

GENTA INC DE/  
Form 10-K  
March 17, 2008

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

**x**

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

**For the Fiscal Year Ended December 31, 2007**

**OR**

**o**

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

**Commission File Number 000-19635**

**GENTA INCORPORATED**

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

**Delaware**

**33-0326866**

(State or other jurisdiction of  
incorporation or organization)

(IRS Employer  
Identification Number)

**200 Connell Drive  
Berkeley Heights, New Jersey**

**07922**

(Address of principal executive offices)

(Zip Code)

**(908) 286-9800**

(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:**

**Title of each class:**

**Name of each exchange on which registered:**

**Common Stock, \$.001 par value**

**NASDAQ Stock Market, LLC**

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

**Securities registered pursuant to Section 12(g) of the Act:**

**NONE**

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

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  No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The approximate aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was \$53,279,771 as of June 30, 2007 (the last business day of the registrant's most recently completed second fiscal quarter).

As of March 7, 2008, the registrant had 36,740,558 shares of Common Stock outstanding.

**Genta Incorporated**

**Table of Contents**

**Part I**

Item 1.

Business

4

Item 1A.

Risk Factors

15

Item 1B.

Unresolved Staff Comments

29

Item 2.

Properties

29

Item 3.

Legal Proceedings

29

Item 4.

Submission of Matters to a Vote of Security Holders

30

**Part II**

Item 5.

Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

31

Item 6.

Selected Consolidated Financial Data

33

Item 7.

Management's Discussion and Analysis of Financial Condition and Results of Operations

34

Item 7A.

Quantitative and Qualitative Disclosure about Market Risk

43

Item 8.

Financial Statements and Supplementary Data

44

Item 9.

Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

70

Item 9A.

Controls and Procedures

70

Item 9B.

Other Information

72

**Part III**

Item 10.

Directors and Executive Officers of the Registrant and Corporate Governance

72

Item 11.

Executive Compensation

72

Item 12.

Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

72

Item 13.

Certain Relationships and Related Transactions and Director Independence

72

Item 14.

Principal Accounting Fees and Services

72

**Part IV**

Item 15.

Exhibits and Financial Statement Schedules

73

Signatures

77

Certifications





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. We intend 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 our 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:

our financial projections;

our projected cash flow requirements and estimated timing of sufficient cash flow;

our current and future license agreements, collaboration agreements, and other strategic alliances;

our ability to obtain necessary regulatory approval for Genasense® from the U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA);

the safety and efficacy of our products;

the commencement and completion of clinical trials;

our ability to develop, manufacture and sell our products;

the adequacy of our capital resources and our ability to obtain sufficient financing to maintain our planned operations;

the adequacy of our patents and proprietary rights;

the impact of litigation that has been brought against us and our officers and directors and any proposed settlement of such litigation;

our ability to regain compliance with NASDAQ's listing qualifications; and

the other risks described under Certain Risks and Uncertainties Related to the Company's Business.

We do 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 our 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 also referred to herein as us , we , our , Genta or the Company , was incorporated in Delaware February 4, 1988. Genta is a biopharmaceutical company engaged in pharmaceutical (drug) research and development, its sole reportable segment. We are dedicated to the identification, development and commercialization of novel drugs for the treatment of cancer and related diseases. Our 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. These technologies include antisense, decoys, and small interfering or micro RNAs. Our 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 anticancer treatments, such as chemotherapy, radiation, and monoclonal antibodies. While Genasense® has displayed some anticancer activity when used by itself, we are 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. We have reported results from randomized Phase 3 trials of Genasense® in seven different diseases: melanoma; chronic lymphocytic leukemia (CLL); multiple myeloma; acute myeloid leukemia (AML); non small cell lung cancer; small cell lung cancer; and prostate cancer. Under our own sponsorship or in collaboration with the U.S. National Cancer Institute (NCI), we are currently conducting additional clinical trials.

In 2003, we submitted a New Drug Application (NDA) to the FDA for the use of Genasense® plus chemotherapy in patients with advanced melanoma. In May 2004, a majority of the Oncologic Drugs Advisory Committee (ODAC) failed to recommend approval of our NDA. As a consequence, we withdrew the NDA, which allows us to potentially resubmit the application. In October 2006, data from this trial was published in a peer-reviewed journal, which reported statistically significant increases in overall response, complete response, durable response and progression-free survival (PFS). An independent review of the X-rays confirmed the major responses with high concordance. An increase in overall survival by intent-to-treat analysis, which was the study's primary endpoint, approached but did not reach statistical significance (P=0.077). Our analysis identified a statistically significant treatment interaction for blood levels of an enzyme known as LDH, which was a prospectively specified component of stratification. When this effect was analyzed by treatment arm, survival was shown to be significantly superior for patients with a non-elevated LDH who received Genasense® (P=0.018; n=508).

In January 2006, we completed a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA), which sought approval for use of Genasense® plus dacarbazine for the treatment of patients with advanced melanoma who had not previously received chemotherapy. In April 2007, we were informed that the Committee for Medicinal Products for Human Use (CHMP) of the EMA had issued a negative opinion on the MAA and we indicated that we would seek re-examination of the MAA by a Scientific Advisory Group. In July 2007, we received notice from the EMA that the requested re-examination reaffirmed the negative opinion for approval of our MAA for Genasense®. We contemplate no further action on the MAA.

In 2007, we filed a complaint and request for correction of information with the FDA under the Federal Data Quality Act. The complaint challenged a key statistical analysis of our data regarding PFS that was used by the FDA at the

ODAC meeting in May 2004. At that meeting, ODAC voted unanimously that PFS was an endpoint that would support full approval in the absence of a survival improvement in patients with advanced melanoma. In February 2008, the FDA informed us that they did not agree with our opinion that their assessment was flawed. We have not yet decided whether to pursue this matter further with the FDA.



In August 2007, we announced that the first patients had been enrolled in a confirmatory Phase 3 trial of Genasense® plus chemotherapy in advanced melanoma. The trial, known as AGENDA, is a randomized, double-blind, placebo-controlled study in which patients are randomly assigned to receive Genasense® plus dacarbazine (DTIC) or DTIC alone. The study targets patients using LDH as a biomarker to identify patients who may be most likely to respond based on data obtained from our preceding trial in melanoma. We expect that AGENDA will accrue approximately 300 patients and will be conducted at 75 to 100 sites worldwide. Accrual is expected to take approximately 18 months, with initial data on PFS expected shortly thereafter.

In CLL, we conducted a randomized Phase 3 trial in 241 patients with relapsed or refractory disease who were treated with fludarabine and cyclophosphamide (Flu/Cy) with or without Genasense®. The trial achieved its primary endpoint: a statistically significant increase (17% vs. 7%;  $P=0.025$ ) in the proportion of patients who achieved a complete response (CR), defined as a complete or nodular partial response. Patients who achieved this level of response experienced disappearance of predefined disease symptoms, including fever, night sweats, fatigue, abdominal discomfort due to an enlarged spleen and impaired mobility due to swollen lymph nodes. A key secondary endpoint, duration of CR, was also significantly longer for patients treated with Genasense® (median not reached but exceeding 36+ months in the Genasense® group, versus 22 months in the chemotherapy-only group).

Several secondary endpoints were not improved by the addition of Genasense®, including overall response rate (i.e., the percentage of patients who achieved CR plus partial response), time-to-disease progression, or overall survival. Adverse events (irrespective of relation to study drugs) during treatment or within 30 days from last dose of treatment that resulted in death occurred in 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®.

In December 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 had previously received fludarabine.

In September 2006, an ODAC meeting voted not to recommend approval of Genasense® in CLL and in December 2006, we received a non-approvable notice from the FDA. We believe that our application met the regulatory requirements for approval and in April 2007, we filed an appeal of this non-approvable notice pursuant to the FDA's Formal Dispute Resolution process that exists within the FDA's Center for Drug Evaluation and Research (CDER). In June 2007, we announced that the initial appeal was denied and that we would further appeal the decision to the next level within CDER. On October 25, 2007, we announced that we had completed the filing of our next-level appeal to CDER. On March 17, 2008, we announced that CDER decided that available data are not adequate to support approval of Genasense® for treatment of patients with CLL. CDER acknowledged that complete response, which was the primary endpoint in the pivotal trial, was an appropriate endpoint for assessing efficacy. FDA also agreed that this endpoint was achieved, and that those results supported the efficacy of the drug. However, CDER concluded that at present there was insufficient confirmatory evidence in the NDA to approve the drug. CDER recommended two alternatives for exploring the efficacy of Genasense® that could provide such confirmatory evidence. One option is to conduct an additional clinical trial. The other option is to collect additional information regarding the clinical course and progression of disease in patients from the previous pivotal trial in order to ascertain whether those data contain sufficient confirmatory evidence. We currently plan to pursue both of these options.

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. In December 2006, we were notified that preliminary analysis from a randomized Phase 3 trial of chemotherapy with or without Genasense® in patients with AML suggested the study was

unlikely to meet its primary endpoint. In February 2007, we announced that preliminary results from a randomized Phase 2 study of Genasense® plus chemotherapy in patients with advanced prostate cancer showed no between-group difference in prostate-specific antigen. While follow-up and analyses of the AML and prostate trials are continuing, we do not believe any of these trials will support regulatory approval of Genasense® in these indications. Similarly negative results were reported in 2007 from randomized Phase 2 trials that were conducted in patients with advanced non small cell lung cancer and also in patients with small cell lung cancer.



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, we markedly reduced spending on the development, sale and marketing of Ganite®, which has resulted in significantly lower sales of Ganite®. In addition, key patents related to the approved use of Ganite® have now expired. We do not currently plan to invest substantial additional funds into the commercialization of Ganite® in the U.S.

We have also been engaged in developing new formulations of gallium-containing compounds that may be orally absorbed. In collaboration with Emisphere Technologies, Inc., we have developed a novel oral formulation of a gallium-containing compound. In the third quarter of 2007, we filed an Investigational New Drug (IND) Exemption with the FDA, and we have completed a single-dose Phase 1 study of this new compound (now known as G4544). The results of this study will be presented at a scientific meeting in the second quarter of 2008. We plan to file new data with the FDA and then to meet with the FDA to discuss the regulatory strategy for approval of G4544 in the U.S. in the second quarter of 2008. We currently intend that G4544 would be approved for cancer-related hypercalcemia, but we also believe that this drug may be useful for treatment of other diseases associated with accelerated bone loss, such as bone metastases, Paget's disease and osteoporosis. We intend to seek a co-development and commercialization partner for G4544.

On March 7, 2008, we entered into a License Agreement (the Agreement) with Daiichi Sankyo Company, Limited, a Japanese corporation based in Tokyo, Japan, whereby we obtained the exclusive license for tasetaxel. Tasetaxel has been placed on clinical hold by the FDA. We plan to develop and implement a response to the FDA that may lift the clinical hold and enable clinical testing to resume. However, there is no guarantee that the FDA will accept this plan, and thus no assurance can be provided that the clinical tests that would be required to secure regulatory approval for marketing can be undertaken.

Pursuant to the agreement, we will pay Daiichi Sankyo \$250,000 within 30 days from signing the agreement. We will also pay four equal installments of \$562,000 per quarter beginning at the end of the second quarter 2008, and also at the end of each subsequent calendar quarter, until the end of the first quarter 2009, for a total of \$2.25 million. The agreement also provides for payments by us upon achievement of certain clinical and regulatory milestones and royalties on net product sales. We will purchase Daiichi's current inventory of tasetaxel and will be responsible for all future development, commercialization, and manufacturing of the drug.

We maintain an active Business Development program and are seeking to acquire additional drugs in these two programs, and possibly other areas, that will enhance the value of our pipeline to our 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 eventually, 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. 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, we are 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 2,000 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 results of most of these trials have been publicly presented at scientific meetings and published in peer-reviewed scientific journals.

8

---



In 2007, the results of several randomized trials of Genasense were presented at scientific meetings. In the first quarter of 2007, we announced preliminary results from a study sponsored by the European Organization for the Research and Treatment of Cancer (EORTC) in 118 patients with hormone-refractory prostate cancer who had not previously received chemotherapy. In this study, patients received standard chemotherapy with docetaxel and were randomly assigned to receive Genasense® or no other treatment. The primary endpoint of this study was to compare response rates, as measured by a decrease of prostate specific antigen (PSA). The preliminary analysis conducted by the EORTC showed that the trial was unlikely to meet its primary endpoint. In the second quarter of 2007, results of a randomized trial sponsored by a large U.S. cooperative oncology group, the Cancer and Leukemia Group B (CALGB), were reported for patients with previously untreated acute myelocytic leukemia. In this trial, 503 patients received standard chemotherapy with daunorubicin and cytosine arabinoside and were randomly assigned to receive Genasense® or no additional therapy. Results of this trial showed no significant difference in overall survival or in the incidence of complete remission. In the third quarter of 2007, results from a randomized Phase 2 trial of Genasense® plus docetaxel in 298 patients with non-small cell lung cancer failed to show that Genasense® increased overall survival, which was the primary endpoint of the trial. In 2007, the CALGB submitted for publication the results of a randomized Phase 2 trial of Genasense® in patients with extensive small cell lung cancer 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 results from this trial indicated that the addition of Genasense® did not increase survival at 12 months.

Based on work accomplished to date, we have focused on three indications for Genasense®: melanoma; CLL; and non-Hodgkin's lymphoma. In addition, we have sought to develop treatment methods for Genasense® that do not involve the use of continuous intravenous (IV) infusions.

