Small-Mid Cap Growth Fund, Franklin Biotechnology Discovery Fund, and SF Capital Partners Ltd., and the November 30, 2001 sale of common stock to SF Capital Partners Ltd. (incorporated by reference to Exhibit 10.73 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635) |
| 10.12          | Employment Letter Agreement, dated as of March 27, 2001, from the Company to Loretta M. Itri, M.D. (incorporated by reference to Exhibit 10.74 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)   |
| 10.13          | Agreement of Lease dated June 28, 2000 between The Connell Company and the Company (incorporated by reference to Exhibit 10.76 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)   |
| 10.13A         | Amendment of Lease, dated June 19, 2002 between The Connell Company and the Company (incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)  |
| 10.14          | Agreement of Sublease dated August 13, 2001 between Expanets, Inc. and the Company (incorporated by reference to Exhibit 10.77 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)   |
| 10.15*         | U.S. Commercialization Agreement dated April 26, 2002, by and between Genta Incorporated and Aventis Pharmaceuticals Inc.   |
| 10.15A*        | Amendment No. 1 dated March 14, 2003 to the U.S. Commercialization Agreement between Genta Incorporated and Aventis Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2003).   |
| 10.16*         | Ex-U.S. Commercialization Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited  |
| 10.17*         | Global Supply Agreement, dated April 26, 2002, by and among Genta Incorporated, Aventis Pharmaceuticals Inc. and Garliston Limited (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)  |
| 10.18*         | Securities Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)  |
| 10.19          | Standstill and Voting Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)  |



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

| Exhibit Number | Description of Document   |
|----------------|---|
| 10.20          | Registration Rights Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)                    |
| 10.21          | Convertible Note Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)              |
| 10.22*         | 5.63% Convertible Promissory Note, due April 26, 2009 (incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)   |
| 10.23*         | Subordination Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)                          |
| 10.24*         | Manufacture and Supply Agreement, dated December 20, 2002, between Genta Incorporated and Avecia Biotechnology Inc. (incorporated by reference to Exhibit 10.88 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, Commission File No. 0-19635)              |
| 10.25          | Employment Agreement, dated as of December 1, 2002, between the Company and Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.89 to the Company's Annual Report on Form 10-K/A for the year ended December 31, 2001, Commission File No. 0-19635)                      |
| 10.26          | Employment Agreement, dated as of August 5, 2003, between the Company and Loretta M. Itri, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, Commission File No. 0-19635)                                 |
| 10.27*         | License Agreement dated August 1, 1991, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)                        |
| 10.27A*        | Amendment to License Agreement, dated December 19, 2000, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)       |
| 10.27AA*       | Second Amendment to License Agreement, dated October 22, 2003, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635) |
| 10.28          | Settlement Agreement and Release, dated October 22, 2003, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.4 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)      |
| 10.29          | Securities Purchase Agreement, dated December 14, 2004, among the Company, Riverview Group, LLC and Smithfield Fiduciary LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 16, 2004, Commission File No. 0-19635)                |
| 10.30          | Form of Subscription Agreement, dated August 5, 2005 among the Company and the purchasers of the Shares (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 8, 2005, Commission File No. 0-19635)  |
| 10.31          | Placement Agency Agreement, dated August 5, 2005 between the Company and Piper Jaffray & Co. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 8, 2005, Commission File No. 0-19635)   |
| 10.32          | Form of Subscription Agreement, dated March 6, 2006 by and among the Company and the Purchasers (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 7, 2006, Commission File No. 0-19635)   |
| 10.33          | Form of Placement Agent Agreement, dated March 6, 2006 by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 7, 2006, Commission File No. 0-19635)                     |
| 10.34          | Form of Confirmation of Purchase, dated March 10, 2006 by and between the Company and certain Investors   |
| 10.35          | Form of Amendment No.1 to Placement Agent Agreement, dated March 10, 2006 by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC  |

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

|      |   |
|------|---|
| 21   | Subsidiaries of the Registrant  |
| 23.1 | Consent of Deloitte & Touche LLP  |
| 31.1 | Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002  |
| 31.2 | Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002  |
| 32.1 | Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2 | Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |

---

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

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 10th day of March 2006.