In August 2007, we announced that the first patients had been enrolled in a confirmatory Phase 3 trial of Genasense® plus chemotherapy in advanced melanoma. The trial, known as AGENDA, is a randomized, double-blind, placebo-controlled study in which patients are randomly assigned to receive Genasense® plus dacarbazine (DTIC) or DTIC alone. The study targets patients using LDH as a biomarker to identify patients who may be most likely to respond, based on data obtained from our preceding trial in melanoma. We expect that AGENDA will accrue approximately 300 patients and will be conducted at 75 to 100 sites worldwide. Accrual is expected to take approximately 18 months, with initial data on PFS expected shortly thereafter. In the fourth quarter of 2007, we reported initial results from a non-randomized trial using Genasense® combined with temozolomide (Temodar®) plus Abraxane® (albumen bound paclitaxel).

While our appeal in CLL has been pending with FDA, we have deferred making a decision on the conduct of future trials in this indication. Finally, although several non-randomized trials have shown activity of Genasense® in patients with advanced non-Hodgkin's lymphoma, we have not initiated any registration-quality trials in this indication due to funding constraints.

In the first quarter of 2007, we completed a trial using a concentrated solution of Genasense® administered by bolus subcutaneous (SC) injection. This trial showed that a total dose of 225 mg could be administered as a single SC injection, which is approximately equivalent to the daily dose used in the Phase 3 trial of Genasense® in CLL. The limiting reaction in this study was a localized and reversible skin rash. In 2007, we began a new Phase 1 trial of Genasense® administered as an IV infusion over 2 hours. This trial showed that the maximally tolerable dose was 900 mg, and we have now advanced that study into a trial at that dose administered twice per week. We have also continued to escalate the single dose of Genasense® up to a total of 1200 mg over 2 hours preceded by a dose of corticosteroids, which appears to ameliorate early infusion reactions. The maximally tolerable dose of Genasense® with corticosteroids has not yet been established in this ongoing study. We are collecting pharmacokinetic and pharmacodynamic data from these trials in an effort to evaluate whether the prior requirement for treatment by

continuous IV infusion can ultimately be eliminated by these more convenient dosing regimens.

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, we eliminated our sales force and significantly reduced our marketing support for Ganite®. Since then, we have continued only minimal marketing support of the product. On March 2, 2006, we announced publication of a randomized, double blind, Phase 2 trial that showed Ganite® was highly effective when compared with Aredia® (pamidronate disodium; Novartis, Inc.) in hospitalized patients with cancer-related hypercalcemia.

### ***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. We do not plan further investments in clinical trials for Ganite® as an anticancer drug, beyond provision of the drug free of charge to investigators.

## **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. On March 23, 2006, Genta and Emisphere Technologies, Inc. (Emisphere) announced that the two companies had entered into an exclusive worldwide licensing agreement to develop an oral

formulation of a gallium-containing compound. A number of candidate formulations have been developed in this collaboration. On August 1, 2007, we announced that, together with Emisphere we submitted an Investigational New Drug Application (IND) to the Endocrinologic and Metabolic Drugs Division of the FDA for a new drug known as G4544. G4544 is a new tablet formulation that enables oral absorption of the active ingredient contained in Ganite®. The IND was allowed by the FDA in September 2007 and initial dosing of normal volunteers with G4544 began in the third quarter of 2007. The results of this trial will be presented at a scientific meeting in the second quarter of 2008. We believe that G4544 may be useful for treatment of many diseases that are associated with accelerated bone loss, including hypercalcemia, bone metastases, Paget's disease and osteoporosis.



## **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.

In December 2000, Genta licensed patents and technology from the National Institutes of Health (NIH) relating to decoys that target a transcription factor known as the cyclic adenosine monophosphate response element binding protein, or CRE-BP. Due to financial constraints, we have terminated all further work on this compound and canceled the NIH license.

## ***c-myb* Antisense**

On October 13, 2006, we announced the initiation of a Phase I clinical trial using a new anticancer drug derived from our DNA/RNA Medicines program. The new compound (G4460) uses antisense technology to target a proto-oncogene known as *c-myb* that regulates key functions in cancer cells. Using an accelerated dosing schedule, this study will evaluate dosing regimens, safety, biologic activity, and down-regulation of *c-myb* in patients with advanced hematologic cancers. The clinical trial is being conducted at the University of Pennsylvania. G4460 has been granted Orphan Drug Designation by the FDA for treatment of patients with chronic myelocytic leukemia (CML). This trial is being sponsored by the University of Pennsylvania, and we have no control over the design or pace of patient accrual into this trial.

## **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. We have no current agents that we consider lead compounds that would justify advancement 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 65 granted patents and 66 pending applications in the U.S. and foreign countries. We endeavor to seek appropriate U.S. and foreign patent protection on our oligonucleotide technology.

We have licensed ten U.S. patents relating to Genasense® and its backbone chemistry that expire between 2008 and 2015. Corresponding patent applications have been filed in three foreign countries. We also own five U.S. patent applications relating to methods of using Genasense® expected to expire in 2020 and 2026, with approximately 50 corresponding foreign patent applications and granted patents.

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 is issued, 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 19.

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 before reimbursement of \$13.5 million, \$28.1 million and \$20.9 million during the years ended December 31, 2007, 2006 and 2005, respectively.

12

---



## **Sales and Marketing**

Currently we do not have a sales force. Personnel who had been hired into our sales teams were terminated following workforce reductions that took place in 2004 and 2006, owing to adverse regulatory decisions. W. Lloyd Sanders, who is presently Senior Vice-President, Commercial Operations, was hired in January 2006 to run our sales and marketing programs.

At the present time, we do not contemplate rebuilding a sales and marketing infrastructure in the United States absent favorable regulatory actions on Genasense®. For international product sales, we may 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. We have a manufacturing and supply agreement with Avecia Biotechnology, Inc., or Avecia, a leading multinational manufacturer of pharmaceutical products, to supply quantities of Genasense®. This agreement renews automatically at the end of each year, unless either party gives one-year notice. 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 manufacturing and supply agreement with Johnson Matthey Inc. that renews automatically at the end of each year, unless either party gives one-year notice. Under the agreement, we will purchase a minimum of 80% of our requirements for quantities of Ganite®; however, there are no minimum purchase requirements.

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, 2007, we had 47 employees, 14 of whom hold doctoral degrees. As of that date, there were 28 employees engaged in research, development and other technical activities, 3 in sales and marketing and 16 in administration. None of our employees are represented by a union. Most of our management and professional employees have had prior experience and positions with pharmaceutical and biotechnology companies. We believe we maintain satisfactory relations with our employees and have not experienced interruptions of operations due to employee relations issues.

## **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 us, 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 us 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 10-K before deciding to invest in shares of our common stock. The risks described below are not the only ones facing us. 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.*

15

---



*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:

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

delays or refusals by regulatory authorities in granting marketing approvals;

our limited financial resources and sales and marketing experience relative to our competitors;

actual and perceived differences between our products and those of our competitors;

the availability and level of reimbursement for our products by third-party payors;

incidents of adverse reactions to our products;

side effects or misuse of our products and the unfavorable publicity that could result; and

the occurrence of manufacturing, supply or distribution disruptions.

We cannot assure you that Genasense® will receive FDA 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, in September 2006, an ODAC meeting voted not to recommend approval of Genasense® in CLL and in December 2006, we received a non-approvable notice from the FDA. We believe that our application met the regulatory requirements for approval and in April 2007, we filed a formal appeal of this non-approvable notice pursuant to the FDA's Formal Dispute Resolution process that exists within the FDA's Center for Drug Evaluation and Research (CDER). In June 2007, we announced that the initial appeal was denied and that we would further appeal the decision to the next level within CDER. On October 25, 2007, we announced that we had completed the filing of our next-level appeal to CDER. On March 17, 2008, we announced that CDER decided that available data are not adequate to support approval of Genasense® for treatment of patients with CLL. CDER acknowledged that complete response, which was the primary endpoint in the pivotal trial, was an appropriate endpoint for assessing efficacy. FDA also agreed that this endpoint was achieved, and that those results supported the efficacy of the drug. However, CDER concluded that at present there was insufficient confirmatory evidence in the NDA to approve the drug. CDER recommended two alternatives for exploring the efficacy of Genasense® that could provide such confirmatory evidence. One option is to conduct an additional clinical trial. The other option is to collect additional information regarding the clinical course and progression of disease in patients from the previous pivotal trial in order to ascertain whether those data contain sufficient confirmatory evidence. We currently plan to pursue both of these options.

In January 2006, we completed a MAA to the EMEA, which sought approval for use of Genasense® plus dacarbazine for the treatment of patients with advanced melanoma who had not previously received chemotherapy. In April 2007, we were informed that the Committee for Medicinal Products for Human Use (CHMP) of the EMEA had issued a negative opinion on the MAA and we indicated that we would seek re-examination of the MAA by a Scientific Advisory Group. In July 2007, we received notice from the EMEA that the requested re-examination reaffirmed the negative opinion for approval of our MAA for Genasense®. We contemplate no further action on the MAA.



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 and we may not be able 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, 2007 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.***

Our operations to date have required significant cash expenditures. 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, seek new product candidates and continue our research and development programs, we will need to raise additional funds. In March 2007, we sold 5.0 million shares of the Company's common stock at a price of \$2.16 per share, raising \$10.2 million, net of fees and expenses. Cash used in operating activities during 2007 was \$31.7 million and at December 31, 2007, we had cash, cash equivalents and marketable securities of \$7.8 million. In February 2008, we sold 6.1 million shares of our common stock at a price of \$0.50 per share, raising approximately \$3.1 million, net of estimated fees and expenses.

We will need to obtain more funding in the future through collaborations or other arrangements with research institutions and corporate partners or public and private offerings of our securities, including debt or equity financing. We may not be able to obtain adequate funds for our operations from these sources when needed or on acceptable terms. Future collaborations or similar arrangements may require us to license valuable intellectual property to, or to share substantial economic benefits with, our collaborators. If we raise additional capital by issuing additional equity or securities convertible into equity, our stockholders may experience dilution and our share price may decline. Any debt financing may result in restrictions on our spending.

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

delay, scale back or eliminate some or all of our research and product development programs;

license third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;

attempt to sell our company;

cease operations; or

declare bankruptcy.

17

---



We will maintain an appropriate level of spending over the upcoming fiscal year, given the uncertainties inherent in our business and our current liquidity position. Presently, with no further financing, we will run out of funds in the second quarter of 2008. We currently do not have any additional financing in place. If we are unable to raise additional financing, we could be required to reduce our spending plans, reduce our workforce, license to others products or technologies we would otherwise seek to commercialize ourselves and sell certain assets. There can be no assurance that we can obtain financing, if at all, on terms acceptable to us.

***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. In November 2004, we received from Aventis a notice of termination of the Collaborative Agreement. In May 2005, we announced that we and Aventis had signed an agreement to terminate our development and commercialization collaboration for Genasense®.

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, 2007, we have incurred a cumulative net deficit of \$438.3 million. We may never achieve revenue sufficient for us to attain profitability. Achieving profitability is unlikely unless Genasense® receives approval from the FDA or EMEA 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. If Genasense® is not approved, if approval is significantly delayed, or if in the event of approval the product is commercially unsuccessful, we do not expect significant sales of other products to offset this loss of potential revenue.

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

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

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

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

preserve trade secrets; and

operate without infringing the patent and other proprietary rights of third parties.

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

We hold numerous U.S., foreign and international patents covering various aspects of our technology, which include novel compositions of matter, 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, including Hatch-Waxman extensions, expired in April 2005.

Genta's patent portfolio includes approximately 65 granted patents and 66 pending applications in the U.S. and foreign countries. We endeavor to seek appropriate U.S. and foreign patent protection on our oligonucleotide technology.

We have licensed ten U.S. patents relating to Genasense® and its backbone chemistry that expire between 2008 and 2015. Corresponding patent applications have been filed in three foreign countries. We also own five U.S. patent applications relating to methods of using Genasense® expected to expire in 2020 and 2026, with approximately 50 corresponding foreign patent applications and granted patents.

***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;

20

---



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. In December 2006, we announced that we had been notified that preliminary results from a randomized Phase 3 trial of chemotherapy with or without Genasense® in patients with AML suggested the study was unlikely to meet its primary endpoint. In February 2007, we announced that preliminary results from a randomized Phase 2 study of Genasense® plus chemotherapy in patients with advanced prostate cancer showed no between-group difference in prostate-specific antigen. While follow-up and analyses of the AML and prostate trials are continuing, we do not believe any of these trials will support regulatory approval of Genasense® in these indications. Similarly negative results were reported in 2007 from randomized Phase 2 trials that were conducted in patients with advanced non small cell lung cancer and also in patients with small cell lung cancer.

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:

inability to obtain sufficient quantities of materials for use in clinical trials;

inability to adequately monitor patient progress after treatment;

unforeseen safety issues;

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

government or regulatory delays.





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

The FDA imposes 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. For example, in December 2006, we received a non-approvable notice from the FDA of an NDA 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 had previously received fludarabine.

We cannot assure you that the FDA 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:

difficulties in assimilating the operations and personnel of acquired companies;

diversion of our management's attention from ongoing business concerns;

our potential inability to maximize our financial and strategic position through the successful incorporation of acquired technology and rights into our products and services;

additional expense associated with amortization of acquired assets;

maintenance of uniform standards, controls, procedures and policies; and

impairment of existing relationships with employees, suppliers and customers as a result of the integration of new management personnel.

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

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

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



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

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

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

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

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

***The outcome of and costs relating to the 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, or the Court, against us and certain of our principal officers on behalf of purported classes of the Company's shareholders who purchased its securities during several class periods. The complaints were consolidated into a single action and alleged 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 the Company's securities. The shareholder class action complaint sought monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. We reached an agreement with plaintiffs to settle the class action litigation in consideration for the issuance of 2.0 million shares of common stock of the Company (adjusted for any subsequent event that results in a change in the number of shares outstanding as of January 31, 2007) and \$18.0 million in cash for the benefit of plaintiffs and the shareholder class. The cash portion of the proposed settlement will be covered by our insurance carriers. Effective June 25, 2007, we and the plaintiffs executed a written Stipulation and Agreement of Settlement which was filed with the Court on August 31, 2007, seeking preliminary approval. The unopposed Motion for Preliminary Approval of Settlement was granted on October 30, 2007, and the Court issued final approval of the Settlement at the Settlement Fairness Hearing on March 3, 2008.

In addition, two separate shareholder derivative actions were 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.





We reached a final agreement with the Federal shareholder derivative plaintiffs to settle the Federal shareholder derivative action. On October 10, 2006, the United States District Court for the District of New Jersey gave preliminary approval to the parties' settlement agreement. On May 7, 2007, the proposed settlement received final approval from the Court. On October 31, 2006, we and the defendants entered into a Release and Settlement Agreement with our insurance carrier, pursuant to which our insurance covered the \$200,000 payment for plaintiffs attorney fees, the costs of notice to shareholders required by the Court's preliminary approval order and defense costs incurred in connection with the action and this amount was paid by our insurance carrier during the three months ended June 30, 2007.

We have continued to deny all of the allegations in all of these proceedings, and settlement and potential settlement do not constitute an admission of guilt or liability.

Based on facts substantially similar to those asserted in the shareholder class actions, the State derivative plaintiffs claimed that defendants had 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' motion for reconsideration was denied and they filed a notice of appeal. On December 11, 2006, plaintiffs filed their appellate brief and on January 18, 2007, we filed our response. In view of the settlement of the Federal derivative action, on June 4, 2007, we filed a motion to dismiss plaintiffs' appeal. That motion was granted on June 25, 2007.

In February 2007, a complaint against us was filed in the Superior Court of New Jersey by Howard H. Fingert, M.D., a former employee of Genta. The complaint alleges, among other things, breach of contract as to our stock option plan and as to a consulting agreement allegedly entered into by us and Dr. Fingert subsequent to termination of Dr. Fingert's employment with us, breach of implied covenant of good faith and fair dealing with respect to our stock option plan and the alleged consulting agreement, promissory estoppel with respect to the exercise of stock options and provision of consulting services after termination of employment, and fraud and negligent misrepresentation with respect to exercise of stock options and provision of consulting services after termination of employment. The complaint seeks monetary damages, including punitive and consequential damages. We filed an answer to the complaint on May 29, 2007, and on August 8, 2007, filed a request for production of documents. On January 4, 2008, the Court dismissed the complaint without prejudice due to Dr. Fingert's failure to produce the requested discovery. Dr. Fingert has 90 days in which to move to vacate the order. We deny the allegations in the complaint and intend to vigorously defend this lawsuit.

In November 2007, a complaint against us was filed in the United States District Court for the District of New Jersey by Ridge Clearing & Outsourcing Solutions, Inc. The complaint alleges, among other things, that we caused or contributed to losses suffered by one of our shareholders which have been incurred by Ridge. Our Answer and Affirmative Defenses were filed on February 27, 2008 to respond to the complaint. We deny the allegations in the complaint and intend to vigorously defend this lawsuit.

### **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 our Board of Directors approved a Stockholder Rights Plan and declared a dividend of one preferred stock purchase right, which we refer to as a 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. 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 stockholders. 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:

the results of preclinical studies and clinical trials by us or our competitors;

announcements of technological innovations or new therapeutic products by us or our competitors;

government regulation;

developments in patent or other proprietary rights by us or our respective competitors, including litigation;

fluctuations in our operating results; and

market conditions for biopharmaceutical stocks in general.

At December 31, 2007, we had 30.6 million shares of common stock outstanding, 2.3 million additional shares reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants and 0.6 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.

At our Annual Meeting of Shareholders held on July 11, 2007, our shareholders authorized our Board of Directors to effect a reverse stock split of all outstanding shares of common stock, and the Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of one for six shares. On July 12, 2007, we filed a Certificate of Amendment to our Restated Certificate of Incorporation, as amended, with the Delaware Secretary of State to effect the reverse stock split. As of July 12, 2007, the effective date of the reverse stock split, every six shares of old common stock were converted into one new share of common stock. Upon the open of trading on July 13, 2007, the new shares of common stock began trading on the NASDAQ Global Market on a split-adjusted basis. As a result of the 1-for-6 reverse stock split, shares of our common stock outstanding were reduced from 183.7 million shares on a pre-split basis to 30.6 million shares on a post-split basis, or 83%. The resulting decrease in the number of shares of our common stock outstanding could potentially adversely affect the liquidity of our common stock, especially in the case of larger block trades.



***Our common stock may be delisted from the NASDAQ Global Market, or NASDAQ.***

On November 2, 2006, we received a notification from the NASDAQ Listing Qualifications Department providing notification that, for the last 30 consecutive business days, the bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion under NASDAQ Marketplace Rule 4450(a)(5), or the Rule. We, in accordance with NASDAQ Marketplace Rule 4450(e)(2), were provided 180 calendar days, or until May 1, 2007, to regain compliance. To regain compliance, the bid price of our common stock had to close at \$1.00 per share or more for a minimum of 10 consecutive business days at any time before May 1, 2007.

On May 2, 2007, we announced that we had received a notice of delisting from the NASDAQ Global Market because the closing bid price of our common stock was not in compliance with the \$1.00 minimum closing bid price requirement, as set forth in Marketplace Rule 4450(a)(5). At our Annual Meeting held on July 11, 2007, our shareholders authorized our Board of Directors to effect a reverse stock split of all outstanding shares of Common Stock, and the Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of one for six shares. On July 12, 2007, we filed a Certificate of Amendment to our Restated Certificate of Incorporation, as amended, with the Delaware Secretary of State to effect the reverse stock split. As of July 12, 2007, the effective date of the reverse stock split, every six shares of old common stock were converted into one new share of common stock. Upon the open of trading on July 13, 2007, the new shares of common stock began trading on the NASDAQ Global Market on a split-adjusted basis. On July 30, 2007, we announced that we had been formally notified by NASDAQ that we had demonstrated compliance with all NASDAQ Marketplace Rules. As a consequence, the NASDAQ Listing Qualifications Panel determined that our common stock will continue to be listed on the NASDAQ Global Market.

On December 24, 2007, we announced that we received a notification from the NASDAQ Listing Qualifications Department providing notification that, for the last 30 consecutive business days, the bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion under NASDAQ Marketplace Rule 4450(a)(5), or the Rule. We, in accordance with NASDAQ Marketplace Rule 4450(e)(2), were provided 180 calendar days, or until June 16, 2008, to regain compliance.

On January 7, 2008, we received a staff determination letter from The NASDAQ Stock Market ( NASDAQ ) stating that we were not in compliance with the minimum \$10,000,000 stockholders equity requirement for continued listing set forth in NASDAQ Marketplace Rule 4450(a)(3). The staff determination letter further states that our common stock would be delisted on January 16, 2008, unless we requested a hearing to appeal the determination to delist our common stock to a NASDAQ Listing Qualifications Panel (the Panel ). We requested such a hearing with the Panel, which automatically stayed the delisting until the Panel reaches a decision. We met with the Panel on February 21, 2008 and it may take up to 30 days after the hearing for the Panel to make a decision on the appeal.

At the hearing, we presented a plan for our continued listing on the NASDAQ Global Market. There can be no assurance that the Panel will grant our request for continued listing on the NASDAQ Global Market. If the Panel determines not to continue to list the Company s common stock on the NASDAQ Global Market, we may request that the Panel permit us to transfer our common stock to the NASDAQ Capital Market. If transferred to the NASDAQ Capital Market, the Company cannot provide assurance that in the future it will continue to meet the initial listing requirements of the NASDAQ Capital Market.

We cannot provide assurance that the Panel will permit us to transfer our common stock to the NASDAQ Capital Market. If the Panel does not permit us to transfer to the NASDAQ Capital Market and determines to delist us, our common stock may trade on the National Association of Securities Dealers OTC Bulletin Board. However, our common stock would not be immediately eligible to trade on the OTC Bulletin Board unless an independent market-maker (not the Company) makes an application to register in and quote the common stock in accordance with the Securities and Exchange Commission s rules and such application is cleared. In the event of a delisting, we intend

to request that a market-maker make an application to register in and quote our common stock on the OTC Bulletin Board, but there can be no assurance that a market maker will make such application or that such application will be approved.



We believe that the listing of our common stock on a recognized national trading market, such as NASDAQ, is an important part of our business and strategy. Such a listing helps our stockholders by providing a readily available trading market with current quotations. Without that, stockholders may have a difficult time getting a quote for the sale or purchase of our stock, the sale or purchase of our stock would likely be made more difficult and the trading volume and liquidity of our stock would likely decline. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded it by other parties. In that regard, the absence of a listing on a recognized national trading market will also affect our ability to benefit from the use of our operations and expansion plans, including for use in licensing agreements, joint ventures, the development of strategic relationships and acquisitions, which are critical to our business and strategy and none of which is currently the subject of any agreement, arrangement or understanding, with respect to any future financing or strategic relationship it may undertake. The delisting from NASDAQ would result in negative publicity and would negatively impact our ability to raise capital in the future.

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

None

**Item 2. *Properties***

We lease approximately 93,000 square feet of office space in Berkeley Heights, New Jersey. Our annual rental costs for this space are approximately \$2.5 million. Our lease on this space terminates in 2010.

**Item 3. *Legal Proceedings***

In 2004, numerous complaints were filed in the United States District Court for the District of New Jersey, or the Court, against Genta and certain of our principal officers on behalf of purported classes of our shareholders who purchased our securities during several class periods. The complaints were consolidated into a single action and alleged that Genta 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 sought monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. We reached an agreement with plaintiffs to settle the class action litigation in consideration for the issuance of 2.0 million shares of our common stock (adjusted for any subsequent event that results in a change in the number of shares outstanding as of January 31, 2007) and \$18.0 million in cash for the benefit of plaintiffs and the shareholder class. The cash portion of the proposed settlement will be covered by our insurance carriers. Effective June 25, 2007, we and the plaintiffs executed a written Stipulation and Agreement of Settlement which was filed with the Court on August 13, 2007, seeking preliminary approval. The unopposed Motion for Preliminary Approval of Settlement was granted on October 30, 2007, and the Court issued final approval of the Settlement at the Settlement Fairness Hearing on March 3, 2008.

We have continued to deny all of the allegations in all of these proceedings, and settlement and potential settlement do not constitute an admission of guilt or liability.





In February 2007, a complaint against us was filed in the Superior Court of New Jersey by Howard H. Fingert, M.D., a former employee of Genta. The complaint alleges, among other things, breach of contract as to our stock option plan and as to a consulting agreement allegedly entered into by us and Dr. Fingert subsequent to termination of Dr. Fingert's employment with us, breach of implied covenant of good faith and fair dealing with respect to our stock option plan and the alleged consulting agreement, promissory estoppel with respect to the exercise of stock options and provision of consulting services after termination of employment, and fraud and negligent misrepresentation with respect to exercise of stock options and provision of consulting services after termination of employment. The complaint seeks monetary damages, including punitive and consequential damages. We filed an answer to the complaint on May 29, 2007, and on August 8, 2007, filed a request for production of documents. On January 4, 2008, the Court dismissed the complaint without prejudice due to Dr. Fingert's failure to produce the requested discovery. Dr. Fingert has 90 days in which to move to vacate the order. We deny the allegations in the complaint and intend to vigorously defend this lawsuit.

In November 2007, a complaint against us was filed in the United States District Court for the District of New Jersey by Ridge Clearing & Outsourcing Solutions, Inc. The complaint alleges, among other things, that we caused or contributed to losses suffered by one of our shareholders which have been incurred by Ridge. Our Answer and Affirmative Defenses were filed on February 27, 2008 to respond to the complaint. We deny the allegations in the complaint and intend to vigorously defend this lawsuit.

**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, 2007.

**PART II**

**Item 5.**

*Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

*Market Information*

Our 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 closing sales prices for the common stock as reported by NASDAQ, adjusted for our 1-for-6 reverse stock split in July 2007.

**High**

**Low**

**2007**

First Quarter

\$

3.36

\$

1.86

Second Quarter

2.46

1.68

Third Quarter

1.80

0.80

Fourth Quarter

1.31

0.52

**2006**

First Quarter

\$

20.16

\$

8.58

Second Quarter

12.84

7.98

Third Quarter

10.80

2.94

Fourth Quarter

5.28

2.64

*Holdings*

There were 590 holders of record of our common stock as of March 9, 2008. We estimate that there are approximately 22,000 beneficial owners of our common stock.

*Dividends*

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.

**Equity Compensation Plan Information**

The following table summarizes the number of outstanding options granted to employees and directors, as well as the number of securities remaining available for future issuance, under our equity compensation plans as of December 31, 2007.