Genta Incorporated

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

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

| <u>Signature</u>  | <u>Capacity</u>   | <u>Date</u>    |
|---|---|----------------|
| <u>/s/ RAYMOND P. WARRELL, JR., M.D.</u><br>Raymond P. Warrell, Jr., M.D. | Chairman and Chief Executive Officer<br>and Director (principal executive officer)  | March 10, 2006 |
| <u>/s/ RICHARD J. MORAN</u><br>Richard J. Moran                           | Senior Vice President, Chief Financial<br>Officer and Corporate Secretary<br>(principal financial and accounting officer) | March 10, 2006 |
| <u>/s/ MARTIN J. DRISCOLL</u><br>Martin J. Driscoll                       | Director  | March 10, 2006 |
| <u>/s/ JEROME E. GROOPMAN, M.D.</u><br>Jerome E. Groopman, M.D.           | Director  | March 10, 2006 |
| <u>/s/ BETSY MCCAUGHEY</u><br>Betsy McCaughey, Ph.D.                      | Director  | March 10, 2006 |
| <u>/s/ CHRISTOPHER P. PARIOS</u><br>Christopher P. Parios                 | Director  | March 10, 2006 |
| <u>/s/ DANIEL D. VON HOFF, M.D.</u><br>Daniel D. Von Hoff, M.D.           | Director  | March 10, 2006 |
| <u>/s/ HARLAN J. WAKOFF</u><br>Harlan J. Wakoff                           | Director  | March 10, 2006 |
| <u>/s/ DOUGLAS G. WATSON</u><br>Douglas G. Watson                         | Director  | March 10, 2006 |

| Exhibit<br>Number | Description of Document  | Sequentially<br>Numbered<br>Pages |
|-------------------|--|-----------------------------------|
| 1.1               | Engagement Letter, dated December 6, 2004 between the Company and Rodman & Renshaw, LLC (incorporated by reference to the Company's Current Report on 8-K filed December 16, 2004, Commission File No. 0-19635)  |                                   |
| 3.1.a             | Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1995, Commission File No. 0-19635)   |                                   |
| 3.1.b             | Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i) to the Company's Current Report on Form 8-K filed on February 28, 1997, Commission File No. 0-19635)                             |                                   |
| 3.1.c             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)                   |                                   |
| 3.1.d             | Amended Certificate of Designations of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)         |                                   |
| 3.1.e             | Certificate of Increase of Series D Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 3(i).5 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)                     |                                   |
| 3.1.f             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).4 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)                   |                                   |
| 3.1.g             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).3 to the Company's Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-19635)                   |                                   |
| 3.1.h             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3(i).8 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)                   |                                   |
| 3.1.i             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.i to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)  |                                   |
| 3.1.j             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.j to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)  |                                   |
| 3.1.k             | Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1.k to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, Commission File No. 0-19635)                  |                                   |
| 3.1.l             | Certificated of Designation of Series G Participating Cumulative Preferred Stock of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on September 21, 2005, Commission File No. 0-19635)                |                                   |
| 3.2               | Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, Commission File No. 0-19635)  |                                   |
| 4.1               | Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1, Commission File No. 333-110238)   |                                   |
| 4.2               | Rights Agreement, dated September 20, 2005, between the Company and Mellion Investor Services LLC, as Rights Agent (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on September 21, 2005, Commission No. 01-19635) |                                   |
| 10.1              |  |                                   |

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

Amended and Restated 1991 Stock Plan of Genta Incorporated (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8, Reg. No. 333-101022)

10.2

Non-Employee Directors' 1998 Stock Option Plan, as amended and restated (incorporated by reference to Exhibit 99.B to the Company's Definitive Proxy Statement on Schedule 14A filed on April 30, 2004, Commission File No. 0-19635)

71

| Exhibit<br>Number | Description of Document   | Sequentially<br>Numbered<br>Pages |
|-------------------|---|-----------------------------------|
| 10.3              | 1998 Stock Incentive Plan, as amended and restated, effective March 19, 2004 (incorporated by reference to Exhibit 99.A to the Company's Definitive Proxy Statement on Schedule 14A filed on April 30, 2004, Commission File No. 0-19635)   |                                   |
| 10.4              | Form of Indemnification Agreement entered into between the Company and its directors and officers (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1, Commission File No. 0-19635)  |                                   |
| 10.5*             | Development, License and Supply Agreement dated February 2, 1989 between the Company and Gen-Probe Incorporated (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1, Commission File No. 0-19635)   |                                   |
| 10.6              | Asset Purchase Agreement, dated as of March 19, 1999, among JBL Acquisition Corp., JBL Scientific Incorporated and the Company (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report filed on Form 10-Q for the quarter ended March 31, 1999, Commission File No. 0-19635)   |                                   |
| 10.7              | Warrant Agreement, dated as of December 23, 1999, among the Company, ChaseMellon Shareholder Services, L.L.C., as warrant agent, and Paramount Capital, Inc. (incorporated by reference to Exhibit 10.67 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)   |                                   |
| 10.8              | Employment Letter Agreement, dated as of October 28, 1999, from the Company to Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.70 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)   |                                   |
| 10.9              | Stock Option Agreement, dated as of October 28, 1999, between the Company and Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.71 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)  |                                   |
| 10.10             | Letter Agreement, dated March 4, 1999, from SkyePharma Plc to the Company (incorporated by reference to Exhibit 10.72 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-19635)  |                                   |
| 10.11             | Subscription Agreement executed in connection with the November 26, 2001 sale of common stock to Franklin Small-Mid Cap Growth Fund, Franklin Biotechnology Discovery Fund, and SF Capital Partners Ltd., and the November 30, 2001 sale of common stock to SF Capital Partners Ltd. (incorporated by reference to Exhibit 10.73 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635) |                                   |
| 10.12             | Employment Letter Agreement, dated as of March 27, 2001, from the Company to Loretta M. Itri, M.D. (incorporated by reference to Exhibit 10.74 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)   |                                   |
| 10.13             | Agreement of Lease dated June 28, 2000 between The Connell Company and the Company (incorporated by reference to Exhibit 10.76 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)   |                                   |
| 10.13A            | Amendment of Lease, dated June 19, 2002 between The Connell Company and the Company (incorporated by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)  |                                   |