**Plan category**

**Number of securities to be issued upon exercise of outstanding options**

**Weighted-average exercise price of outstanding options**

**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first column)**

Equity compensation plans approved by security holders

2,268,272

\$

23.43

597,623

Equity compensation plans not approved by security holders

5,413,000

1.39

3,087,000

Total

7,681,272

\$

7.89

3,684,623

31





## Performance Graph

*The following Performance Graph and related information shall not be deemed soliciting material or to be filed with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.*

The following table compares total Shareholder returns for Genta over the last five years to the NASDAQ Composite Index and the NASDAQ Biotechnology Index assuming a \$100 investment made on December 31, 2002. The stock performance shown on the graph below is not necessarily indicative of future price performance.

12/02

12/03

12/04

12/05

12/06

12/07

**Genta Incorporated**

**100.00**

**135.63**

**22.89**

**18.99**

**5.75**

**1.13**

**NASDAQ Composite**

**100.00**

**149.75**

**164.64**

**168.60**

**187.83**

**205.22**

**NASDAQ Biotechnology**

**100.00**

**146.95**

**164.05**

**185.29**

**183.09**

**186.22**

*Use of proceeds*

In March 2007, we sold 5.0 million shares of our common stock at a price of \$2.16 per share, raising net proceeds of \$10.2 million. In September 2006, the Company sold 3.3 million shares of its common stock at a price of \$4.74 per share, raising net proceeds of \$14.9 million. In March 2006, the Company sold 3.2 million shares of its common stock at a price of \$12.90 per share, raising net proceeds of \$37.7 million. The net proceeds from the sale of the common stock were used for research and development, the establishment of the AGENDA Phase 3 trial, commercialization expenses, and for general corporate purposes.

*Purchases of equity securities by the issuer and affiliated purchasers*

None



**Item 6. Selected Consolidated Financial Data**

**Years Ended December 31,**

(In thousands, except share data)

**2007**

**2006**

**2005**

**2004**

**2003**

**Consolidated Statements of Operations Data:**

Revenues:

License fees and royalties

\$

\$

\$

5,241

\$

3,022

\$

1,045

Development funding

20,988

12,105

4,194

Product sales net

580

708

356

(512

)

1,420

Total revenues

580

708

26,585

14,615

6,659

Cost of goods sold

90

108

52

170

404

Provision for excess inventory

1,350

Total cost of goods sold

90

108

52

1,520

404

Operating expenses:

Research and development

13,491

28,064

20,902

71,494

83,084

Selling, general and administrative

16,865

25,152

16,100

28,576

29,831

Provision for settlement of litigation, net

(4,240

)

5,280

Write-off of prepaid royalty

1,268

Loss on disposition of property and equipment

4

1,254

3

Total operating expenses gross

26,116

59,764

37,006

101,324

112,918

sanofi-aventis reimbursement

(6,090

)

(43,292

)

(55,891

)

Total operating expenses net

26,116

59,764

30,916

58,032

57,027

Gain on forgiveness of debt

1,297

11,495

Other income/(expense) net

836

1,454

502

(147

)

669

Loss before income taxes

(24,790

)

(57,710

)

(2,584

)

(33,589

)

(50,103

)

Income tax benefit/(expense)

1,470

929

381

904

(6

)

Net loss

\$

(23,320

)

\$

(56,781

)

\$

(2,203

)

\$

(32,685

)

\$

(50,109

)

Net loss per basic and diluted share

\$

(0.79

)

\$

(2.52

)

\$

(0.13

)

\$

(2.46

)

\$

(4.00

)

Shares used in computing net loss per basic and diluted share

29,621

22,553

17,147

13,300

12,516

**As of December 31,**

**2007**

**2006**

**2005**

**2004**

**2003**

**Consolidated Balance Sheet Data:**

Cash, cash equivalents and marketable securities

\$

7,813

\$

29,496

\$

21,282

\$

42,247

\$

82,929

Working capital

877

12,682

11,703

(4,269

)

81,252

Total assets

29,293

51,778

27,386

50,532

114,675

Total stockholders' equity

2,931

14,642

15,697

1,752

12,254





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

### **Overview**

Genta Incorporated is a biopharmaceutical company engaged in pharmaceutical research and development. We are 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 and we expect to incur substantial operating losses due to continued requirements for ongoing and planned research and development activities, pre-clinical and clinical testing, manufacturing activities, regulatory activities and establishment of a sales and marketing organization. From our inception to December 31, 2007, we have incurred a cumulative net deficit of \$438.3 million. Our recurring losses from operations and our negative cash flow from operation raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. We expect that such losses will continue at least until our lead product, Genasense®, receives approval from the FDA or EMEA for commercial sale in one or more indications. Achievement of profitability is currently dependent on the timing of Genasense® regulatory approvals. We have experienced significant quarterly fluctuations in operating results and we expect that these fluctuations in revenues, expenses and losses will continue.

We had \$7.8 million of cash, cash equivalents and marketable securities on hand at December 31, 2007. In March 2007, we sold 5.0 million shares of our common stock at a price of \$2.16 per share, raising net proceeds of \$10.2 million. Cash used in operating activities during the year ended December 31, 2007, was \$31.7 million. On February 13, 2008, we sold 6.1 million shares of our common stock at a price of \$0.50 per share, raising approximately \$3.1 million, net of estimated fees and expenses.

Irrespective of whether a NDA or MAA for Genasense® are approved, we anticipate that we will require additional cash in order to maximize the commercial opportunity and continue its clinical development opportunities. Alternatives available to us to sustain our operations include 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. We will need substantial additional funds before we can expect to realize significant product revenue.

We will maintain an appropriate level of spending over the upcoming fiscal year, given the uncertainties inherent in our business and our current liquidity position. Presently, with no further financing, we will run out of funds in the second quarter of 2008. We currently do not have any additional financing in place. If we are unable to raise additional financing, we could be required to reduce our spending plans, reduce our workforce, license to others products or technologies we would otherwise seek to commercialize ourselves and sell certain assets. There can be no assurance that we can obtain financing, if at all, on terms acceptable to us.

In March 2007, we announced that we had entered into a Supply and Distribution Agreement with IDIS Limited (a privately owned company based in the United Kingdom) whereby IDIS will distribute Ganite® and Genasense® on a named patient basis. The global agreement covers territories outside the United States. Named patient distribution refers to the distribution or sale of a product to a specific healthcare professional for the treatment of an individual patient. IDIS will manage the named patient programs for us.

The IDIS agreement provides that we will supply the two products to IDIS on a consignment basis. We will be paid after sales are made by IDIS, which payment shall be based off of a monthly sales report received from IDIS. We will invoice IDIS based upon this monthly report, which invoice shall be calculated based upon a price minus a fee credited to IDIS. The agreement also provides for distribution by IDIS of a limited amount of drug product free of charge to indigent patients. We intend that a percentage of proceeds from the named patient program will be used to

support the compassionate use program. We have agreed to pay IDIS a termination fee in the event we terminate either or both products within the first three years of the agreement. The first sale under this program occurred in 2007.

Our financial results have been and will continue to be significantly affected by FDA and EMEA actions with respect to Genasense®.



In 2003, we submitted a NDA to the FDA in 2003 for the use of Genasense® plus chemotherapy in patients with advanced melanoma. In May 2004, a majority of the ODAC failed to recommend approval of our NDA. As a consequence, we withdrew the NDA, which allows us to potentially resubmit the application. In October 2006, data from this trial was published in a peer-reviewed journal, which reported statistically significant increases in overall response, complete response, durable response and progression-free survival (PFS). An independent review of the X-rays confirmed the major responses with high concordance. An increase in overall survival by intent-to-treat analysis, which was the study's primary endpoint, approached but did not reach statistical significance ( $P=0.077$ ). Our analysis identified a statistically significant treatment interaction for blood levels of an enzyme known as LDH, which was a prospectively specified component of stratification. When this effect was analyzed by treatment arm, survival was shown to be significantly superior for patients with a non-elevated LDH who received Genasense® ( $P=0.018$ ;  $n=508$ ).

In January 2006, we completed a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA), which sought approval for use of Genasense® plus dacarbazine for the treatment of patients with advanced melanoma who had not previously received chemotherapy. In April 2007, we were informed that the Committee for Medicinal Products for Human Use (CHMP) of the EMA had issued a negative opinion on the MAA and we indicated that we would seek re-examination of the MAA by a Scientific Advisory Group. In July 2007, we received notice from the EMA that the requested re-examination reaffirmed the negative opinion for approval of our MAA for Genasense®. We contemplate no further action on the MAA.

In April 2007, we filed a formal complaint and request for correction of information with the FDA under the Federal Data Quality Act. The complaint challenged a key statistical analysis of our data regarding PFS that was used by FDA at the ODAC meeting in May 2004. At that meeting, ODAC voted unanimously that PFS was an endpoint that would support full approval in the absence of a survival improvement in patients with advanced melanoma. In February 2008, FDA informed us that they did not agree with our opinion that their assessment was flawed. We have not decided whether to pursue this matter further with the FDA.

In August 2007, we announced that the first patients had been enrolled in a confirmatory Phase 3 trial of Genasense® plus chemotherapy in advanced melanoma. The trial, known as AGENDA, is a randomized, double-blind, placebo-controlled study in which patients are randomly assigned to receive Genasense® plus dacarbazine (DTIC) or DTIC alone. The study targets patients using LDH as a biomarker to identify patients who may be most likely to respond, based on data obtained from our preceding trial in melanoma. We expect that AGENDA will accrue approximately 300 patients and will be conducted at 75 to 100 sites worldwide. Accrual is expected to take approximately 18 months, with initial data on PFS expected shortly thereafter.

In CLL, we conducted a randomized Phase 3 trial in 241 patients with relapsed or refractory disease who were treated with fludarabine and cyclophosphamide (Flu/Cy) with or without Genasense®. The trial achieved its primary endpoint: a statistically significant increase (17% vs. 7%;  $P=0.025$ ) in the proportion of patients who achieved a complete response (CR), defined as a complete or nodular partial response. Patients who achieved this level of response experienced disappearance of predefined disease symptoms, including fever, night sweats, fatigue, abdominal discomfort due to an enlarged spleen and impaired mobility due to swollen lymph nodes. A key secondary endpoint, duration of CR, was also significantly longer for patients treated with Genasense®, (median not reached but exceeding 36+ months in the Genasense® group, versus 22 months in the chemotherapy-only group).

Several secondary endpoints were not improved by the addition of Genasense® including overall response rate (i.e., the percentage of patients who achieved CR plus partial response), time-to-disease progression, or overall survival. Adverse events (irrespective of relation to study drugs) during treatment or within 30 days from last dose of treatment that resulted in death occurred in 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®.

In December 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 had previously received fludarabine.



In September 2006, an ODAC meeting voted not to recommend approval of Genasense® in CLL, and in December 2006, we received a non-approvable notice from the FDA. We believe that our application met the regulatory requirements for approval, and in April 2007, we filed an appeal of this non-approvable notice pursuant to the FDA's Formal Dispute Resolution process that exists within the FDA's Center for Drug Evaluation and Research (CDER). In June 2007, we announced that the initial appeal was denied and that we would further appeal the decision to the next level within CDER. On October 25, 2007, we announced that we had completed the filing of our next-level formal appeal to CDER. On March 17, 2008, we announced that CDER decided that available data are not adequate to support approval of Genasense® for treatment of patients with CLL. CDER acknowledged that complete response, which was the primary endpoint in the pivotal trial, was an appropriate endpoint for assessing efficacy. FDA also agreed that this endpoint was achieved, and that those results supported the efficacy of the drug. However, CDER concluded that at present there was insufficient confirmatory evidence in the NDA to approve the drug. CDER recommended two alternatives for exploring the efficacy of Genasense® that could provide such confirmatory evidence. One option is to conduct an additional clinical trial. The other option is to collect additional information regarding the clinical course and progression of disease in patients from the previous pivotal trial in order to ascertain whether those data contain sufficient confirmatory evidence. We currently plan to pursue both of these options.

In December 2006, due to FDA's non-approval of our NDA for CLL, we initiated a series of steps designed to conserve cash in order to focus on our oncology development operations. We reduced our workforce by 34 positions, or approximately 35%, including the elimination of 18 positions classified as research and development, 9 in sales and marketing and 7 in administration. Severance costs of \$0.7 million were recognized in our operating expenses, including \$0.3 million in research and development expenses and \$0.4 million in selling, general and administrative expenses in the Company's Consolidated Statements of Operations. Payment of the severance began in January 2007.

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. In December 2006, we were notified that preliminary analysis from a randomized Phase 3 trial of chemotherapy with or without Genasense® in patients with acute myeloid leukemia, (AML), suggested the study was unlikely to meet its primary endpoint. In February 2007, we announced that preliminary results from a randomized Phase 2 study of Genasense® plus chemotherapy in patients with advanced prostate cancer showed no between-group difference in prostate-specific antigen. While follow-up and analyses of the AML and prostate trials are continuing, we do not believe any of these trials will support regulatory approval of Genasense® in these indications. Similarly negative results were reported in 2007 from randomized Phase 2 trials that were conducted in patients with advanced non small cell lung cancer and also in patients with small cell lung cancer.

## **Results of Operations**

### **Summary Operating Results For the years ended December 31,**

**\$ Change**

**(\$ thousands)**

**2007**

**2006**

**2005**

**07 vs. 06**

**06 vs. 05**

Revenues:

License fees and royalties

\$

\$

\$

5,241

\$

\$

(5,241

)

Development funding

20,988

(20,988

)

Product sales net

580

708

356

(128

)

352

Total revenues

580

708

26,585

(128

)

(25,877

)

Cost of goods sold

90

108

52

(18

)

56

Operating expenses:

Research and development

13,491

28,064

20,902

(14,573

)

7,162

Selling, general and administrative

16,865

25,152

16,100

(8,287

)

9,052

Provision for settlement of litigation, net

(4,240

)

5,280

(9,520

)

5,280

Write-off of prepaid royalty

1,268

(1,268

)

1,268

Loss on disposition of equipment

4

(4

)

Total operating expenses gross

26,116

59,764

37,006

(33,648

)

22,758

Less: sanofi-aventis reimbursement

(6,090

)

6,090

Total operating expenses net

26,116

59,764

30,916

(33,648

)

28,848

Gain on forgiveness of debt

1,297

(1,297

)

Other income/(expense), net

836

1,454

502

(618

)

952

Loss before income taxes

(24,790

)

(57,710

)

(2,584

)

32,920

(55,126

)

Income tax benefit

1,470

929

381

541

548

Net loss

\$

(23,320

)

\$

(56,781

)

\$

(2,203

)

\$

33,461

\$

(54,578

)

36





### Total revenues

Total revenues were \$0.6 million in 2007 and \$0.7 million in 2006 compared with \$26.6 million in 2005. License fees and development funding revenues of \$26.2 million in 2005 were generated by the accelerated recognition of the initial \$10.0 million licensing fee and \$40.0 million development funding received from Aventis, a member of the sanofi-aventis Group (Aventis), in 2002, under the Collaborative Agreement between Aventis and us regarding the development and commercialization of Genasense®. In November 2004, we received from Aventis a notice of termination of the Collaborative Agreement. Under the terms of the Collaborative Agreement, Aventis continued to fund ongoing development activities through May 2005. We 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, we determined that the period over which the remaining deferred revenue should be recognized was through May 2005. In May 2005, we announced that we had signed an agreement with Aventis to finalize the termination of our development and commercialization collaboration for Genasense®.

Product sales-net of Ganite® were \$0.6 million in 2007 compared with \$0.7 million in 2006. Product sales-net for 2007 also include sales of \$60 thousand of Genasense® through the named-patient program managed for us by IDIS. Product sales-net in 2007 and 2006 included favorable adjustments to a reserve for returns of Ganite® of \$0.1 million and \$0.3 million, respectively. Product sales-net of Ganite® during 2005 were \$0.4 million.

### Cost of goods sold

Lower cost of goods sold in 2007 than in 2006 is the result of lower sales of Ganite®, as well as sales of Genasense® which have no associated inventory cost. Higher cost of goods sold in 2006 than in 2005 is the result of higher product sales of Ganite®.

### Research and development expenses

Research and development expenses were \$13.5 million in 2007 compared with \$28.1 million in 2006. The prior year included higher manufacturing and other expenses incurred in preparation for the possible commercial launch of Genasense® and expenses related to regulatory review. The decline in expenses in 2007 reflects the comparison to this higher level of expenses in 2006, as well as the impact of our staff reduction in December 2006. In addition, share-based compensation declined by \$0.5 million, (see Note 16 to our Consolidated Financial Statements). Research and development expenses incurred on the Genasense® project in 2007 were approximately \$10.3 million, representing 76% of research and development expenses.

During the fourth quarter of 2007, we revised our estimate of certain accrued expenses in the amount of \$4.7 million, since such amount is no longer deemed probable.

Research and development expenses before reimbursement were \$28.1 million in 2006, compared with \$20.9 million in 2005. This increase is primarily due to expenses incurred in preparation for the production of Genasense® and expenses related to regulatory review. In addition, expenses in 2006 include the recognition of \$1.0 million of share-based compensation expense, resulting from the adoption of SFAS 123R, *Share-Based Payment*, on January 1, 2006 and \$0.3 million of severance expenses as a result of our staff reduction in December 2006 due to the FDA's non-approval of our NDA for CLL. Research and development expenses incurred on the Genasense® project in 2006 were approximately \$25.5 million, representing 91% of research and development expenses. In 2005, approximately

\$19.5 million or 93% of research and development expenses before reimbursement were incurred on the Genasense® project.

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 subject to wide variability. 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 that review 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.

37

---



Selling, general and administrative expenses

Selling, general and administrative expenses were \$16.9 million in 2007, compared with \$25.2 million in 2006. The prior year included a buildup of sales and marketing expenses incurred in preparation for a possible commercial launch of Genasense®. The decline in expenses in 2007 reflects the comparison to this higher level of expenses in 2006, as well as the impact of our December 2006 staff reduction. In addition, depreciation expense declined by \$0.8 million and share-based compensation declined by \$1.1 million, (see Note 16 to our Consolidated Financial Statement).

Selling, general and administrative expenses were \$25.2 million in 2006 compared to \$16.1 million in 2005. This increase is primarily due to sales and marketing expenses incurred in preparation for the anticipated commercial launch of Genasense® and higher payroll expense resulted from the hiring of an experienced sales and marketing management team throughout 2006. Selling, general and administrative expenses in 2006 also include the recognition of \$2.0 million of share-based compensation expense, resulting from the adoption of SFAS 123R and \$0.4 million of severance expense as a result of our staff reduction in December 2006.

Provision for settlement of litigation, net

In 2004, numerous legal complaints were filed against Genta and certain of our officers on behalf of certain classes of our shareholders who purchased our securities during several class periods. The complaints were consolidated into a single action against us. We have reached an agreement in principle with plaintiffs to settle the class action litigation in consideration for issuance of 2.0 million shares of our common stock and \$18.0 million in cash for the benefit of plaintiffs and the shareholder class. The cash portion of the proposed settlement will be covered by our insurance carriers. Effective June 25, 2007, we and the plaintiffs executed a written Stipulation and Agreement of Settlement which was filed with the Court on August 13, 2007, seeking preliminary approval. The unopposed Motion for Preliminary Approval of Settlement was granted on October 30, 2007, and the Court issued final approval of the Settlement at the Settlement Fairness Hearing on March 3, 2008. In 2006, we recorded an expense of \$5.3 million, which was composed of the 2.0 million shares of our common stock valued at a market price of \$2.64 on December 31, 2006, (the shares and market price have been adjusted for our one-for-six reverse split in July 2007). This amount will continue to be adjusted based on the market price of our stock until final Court approval of the settlement, at which time, the number of shares to be issued will be fixed and the dollar amount of those shares will be determinable. We also recorded a liability for the settlement of litigation of \$23.2 million, which was recorded in accounts payable and accrued expenses and an insurance receivable of \$18.0 million, which was recorded in prepaid expenses and other current assets (see Note 20 to our Financial Statements). At December 31, 2007, the 2.0 million shares were valued at a market price of \$0.52, resulting in a reduction in the liability for the settlement of litigation of \$4.2 million and a lowering of the liability for the settlement of litigation to \$19.0 million.

Write-off of prepaid royalty

In December 2000, we recorded \$1.3 million as the fair value for our commitment to issue 27,056 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 our products containing the antisense technology licensed from such university. These shares were issued in 2001. On December 15, 2006, we received a non-approvable notice from the FDA for our NDA for the use of Genasense® plus chemotherapy in patients with CLL. As a result, we accounted for the impairment of these prepaid royalties and recorded a write-off of this asset, (see Note 10 to our Financial Statements).

sanofi-aventis reimbursement

In May 2005, we announced that Genta and Aventis had finalized a termination agreement, providing for no future financial obligations by either party. Consequently, none of the research and development expenses incurred by us after 2005 were reimbursable.

38

---



Gain on forgiveness of debt

Gain on forgiveness of debt of \$1.3 million in 2005 is the result of the termination of the Collaborative Agreement with Aventis. In 2005, pursuant to the terms of the Collaborative Agreement, \$2.8 million of reimbursable costs accrued and owed to us by Aventis were applied against the Line of Credit with Aventis and the remaining balance of \$1.3 million was forgiven.

Other income/(expense), net

Other income/(expense), net of \$0.8 million in 2007 declined from \$1.5 million for the prior year, primarily due to lower interest income, resulting from lower investment balances, along with higher interest expense. Other income/(expense), net of \$1.5 million in 2006 favorably compared to other income/(expense), net of \$0.5 million in 2005, primarily due to higher interest income, resulting from higher investment balances and realized gains on the maturity of marketable securities.

Income tax benefit

New Jersey has enacted legislation permitting certain corporations located in the state to sell state tax loss carryforwards and state research and development credits. We sold portions of our New Jersey net operating losses and received a payment of \$1.5 million in 2007 and \$0.9 million in both 2006 and 2005 that is recognized as income tax benefit. In 2005, the benefit was partially offset by \$0.5 million of an accrued income tax expense that arose from a State of New Jersey tax audit for the years 2000 through 2004. The State has taken the position that amounts reimbursed to us by Aventis for co-development expenditures during the audit period are subject to New Jersey's Alternative Minimum Assessment. We appealed this decision to the State, and on February 13, 2008, the State notified us that our appeal had not been granted. We believe the State's position is unjustified and are considering the option of taking this matter before the Tax Court.

If still available under New Jersey law, we will attempt to sell our remaining tax losses in 2008. The amount of tax losses that we may be able to sell will increase as we incur additional tax losses during 2008. We can not be assured that the New Jersey program will continue next year, nor can we estimate what percentage of our saleable tax benefits New Jersey will permit us to sell, how much money will be received in connection with the sale, if we will be able to find a buyer for our tax benefits or if such funds will be available in a timely manner.

Net loss

Genta incurred a net loss of \$23.3 million or \$0.79 per share, for 2007, \$56.8 million, or \$2.52 per share, for 2006, and \$2.2 million, or \$0.13 per share, for 2005.

The lower net loss in 2007 is primarily due to a comparison with a prior year that reflected a buildup of sales, marketing and manufacturing expenses incurred in anticipation of a possible commercial launch of Genasense®. In addition, the lower loss in 2007 reflects our staff reduction in December 2006, lower share-based compensation expense, lower depreciation expense and includes a benefit of \$4.2 million due to a reduction in the provision for settlement of litigation.

The higher loss in 2006 is primarily due to a comparison with a prior year that included revenues of \$26.2 million from the accelerated recognition of the license fee and development funding and \$6.1 million from the reimbursement for research and development expenses. In addition, 2006 results reflected higher operating expenses, including spending in anticipation of approval and commercial launch of Genasense®, \$5.3 million for the provision for settlement of litigation, \$1.3 million for the write-off of a prepaid royalty and \$3.0 million from the implementation of

SFAS 123R.

39

---



## Recent Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 141(R), *Business Combinations* (SFAS 141(R)), which replaces FAS 141. SFAS 141(R) establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any controlling interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141(R) is to be applied prospectively to business combinations for which the acquisition date is on or after an entity's fiscal year that begins after December 15, 2008. We will assess the impact of SFAS 141(R) if and when a future acquisition occurs.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51* (SFAS 160). SFAS 160 establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Specifically, this statement requires the recognition of a noncontrolling interest (minority interest) as equity in the consolidated financial statements and separate from the parent's equity. The amount of net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement. SFAS 160 clarifies that changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, this statement requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. SFAS 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. We do not expect that adoption of this standard will have a material impact on our financial statements.

In December 2007, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin 110 (SAB 110), which permits entities, under certain circumstances, to continue to use the simplified method of estimating the expected term of plain options as discussed in SAB No. 107 and in accordance with SFAS 123R. The guidance in this release is effective January 1, 2008. The impact of this standard on the consolidated financial statements is not expected to be material.

In December 2007, the FASB issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, which is effective for calendar year companies on January 1, 2009. The Task Force clarified the manner in which costs, revenues and sharing payments made to, or received by a partner in a collaborative arrangement should be presented in the income statement and set forth certain disclosures that should be required in the partners' financial statements. We are currently assessing the potential impacts of implementing this standard.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, which is effective for calendar year companies on January 1, 2008. The Task Force concluded that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. We are currently assessing the potential impacts of implementing this standard.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 permits all entities to choose to elect, at specified election dates, to measure eligible financial instruments at fair value. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date and recognize upfront costs and fees related to

those items in earnings as incurred and not deferred. SFAS 159 applies to fiscal years beginning after November 15, 2007, with early adoption permitted for an entity that has also elected to apply the provisions of SFAS No. 157, Fair Value Measurements (SFAS 160). We do not expect that adoption of this standard will have a material impact on our financial statements.



In September 2006, the FASB issued SFAS 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States of America and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements. Accordingly, this pronouncement does not require any new fair value measurements. We are required to adopt SFAS 157 beginning January 1, 2008. We do not expect that adoption of this standard will have a material impact on its financial statements.

### **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. We believe that the following represents our critical accounting policies:

*Revenue recognition.* Our policy is to recognize revenues under license arrangements when delivery has occurred or services have been rendered, persuasive evidence of an arrangement exists, the fee is fixed and determinable and collectibility is reasonably assured. Royalties are recognized when earned. Consistent with Staff Accounting Bulletin No. 104, *Revenue Recognition*, initial funding of ongoing development received from Aventis, after the achievement of certain research and development milestones were being recognized on a straight-line basis over the original estimated useful life of the related first-to-expire patent of 115 months. On November 8, 2004, we received from Aventis notice of termination of the agreements between Genta and Aventis, with an effective termination date of May 8, 2005. Accordingly, we 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 5 to our financial statements).

We recognize 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.

Under our Supply and Distribution Agreement with IDIS Limited, we will supply Ganite® and Genasense® to IDIS on a consignment basis. We recognize revenue when IDIS reports that it has delivered product to customers, which is the point in time that title to the product and risk of loss has passed. The first sales under this program occurred during 2007.