| Exhibit<br>Number | Description of Document  | Sequentially<br>Numbered<br>Pages |
|-------------------|--|-----------------------------------|
| 10.14             | Agreement of Sublease dated August 13, 2001 between Expanets, Inc. and the Company (incorporated by reference to Exhibit 10.77 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001, Commission File No. 0-19635)  |                                   |
| 10.15*            | U.S. Commercialization Agreement dated April 26, 2002, by and between Genta Incorporated and Aventis Pharmaceuticals Inc.  |                                   |
| 10.15A*           | Amendment No. 1 dated March 14, 2003 to the U.S. Commercialization Agreement between Genta Incorporated and Aventis Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2003).                      |                                   |
| 10.16*            | Ex-U.S. Commercialization Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)                 |                                   |
| 10.17*            | Global Supply Agreement, dated April 26, 2002, by and among Genta Incorporated, Aventis Pharmaceuticals Inc. and Garliston Limited (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635) |                                   |
| 10.18*            | Securities Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)                       |                                   |
| 10.19             | Standstill and Voting Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)                     |                                   |
| 10.20             | Registration Rights Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)                       |                                   |
| 10.21             | Convertible Note Purchase Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)                 |                                   |
| 10.22*            | 5.63% Convertible Promissory Note, due April 26, 2009 (incorporated by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)  |                                   |
| 10.23*            | Subordination Agreement, dated April 26, 2002, by and between Genta Incorporated and Garliston Limited (incorporated by reference to Exhibit 10.9 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, Commission File No. 0-19635)                             |                                   |
| 10.24*            | Manufacture and Supply Agreement, dated December 20, 2002, between Genta Incorporated and Avecia Biotechnology Inc. (incorporated by reference to Exhibit 10.88 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002, Commission File No. 0-19635)                 |                                   |
| 10.25             | Employment Agreement, dated as of December 1, 2002, between the Company and Raymond P. Warrell, Jr., M.D. (incorporated by reference to Exhibit 10.89 to the Company's Annual Report on Form 10-K/A for the year ended December 31, 2001, Commission File No. 0-19635)                         |                                   |
| 10.26             | Employment Agreement, dated as of August 5, 2003, between the Company and Loretta M. Itri, M.D. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, Commission File No. 0-19635)                                    |                                   |

| Exhibit<br>Number | Description of Document   | Sequentially<br>Numbered<br>Pages |
|-------------------|---|-----------------------------------|
| 10.27*            | License Agreement dated August 1, 1991, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)                        |                                   |
| 10.27A*           | Amendment to License Agreement, dated December 19, 2000, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)       |                                   |
| 10.27AA*          | Second Amendment to License Agreement, dated October 22, 2003, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635) |                                   |
| 10.28             | Settlement Agreement and Release, dated October 22, 2003, between Genta Incorporated and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 99.4 to the Company's Current Report on Form 8-K filed on October 28, 2003, Commission File No. 0-19635)      |                                   |
| 10.29             | Securities Purchase Agreement, dated December 14, 2004, among the Company, Riverview Group, LLC and Smithfield Fiduciary LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 16, 2004, Commission File No. 0-19635)                |                                   |
| 10.30             | Form of Subscription Agreement, dated August 5, 2005 among the Company and the purchasers of the Shares (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 8, 2005, Commission File No. 0-19635)  |                                   |
| 10.31             | Placement Agency Agreement, dated August 5, 2005 between the Company and Piper Jaffray & Co. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 8, 2005, Commission File No. 0-19635)   |                                   |
| 10.32             | Form of Subscription Agreement, dated March 6, 2006 by and among the Company and the Purchasers (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 7, 2006, Commission File No. 0-19635)   |                                   |
| 10.33             | Form of Placement Agent Agreement, dated March 6, 2006 by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 7, 2006, Commission File No. 0-19635)                     |                                   |
| 10.34             | Form of Confirmation of Purchase, dated March 10, 2006 by and between the Company and certain Investors   |                                   |
| 10.35             | Form of Amendment No. 1 to Placement Agent Agreement, dated March 10, 2006 by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC   |                                   |
| 21                | Subsidiaries of the Registrant  |                                   |
| 23.1              | Consent of Deloitte & Touche LLP  |                                   |
| 31.1              | Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002  |                                   |
| 31.2              | Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002  |                                   |
| 32.1              | Certification by Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002   |                                   |
| 32.2              | Certification by Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002   |                                   |