*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, which terminated in May 2005, were recorded as a reduction to expense in the Consolidated Statements of Operations (see Note 5 to our financial statements).

### **Liquidity and Capital Resources**

At December 31, 2007, we had cash, cash equivalents and marketable securities totaling \$7.8 million compared with \$29.5 million at December 31, 2006. During 2007, cash used in operating activities was \$31.7 million compared with \$44.7 million in 2006, reflecting additional spending in the prior year in anticipation of potential commercial approval and product launch of Genasense®.

On February 13, 2008, the Company sold 6.1 million shares of the Company's common stock at a price of \$0.50 per share, raising approximately \$3.1 million, net of estimated fees and expenses.



In March 2007, we sold 5.0 million shares of our common stock at a price of \$2.16 per share, raising net proceeds of \$10.2 million.

At December 31, 2006, cash, cash equivalents and marketable securities of \$29.5 million increased from \$21.3 million at December 31, 2005, reflecting increased stock issuance during 2006. During 2006, cash flow used in operating activities was \$44.7 million compared with \$37.0 million in 2005, due to additional spending in 2006 in anticipation of commercial approval and product launch of Genasense®.

In September 2006, the Company sold 3.3 million shares of its common stock at a price of \$4.74 per share, raising \$14.9 million, net of fees and expenses.

In March 2006, the Company sold 3.2 million shares of its common stock at a price of \$12.90 per share, raising \$37.7 million, net of fees and expenses.

In March 2006, the Board of Directors approved an amendment to increase the number of shares of authorized common stock to 250.0 million shares from 150.0 million shares. In June 2006, the Company's stockholders approved this amendment at the Company's Annual Meeting of Stockholders.

During 2007, the Company issued notes payable to finance premiums for its corporate insurance policies of \$1.1 million at interest rates running from 5.2% to 5.9% and during 2006, \$1.2 million at 5.4% to 5.6%. Payments were scheduled for seven or ten equal monthly installments for the notes initiated in 2007 and over seven equal monthly installments for the notes initiated in 2006. The remaining balance on the notes payable was \$0.5 million at December 31, 2007 and \$0.6 million at December 31, 2006. We will attempt to finance our insurance premiums in 2008.

We will maintain an appropriate level of spending over the upcoming fiscal year, given the uncertainties inherent in our business and our current liquidity position. Presently, with no further financing, we will run out of funds in the second quarter of 2008. We currently do not have any additional financing in place. If we are unable to raise additional financing, we could be required to reduce our spending plans, reduce our workforce, license to others products or technologies we would otherwise seek to commercialize ourselves and sell certain assets. There can be no assurance that we can obtain financing, if at all, on terms acceptable to us.

Irrespective of whether an NDA or MAA for Genasense® are approved, we will require additional cash in order to maximize this commercial opportunity and continue its clinical development opportunities. We have had discussions with other companies regarding partnerships for the further development and global commercialization of Genasense®. Additional alternatives available to us to sustain our operations include financing arrangements with potential corporate partners, debt financing, asset-based loans, royalty-based financing, equity financing 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.

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





**Contractual Obligations**

Future contractual obligations at December 31, 2007 are as follows (\$ thousands):

**Total**

**Less than  
1 year**

**1 - 3 years**

**3 - 5 years**

**More than  
5 years**

Notes payable

\$

512

\$

512

\$

0

\$

0

\$

0

Uncertain tax positions\*

\$

776

\$

776

\$

0

\$

0

\$

0

Operating lease obligations

\$

5,654

\$

2,634

\$

3,020

\$

0

\$

0

Total

\$

6,942

\$

3,922

\$

3,020

\$

0

\$

0

\*

see Note 13 to the Consolidated Financial Statements

Virtually all of the operating lease obligations result from our lease of approximately 93 thousand square feet of office space in Berkeley Heights, New Jersey. Our lease on this space terminates in 2010.

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 its 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. In addition, not included in the above table are potential milestone payments to be made to Emisphere and other suppliers of services, since such payments are contingent on the occurrence of certain events.

On March 7, 2008, we entered into a License Agreement (the Agreement) with Daiichi Sankyo Company, Limited, a Japanese corporation based in Tokyo, Japan, whereby we obtained the exclusive license for tasetaxel. Tasetaxel has been placed on clinical hold by the FDA. We plan to develop and implement a response to FDA that may lift the clinical hold and enable clinical testing to resume. However, there is no guarantee that FDA will accept this plan, and thus no assurance can be provided that the clinical tests that would be required to secure regulatory approval for marketing can be undertaken.

Pursuant to the agreement, we will pay Daiichi Sankyo \$250,000 within 30 days from signing the agreement. We will also pay four equal installments of \$562,000 per quarter beginning at the end of the second quarter 2008, and also at the end of each subsequent calendar quarter, until the end of the first quarter 2009, for a total of \$2.25 million. The agreement also provides for payments by us upon achievement of certain clinical and regulatory milestones and royalties on net product sales. We will purchase Daiichi's current inventory of tasetaxel and will be responsible for all future development, commercialization, and manufacturing of the drug.

#### **Off-Balance Sheet Arrangements**

We have 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 consolidated 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.

Our 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, 2007. Therefore there will be no ongoing exposure to a potential 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 Supplementary Data**

**Genta Incorporated**

**Index to Financial Statements**

Report of Independent Registered Public Accounting Firm

45

Consolidated Balance Sheets as of December 31, 2007 and 2006

46

Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005

47

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2007, 2006 and 2005

48

Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005

49

Notes to Consolidated Financial Statements

50





**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, 2007 and 2006, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2007. 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, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007, 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 2 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 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 3 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment*, effective January 1, 2006, and Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109*, effective January 1, 2007.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company s internal control over financial reporting as of December 31, 2007, 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 17, 2008 expressed an unqualified opinion on the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey

March 17, 2008



**GENTA INCORPORATED**

**CONSOLIDATED BALANCE SHEETS**

(In thousands, except par value data)

**December 31,  
2007**

**December 31,  
2006**

ASSETS

Current assets:

Cash and cash equivalents

\$

5,814

\$

9,554

Marketable securities (Note 4)

1,999

19,942

Accounts receivable net of allowances of \$38 at December 31, 2007  
and \$42 at December 31, 2006, respectively

31

17

Inventory (Note 7)

225

308

Prepaid expenses and other current assets (Note 8)

19,170

19,997

Total current assets

27,239

49,818

Property and equipment, net (Note 9)

323

271

Other assets

1,731

1,689

Total assets

\$

29,293

\$

51,778

LIABILITIES AND STOCKHOLDERS EQUITY

Current liabilities:

Accounts payable and accrued expenses (Note 8 and Note 11)

\$

25,850

\$

36,494

Notes payable (Note 12)

512

642

Total current liabilities

26,362

37,136

Commitments and contingencies (Note 14 and Note 20)

Stockholders' equity (Note 15):

Preferred stock, 5,000 shares authorized:

Series A convertible preferred stock, \$.001 par value;  
8 shares issued and outstanding, liquidation value of \$385  
at December 31, 2007 and December 31, 2006, respectively

Series G participating cumulative preferred stock, \$.001 par value;  
0 shares issued and outstanding at December 31, 2007  
and December 31, 2006, respectively

Common stock, \$.001 par value; 250,000 shares authorized,  
30,621 and 25,621 shares issued and outstanding at December 31, 2007  
and December 31, 2006, respectively

31

26

Additional paid-in capital

441,159

429,553

Accumulated deficit

(438,288

)

(414,968

)

Accumulated other comprehensive income

29

31

Total stockholders' equity

2,931

14,642

Total liabilities and stockholders' equity

\$

29,293

\$

51,778

See accompanying notes to consolidated financial statements.





**GENTA INCORPORATED**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**Years Ended December 31,**

**(In thousands, except per share data)**

**2007**

**2006**

**2005**

Revenues:

License fees and royalties (Note 3 and Note 5)

\$

\$

\$

5,241

Development funding (Note 3 and Note 5)

20,988

Product sales net

580

708

356

Total revenues

580

708

26,585

Cost of goods sold

90

108

52

Operating expenses:

Research and development

13,491

28,064

20,902

Selling, general and administrative

16,865

25,152

16,100

Provision for settlement of litigation, net (Note 8 and Note 20)

(4,240

)

5,280

Write-off of prepaid royalty (Note 10).

1,268

Loss on disposition of equipment

4

Total operating expenses gross

26,116

59,764

37,006

sanofi-aventis reimbursement (Note 5)

(6,090

)

Total operating expenses net

26,116

59,764

30,916

Other income/(expense), net:

Gain on forgiveness of debt (Note 5)

1,297

Gain on maturity of marketable securities

159

310

63

Interest income, net

837

1,216

591

Interest expense

(160

)

(72

)

(152

)

Total other income, net

836

1,454

1,799

Loss before income taxes

(24,790

)

(57,710

)

(2,584

)

Income tax benefit (Note 13)

1,470

929

381

Net loss

\$

(23,320

)

\$

(56,781

)

\$

(2,203

)

Net loss per basic and diluted share

\$

(0.79

)

\$

(2.52

)

\$

(0.13

)

Shares used in computing net loss per basic and diluted share

29,621

22,553

17,147

See accompanying notes to consolidated financial statements.

47

---



**GENTA INCORPORATED**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

**For the Years Ended December 31, 2007, 2006 and 2005**

**Convertible  
Preferred Stock**

**Common Stock**

**Additional  
Paid-in  
Capital**

**Accumulated  
Deficit**

**Deferred  
Compensation**

**Accumulated  
Other  
Comprehensive  
Income (Loss)**

**Total  
Stockholders  
Equity**

(In thousands)

**Shares**

**Amount**

**Shares**

**Amount**

**Balance at January 1, 2005**

10

\$

15,893

\$

16

\$

357,793

\$

(355,984

)

\$

(41

)

\$

(32

)

\$

1,752

Net loss

(2,203

)

(2,203

)

Net change in value of marketable securities

92

92

Issuance of common stock, net of issuance costs of \$1,521

3,177

3

16,012

16,015

Other conversions

Compensation expense related to certain stock options issued in 1999 and 2000

41

41

**Balance at December 31, 2005**

10

\$

19,092

\$

19

\$

373,805

\$

(358,187

)

\$

\$

60

\$

15,697

Net loss

(56,781

)

(56,781

)

Net change in value of marketable securities

(29

)

(29

)

Issuance of common stock, net of issuance costs of \$3,125

3,167

3

37,722

37,725

Issuance of common stock in connection with conversion of Series A preferred stock

(2

)

3

Issuance of common stock, net of issuance costs of \$925

3,333

4

14,871

14,875

Issuance of common stock in connection with exercise of stock options

26

156

156

Stock-based compensation expense

2,999

2,999

**Balance at December 31, 2006**

8

\$

25,621

\$

26

\$

429,553

\$

(414,968

)

\$

\$

31

\$

14,642

Net loss

(23,320

)

(23,320

)

Net change in value of marketable securities

(2

)

(2

)

Issuance of common stock, net of issuance costs of \$562

5,000

5

10,233

10,238

Stock-based compensation expense

1,373

1,373

**Balance at December 31, 2007**

8

\$

30,621

\$

31

\$

441,159

\$

(438,288)

)

\$

\$

29

\$

2,931

48

---



**GENTA INCORPORATED**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**Years Ended December 31,**

(In thousands)

**2007**

**2006**

**2005**

**Operating activities:**

Net loss

\$

(23,320

)

\$

(56,781

)

\$

(2,203

)

Adjustments to reconcile net loss to net cash used in operating activities:

Depreciation and amortization

170

942

2,074

Loss on disposition of equipment

4

Non-cash reimbursement of research & development expense (Note 5)

(6,090

)

Amortization of deferred revenues (Note 5)

(26,228

)

Share-based compensation (Note 16)

1,373

2,999

Provision for sales returns

(133

)

(300

)

Gain on maturity of marketable securities

(159

)

(310

)

(63

)

Provision for settlement of litigation, net (Note 8)

(4,240

)

5,280

Write-off of prepaid royalty (Note 10)

1,268

Provision for excess inventory

(21

)

Gain on forgiveness of debt (Note 5)

(1,297

)

Compensation expense related to certain stock options issued in 1999 and 2000

41

Changes in operating assets and liabilities:

Accounts receivable

(14

)

42

(59

)

Inventory

83

88

(21

)

Prepaid expenses and other current assets

627

(142

)

255

Accounts payable and accrued expenses

(6,071

)

2,264

(3,389

)

Other assets

(42

)

(40

)

(29

)

Net cash used in operating activities

(31,726

)

(44,690

)

(37,026

)

**Investing activities:**

Purchase of marketable securities (Note 4)

(13,900

)

(56,784

)

(21,839

)

Maturities of marketable securities (Note 4)

32,000

49,091

15,784

Purchase of property and equipment

(222

)

(136

)

(56

)

Proceeds from sale of equipment

34

Net cash provided by (used in) investing activities

17,878

(7,829

)

(6,077

)

**Financing activities:**

Issuance of common stock, net (Note 15)

10,238

52,691

16,015

Borrowings under note payable (Note 12)

1,155

1,174

1,233

Repayments of note payable (Note 12)

(1,285

)

(1,261

)

(1,320

)

Issuance of common stock upon exercise of stock options (Note 17)

155

Net cash provided by financing activities

10,108

52,759

15,928

Increase (decrease) in cash and cash equivalents

(3,740

)

240

(27,175

)

Cash and cash equivalents at beginning of year

9,554

9,314

36,489

Cash and cash equivalents at end of year

\$

5,814

\$

9,554

\$

9,314

See accompanying notes to consolidated financial statements.

49

---

## **GENTA INCORPORATED**

### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**For the years ended December 31, 2007, 2006 and 2005**

**1.**

#### **Reverse Stock Split**

At the Annual Meeting of Genta Incorporated ( Genta or the Company ) on July 11, 2007, the Company's shareholders authorized its Board of Directors to effect a reverse stock split of all outstanding shares of common stock, and the Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of one for six shares, which became effective on July 13, 2007. All share and per share data in these consolidated financial statements and related notes hereto have been retroactively adjusted to account for the effect of the reverse stock split for all periods presented.

**2.**

#### **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 for commercial sale in one or more indications. Achievement of profitability for the Company is currently dependent on the timing of Genasense® regulatory approval. Any adverse events with respect to approvals by the U.S. Food and Drug Administration ( FDA ) and/or European Medicines Agency ( EMEA ) could negatively impact the Company's ability to obtain additional funding or identify potential partners.

The Company had \$7.8 million of cash, cash equivalents and marketable securities on hand at December 31, 2007. In March 2007, the Company sold 5.0 million shares of its common stock at a price of \$2.16 per share, raising net proceeds of \$10.2 million. Net cash used in operating activities during 2007 was \$31.7 million, which represents an average monthly outflow of \$2.6 million.

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 operation 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.

The Company will require additional cash in order to maximize its commercial opportunities and continue its clinical development opportunities. The Company has had discussions with other companies regarding partnerships for the further development and global commercialization of Genasense®. Additional alternatives available to the Company

to subsequently sustain its operations include financing arrangements with potential corporate partners, debt financing, asset-based loans, royalty-based financings, equity financing 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.

If the Company is unable to raise additional funds, it will need to do one or more of the following:

delay, scale back or eliminate some or all of the Company's research and product development programs and sales and marketing activity;

license third parties to develop and commercialize products or technologies that the Company would otherwise seek to develop and commercialize themselves;

attempt to sell the Company;

cease operations; or

declare bankruptcy.



The Company will continue to maintain an appropriate level of spending over the upcoming fiscal year, given the uncertainties inherent in our business and our current liquidity position. Presently, with no further financing, Management projects that it will run out of funds in the second quarter of 2008. The Company currently does not have any additional financing in place. If the Company is unable to raise additional financing, it could be required to reduce its spending plans, reduce its workforce, license to others products or technologies it would otherwise seek to commercialize itself and sell certain assets. There can be no assurance that the Company can obtain financing, if at all, on terms acceptable to it.

### 3.

#### **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. 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.

##### *Revenue Recognition*

The Company 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.

Under the Company's Supply and Distribution Agreement with IDIS, the Company will supply Ganite® and Genasense® to IDIS on a consignment basis. The Company recognizes revenue when IDIS reports that it has delivered product to customers, which is the point in time that title to the product and risk of loss has passed. The first sales under this program of \$60 thousand occurred during 2007.

In April 2002, the Company entered into a development and commercialization agreement ( Collaborative Agreement ) with Aventis, a member of the sanofi-aventis group ( Aventis ). In November 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 remaining deferred revenue was recognized over the six-month termination notice period from November 2004 to May 2005.

#### *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, which terminated in May 2005, were recorded as a reduction to expenses in the Consolidated Statements of Operations.

In 2006, the Company entered into an exclusive, worldwide licensing agreement with Emisphere Technologies, Inc., ( Emisphere ), to develop an oral formulation of a gallium-containing compound. Under the terms of the agreement, Genta will pay Emisphere up to \$24.0 million only upon the achievement of certain milestones during the course of product development and royalties based upon sales. To date, no milestone payments have been made.

#### *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. 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 corporate 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.

#### *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, 2007 and December 31, 2006, recorded a valuation allowance to reduce these assets to zero to reflect that, more likely than not, they will not be realized.

In July 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109 ( FIN 48 )*, which clarifies the accounting and disclosure for uncertainty in tax positions, as defined. The Company adopted the provisions of FIN 48 as of January 1, 2007 and has analyzed filing positions in all of the federal and state jurisdictions where it is required to file income tax returns, as well as all open tax years in these jurisdictions.

The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to FIN 48. In addition, the Company did not record a cumulative effect adjustment related to the adoption of FIN 48. If such adjustment was recorded, it would have been fully offset by a change in a valuation allowance.

The Company's policy for recording interest and penalties associated with audits is that penalties and interest expense are recorded in interest expense in the Company's Consolidated Statements of Operations.

#### *Stock Options*

Effective January 1, 2006, Genta adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, ( SFAS 123R ), using the modified prospective transition method and therefore has not restated results for prior periods. Under the new standard, all share-based payments including grants of employee stock options are recognized in the Consolidated Statement of Operations based on their fair values, as pro-forma disclosure is no longer an alternative. The amount of compensation cost is measured based on the grant-date fair value of the equity instrument issued. The Company utilizes a Black-Scholes option-pricing model to measure the fair value of stock options granted to employees. See Note 16 to our Consolidated Financial Statements for a further discussion on share-based compensation.

#### *Net Loss Per Common Share*

Net loss per common share for the year ended December 31, 2007, 2006 and 2005, 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 have been excluded from the calculation of the diluted net loss per common share because the inclusion of such securities would be antidilutive. The potentially dilutive securities include 2.3 million 2.1 million and 1.8 million shares in 2007, 2006 and 2005, respectively, reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants.

#### **Recent Accounting Pronouncements**

In December 2007, the FASB issued SFAS 141(R), *Business Combinations ( SFAS 141(R) )*, which replaces FAS 141. SFAS 141(R) establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any controlling

interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141(R) is to be applied prospectively to business combinations for which the acquisition date is on or after an entity's fiscal year that begins after December 15, 2008. The Company will assess the impact of SFAS 141(R) if and when a future acquisition occurs.



In December 2007, the FASB issued SFAS 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* ( SFAS 160 ). SFAS 160 establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Specifically, this statement requires the recognition of a noncontrolling interest (minority interest) as equity in the consolidated financial statements and separate from the parent's equity. The amount of net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement. SFAS 160 clarifies that changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, this statement requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. SFAS 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The Company does not expect that adoption of this standard will have a material impact on its financial statements.

In December 2007, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin 110 ( SAB 110 ), which permits entities, under certain circumstances, to continue to use the simplified method of estimating the expected term of plain options as discussed in SAB No. 107 and in accordance with SFAS 123R. The guidance in this release is effective January 1, 2008. The impact of this standard on the consolidated financial statements is not expected to be material.

In December 2007, the FASB issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, which is effective for calendar year companies on January 1, 2009. The Task Force clarified the manner in which costs, revenues and sharing payments made to, or received by a partner in a collaborative arrangement should be presented in the income statement and set forth certain disclosures that should be required in the partners' financial statements. The Company is currently assessing the potential impacts of implementing this standard.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, which is effective for calendar year companies on January 1, 2008. The Task Force concluded that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided. The Company is currently assessing the potential impacts of implementing this standard.

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159). SFAS 159 permits all entities to choose to elect, at specified election dates, to measure eligible financial instruments at fair value. An entity shall report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date and recognize upfront costs and fees related to those items in earnings as incurred and not deferred. SFAS 159 applies to fiscal years beginning after November 15, 2007, with early adoption permitted for an entity that has also elected to apply the provisions of SFAS 157, *Fair Value Measurements*. The Company does not expect that adoption of this standard will have a material impact on its financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States of America and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements. Accordingly, this pronouncement does not require any new fair value measurements. The Company is required to adopt SFAS 157 beginning January 1, 2008. The Company does not expect that adoption of this standard will have a material impact on its financial statements.





4.

**Marketable Securities**

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

**December 31,**

**2007**

**2006**

Cost

\$

1,970

\$

19,911

Gross unrealized gains

29

31

Gross unrealized losses

Fair value

\$

1,999

\$

19,942

The fair value of each marketable security has been compared to its cost and therefore, unrealized gains of approximately \$29 thousand and \$31 thousand have been recognized in accumulated other comprehensive income in the Company's Consolidated Balance Sheets at December 31, 2007 and December 31, 2006, respectively.

5.

**Collaborative Agreement**

In April 2002, we entered into a series of agreements with Aventis regarding the development and commercialization of Genasense®. In November 2004, the Company received from Aventis notice of termination of the agreements between Genta and Aventis. In May 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. 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 and the remaining balance of \$1.3 million was forgiven.

Also, 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. 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 2005.

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. 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 during 2005 under the Collaborative Agreement follows (\$ thousands):

**Twelve Months  
Ended  
December 31,  
2005**

Research and development expenses, gross

\$

20,902

Less expense reimbursement

(6,090

)

Research and development expenses, net

\$

14,812

None of the research and development expenses incurred by the Company after May 10, 2005 were reimbursable.



6.

**Workforce reduction**

In December 2006, due to FDA's non-approval of the Company's NDA for CLL, the Company initiated a series of steps that are designed to conserve cash in order to focus on its oncology development operations. The Company reduced its workforce by 34 positions, or approximately 35%, including the elimination of 18 positions classified as research and development, 9 in sales and marketing and 7 in administration. Severance costs of \$0.7 million were recognized in operating expenses in December 2006, including \$0.3 million in research and development expenses and \$0.4 million in selling, general and administrative expenses in the Company's Consolidated Statements of Operations. Payment of the severance began in January 2007 and was completed by June 30, 2007.

7.

**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,**

**2007**

**2006**

Raw materials

\$

24

\$

24

Work in process

94

Finished goods

201

190

\$

225

\$

308

The Company has substantial quantities of Genasense® drug supply which are recorded at zero cost. Such inventory would be available for the commercial launch of this product, should Genasense® be approved.

**8.****Reduction in Liability for Legal Settlement**

The Company reached an agreement to settle a class action litigation in consideration for issuance of 2.0 million shares of common stock of the Company (adjusted for any subsequent event that results in a change in the number of shares outstanding as of January 31, 2007) and \$18.0 million in cash for the benefit of plaintiffs and the shareholder class, (see Note 20 to the Consolidated Financial Statements). The cash portion of the proposed settlement will be covered by the Company's insurance carriers. Effective June 25, 2007, the Company and plaintiffs executed a written Stipulation and Agreement of Settlement, which was filed with the Court on August 13, 2007, seeking preliminary approval. The unopposed Motion for Preliminary Approval of Settlement was granted on October 30, 2007, and the Court issued final approval of the Settlement at the Settlement Fairness Hearing on March 3, 2008. The Company has also entered into release and settlement agreements with its insurance carriers, pursuant to which insurance will cover the settlement fee and various costs incurred in connection with the action. Under FASB Statement No. 5, *Accounting for Contingencies* and FASB Interpretation No. 14, *Reasonable Estimation of the Amount of a Loss, an interpretation of FASB Statement No. 5*, the Company recorded an expense of \$5.3 million, comprised of 2.0 million shares of the Company's common stock valued at a market price of \$2.64 on December 31, 2006. At December 31, 2007, the revised estimated value of the common shares portion of the litigation settlement is \$1.0 million, based on a closing price of Genta's common stock of \$0.52 per share as of December 31, 2007, resulting in a reduction in the provision of \$4.2 million recognized in the year ended December 31, 2007. The amount of the liability will continue to be adjusted based on the market price of the Company's stock until final approval of the settlement by the Court, at which time the value of the shares to be issued will be fixed. The liability for the settlement of litigation, originally recorded at \$23.2 million at December 31, 2006, is measured at \$19.0 million at December 31, 2007 and is included in accounts payable and accrued expenses in the Company's Consolidated Balance Sheets. An insurance receivable of \$18.0 million is included in prepaid expenses and other current assets in the Company's Consolidated Balance Sheets.



9.

**Property and Equipment, Net**

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

**Estimated  
Useful Lives**

**December 31,**

**2007**

**2006**

Computer equipment

3

\$

2,855

\$

2,950

Software

3

3,211

3,406

Furniture and fixtures

5

936

936

Leasehold improvements

Life of lease

420

410

Equipment

5

182

182

7,604

7,884

Edgar Filing: GENTA INC DE/ - Form 10-K  
Less accumulated depreciation and amortization

(7,281

)

(7,613

)

\$

323

\$

271

**10.**

**Write-off of Prepaid Royalty**

In December 2000, the Company recorded \$1.3 million as the fair value for its commitment to issue 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 2001. The Company

planned to amortize the prepaid royalties upon the commercialization of Genasense®. On December 15, 2006, the Company received a non-approvable notice from the FDA for its NDA for the use of Genasense® plus chemotherapy in patients with CLL. As a result, in December 2006, the Company accounted for the impairment of these prepaid royalties by recording a write-off of this asset.

**11.**

**Accounts Payable and Accrued Expenses**

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

**December 31,**

**2007**

**2006**

Accounts payable

\$

2,519

\$

5,493

Accrued severance

747

Accrued compensation

488

2,323

Reserve for settlement of litigation obligation

19,040

23,480

Other accrued expenses

3,803

4,451

\$

25,850

\$

36,494

The carrying amount of accounts payable approximates fair value due to the short-term nature of these instruments.

**12.**

**Notes Payable**

During 2007, the Company issued notes payable to finance premiums for its corporate insurance policies of \$1.1 million at interest rates running from 5.2% to 5.9% and during 2006, \$1.2 million at 5.4% to 5.6%. Payments were scheduled for seven or ten equal monthly installments for the notes initiated in 2007 and over seven equal monthly installments for the notes initiated in 2006. The notes payable balance at December 31, 2007 and December 31, 2006 was \$0.5 million and \$0.6 million, respectively. The carrying amount of notes payable approximates fair value due to the short-term nature of these instruments.



13.

**Income Taxes**

Significant components of the Company's deferred tax assets as of December 31, 2007 and 2006 and related valuation reserves are presented below (\$ thousands):

**December 31,**

**2007**

**2006**

Deferred tax assets:

Deferred compensation

\$

772

\$

772

Net operating loss carryforwards

130,111

122,514

Research and development credit and Orphan Drug credit carryforwards

41,484

38,586

Purchased technology and license fees

4,850

4,850

Depreciation and amortization, net

261

342

Share-based compensation expense

892

648

Provision for settlement of litigation, net

458

2,323

Write-off of prepaid royalties

558

558

New Jersey Alternative Minimum Assessment (AMA) Tax

730

730

New Jersey research and development credits

5,612

5,306

Provision for excess inventory

714

714

Reserve for product returns

2

92

Accrued liabilities

355

2,142

Other, net

323

236

Total deferred tax assets

187,122

179,813

Valuation allowance for deferred tax assets

(187,122

)

(179,813

)

Net deferred tax assets

\$

\$

Deferred tax liabilities:

Net deferred tax liabilities

\$

\$

A full valuation allowance has been provided at December 31, 2007 and 2006, respectively, to reserve for deferred tax assets, as it appears more likely than not that net deferred tax assets will not be realized.

Effective January 1, 2007 the company adopted FIN 48. As of January 1, 2007 and December 31, 2007, the Company recorded a liability for \$712 thousand and \$776 thousand, respectively, of unrecognized tax benefits (UTB's), of which \$776 thousand is included in accounts payable and accrued expenses on the Company's Consolidated Balance Sheets. In addition, as of January 1, 2007 and December 31, 2007, the Company reduced its deferred tax assets by \$854 thousand and \$1,033 thousand, respectively. However, the Company recorded a full valuation allowance on its net deferred tax assets and reduced its valuation allowance on these respective amounts. The amount of UTB's that would have an impact on the effective tax rate, if recognized, is \$533 thousand.

A reconciliation of the total amount of unrecognized tax benefits (UTB's) is as follows:

(\$ in thousands)

Unrecognized tax benefits: January 1, 2007

\$

1,388

Gross increases: Tax positions taken in prior periods

Gross decreases: Tax positions taken in prior periods

Gross Increases- Current period tax positions

\$

179

Lapse of Statute of Limitations

Unrecognized tax benefits: December 31, 2007

\$

1,567



The Company files corporate tax returns at the federal level and in the State of New Jersey. The open tax years that are subject to examination for these jurisdictions are 2004 through 2007 for federal returns and 2002 through 2007 for tax returns for the State of New Jersey.

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 and received a payment of \$1.5 million in 2007 and received a payment of \$0.9 million in 2006, recognized as income tax benefit.

If still available under New Jersey law, the Company will attempt to sell its tax loss carryforwards in 2008. We cannot be assured that the New Jersey program will continue in 2008, 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.

The Company's Federal tax returns have never been audited. In January 2006, the State of New Jersey concluded its fieldwork with respect to a tax audit for the years 2000 through 2004. The State of New Jersey took the position that amounts reimbursed to Genta by Aventis Pharmaceutical Inc. for co-development expenditures during the audit period were subject to Alternative Minimum Assessment (AMA), resulting in a liability at that time of approximately \$533 thousand. Although the Company and its outside tax advisors believe the State's position on the AMA liability is unjustified, there is little case law on the matter and it is probable that the Company will be required to ultimately pay the liability. In March 2007, the Company received a formal assessment from the State of New Jersey for \$712 thousand. As of December 31, 2007, the Company had accrued a tax liability of \$533 thousand, penalties of \$27 thousand and interest of \$216 thousand related to this assessment. The Company appealed this decision to the State and on February 13, 2008, the State notified the Company that its appeal had not been granted. The Company believes the State's position is unjustified and is considering the option of taking this matter before the Tax Court.

The Company recorded \$139 thousand, \$66 thousand and \$11 thousand in interest expense related to the State of New Jersey assessment during 2007, 2006 and 2005, respectively.

At December 31, 2007, the Company has federal and state net operating loss carryforwards of approximately \$310.8 million and \$234.9 million, respectively. The federal tax loss carryforward began expiring in 2003. The Company also has Research and Development credit and Orphan Drug credit carryforwards totaling \$41.8 million, which began expiring in 2003.

## 14.

### Operating Leases

At both December 31, 2007 and December 31, 2006, the Company maintained \$1.7 million in restricted cash balances with financial institutions related to lease obligations on its corporate facilities. These amounts are included in other assets in the Company's Consolidated Balance Sheets. 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, 2007 are as follows (\$ thousands):

2008

\$

2,634

2009

2,591

2010

429

2011

2012

Thereafter

\$

5,654



Annual rent expense incurred by the Company in 2007, 2006 and 2005 was \$2.6 million, \$2.5 million and \$2.4 million, respectively.

**15.**

**Stockholders Equity**

*Common Stock*

At the Company's Annual Meeting of Stockholders on July 11, 2007, the Company's shareholders authorized its Board of Directors to effect a reverse stock split of all outstanding shares of common stock, and the Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of one for six shares.

In March 2007, the Company sold 5.0 million shares of the Company's common stock at a price of \$2.16 per share, raising \$10.2 million, net of fees and expenses.

In September 2006, the Company sold 3.3 million shares of its common stock at a price of \$4.74 per share, raising \$14.9 million, net of fees and expenses.

In March 2006, the Company issued 3.2 million shares of its common stock at a price of \$12.90 per share, raising \$37.7 million, net of fees and expenses.

In March 2006, the Board of Directors approved an amendment to increase the number of shares of authorized common stock to 250.0 million shares from 150.0 million shares. In June 2006, the Company's stockholders approved this amendment at the Company's Annual Meeting of Stockholders.

*Preferred Stock Purchase Right*

In 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 30, 2007 and December 31, 2006, each share of Series A Preferred Stock was convertible into 2.3469 and 1.9969 shares of common stock, respectively. At December 31, 2007 and December 31, 2006, the Company had 7,700 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 \$0.4 million at December 31, 2007.

*Series G Preferred Stock*

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

*Warrants*

The Company does not have any outstanding common stock warrants at December 31, 2007.



*Common Stock Reserved*

At December 31, 2007, the Company had 30.6 million shares of common stock outstanding, 2.3 million additional shares reserved for the conversion of convertible preferred stock and the exercise of outstanding options and 0.6 million additional shares of common stock authorized for issuance and remaining to be granted under the Company's Non-Employee Directors' 1998 Stock Option Plan, as amended and restated and 1998 Stock Incentive Plan, as amended and restated. In addition, the Company has reserved 8.5 million shares and granted 5.4 million options under the 2007 Stock Option Plan, subject to shareholder approval, (see Note 17 to the Consolidated Financial Statements).

**16.****Share-Based Compensation**

Effective January 1, 2006, the Company adopted SFAS 123R, which requires the Company to measure the cost of employee services received in exchange for all equity awards granted based on the fair value of the award as of the grant date. SFAS 123R superseded Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), and Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25). The Company adopted SFAS 123R using the modified prospective transition method, which required the Company to record compensation cost related to unvested stock awards as of December 31, 2005 by recognizing the unamortized grant date fair value of these awards over the remaining requisite service periods of those awards, with no change in historical reported earnings. Awards granted after December 31, 2005 are valued at fair value in accordance with the provisions of SFAS 123R and are recognized on a straight-line basis over the requisite service periods of each award. The standard also requires the Company to estimate forfeiture rates for all unvested awards, which it has done for 2007 based on its historical experience.

The Company estimates the fair value of each option award on the date of the grant using the Black-Scholes option valuation model. Expected volatilities are based on the historical volatility of the Company's common stock over a period commensurate with the options' expected term. The expected term represents the period of time that options granted are expected to be outstanding and is calculated in accordance with the Securities and Exchange Commission (SEC) guidance provided in the SEC's Staff Accounting Bulletin 107 (SAB 107), using a simplified method. The risk-free interest rate assumption is based upon observed interest rates appropriate for the expected term of the Company's stock options. The following table summarizes the weighted-average assumptions used in the Black-Scholes model for options granted during the years ended December 31 2007, 2006 and 2005, respectively:

**2007****2006****2005**

Expected volatility

102

%

97

%

116

%

Expected dividends

Expected term (in years)

6.25

6.25

6.25

Risk-free rate

4.8

%

4.6

%

4.4

%

Prior to 2006, the Company accounted for share-based compensation in accordance with APB 25 using the intrinsic value method, which did not require that compensation cost be recognized for the Company's stock options, provided the option exercise price was not less than the common stock's fair market value on the date of the grant. The Company provided pro-forma disclosure amounts in accordance with SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure*, as if the fair value method defined by SFAS No. 123 had been applied to its share-based compensation. The Company's net loss and net loss per share for the year ended December 31, 2005 would have been increased if compensation cost related to stock options had been recorded in the financial statements based on fair value at the grant dates.



The following table sets forth the pro-forma net loss as if the fair value method had been applied to all awards:

**(\$ thousands, except per share data)**

**Year Ended  
December 31, 2005**

Net loss applicable to common shares, as reported

\$

(2,203

)

Add: Equity related employee compensation expense related to certain stock options issued in 1999 and 2000 included in reported net loss, net of related tax effects

41

Deduct: Total share-based employee compensation expense determined under fair value based method for all awards, net of related tax effects

(6,206

)

Pro forma net loss

\$

(8,368

)

Net loss per share attributable to common shareholders:

As reported: Basic and diluted

\$

(0.13

)

Pro forma: Basic and diluted

\$

(0.49

)

The share-based compensation expense recognized for the years ended December 31, 2007 and December 31, 2006 follows:

**Year Ended  
December 31**

**(\$ thousands, except per share data)**

**2007**

**2006**

Research and development expenses

\$

521

\$

997

Selling, general and administrative

852

2,002

Total share-based compensation expense

\$

1,373

\$

2,999

Share-based compensation expense, per basic and diluted common share

\$

0.05

\$

0.13

17.

### **Stock Option Plans**

As of December 31 2007, the Company has three share-based compensation plans, which are described below:

#### *2007 Stock Incentive Plan*

On September 17, 2007, the Company's Board of Directors approved the Company's 2007 Stock Incentive Plan (the 2007 Plan), pursuant to which 8.5 million shares of the Company's common stock will be authorized for issuance, subject to approval of the Company's shareholders. Awards may be made under the plan to officers, employees, directors and consultants in the form of incentive stock options, non-qualified stock options, stock appreciation rights, dividend equivalent rights, restricted stock, restricted stock units and other stock-based awards. Awards granted under the plan prior to shareholder approval of the plan are subject to and conditioned upon receipt of such approval on or before September 17, 2008. Should such shareholder approval not be obtained on or before such date, the plan will terminate and any awards granted pursuant to the plan will terminate and cease to be outstanding.

On September 17, 2007 and September 20, 2007, the Board of Directors approved the issuance of a combined total of 5.4 million options under the 2007 Plan. Most of these awards vest over a three-year period in increments of 50%, 25% and 25%, beginning on the first anniversary of the date of the grant. The Company has not recognized compensation expense for these grants, because a grant date as defined in SFAS 123R has not occurred. This is because the grant of these options is contingent upon shareholder approval, which cannot be assured.





*Acquisition Bonus Program*

On September 17, 2007, the Board of Directors approved an Acquisition Bonus Program. Under the program, participants are eligible to share in a portion of the proceeds realized from a change in control of the Company that occurs prior to the earlier of (i) December 31, 2008 or (ii) the approval by the Company's shareholders of the 2007 Stock Incentive Plan.

Pursuant to the program, participants selected by the Board of Directors will be awarded a number of units with a designated base value. The amount of a participant's bonus award will be determined by multiplying (i) the difference between the unit value and the base value by (ii) the number of units awarded to such participant. The unit value for each unit will be determined by dividing the change in control proceeds (as defined in the award agreement) by the total number of shares of the Company's common stock outstanding at the time of the change in control. The units will be subject to a vesting schedule, if any, determined by the Board of Directors at the time the unit award is made. Bonus awards will generally be paid in cash within 30 days after the later of (i) the effective date of the change in control or (ii) the date the change in control proceeds are paid to the Company's shareholders. The maximum number of units that may be awarded under the Acquisition Bonus Program is 8.5 million units, which equals the number of shares of the Company's common stock that are authorized for issuance under the 2007 Plan. On September 27, 2007, 5.4 million acquisition bonus units were granted under the Acquisition Bonus Program.

Any stock options granted to a participant under the 2007 Plan will terminate and cease to be outstanding in the event the participant becomes entitled to receive a payment under the Acquisition Bonus Program.

*1998 Stock Incentive Plan*

Pursuant to the Company's 1998 Stock Incentive Plan, as amended (the "1998 Plan"), 3.4 million shares have been provided for the grant of stock options to employees, directors, consultants and advisors of the Company. In June 2006, the Company's stockholders approved an amendment to increase the total number of shares of common stock authorized for issuance under the 1998 Plan from 3.1 million to 3.4 million shares. Option awards must be granted with an exercise price at not less than the fair market price of the Company's common stock on the date of the grant; those option awards generally vest over a four-year period in equal increments of 25%, beginning on the first anniversary of the date of the grant. All options granted have contractual terms of ten years from the date of the grant.



The following table summarizes the option activity under the 1998 Plan as of December 31, 2007 and changes during the three years then ended:

**Stock Options**

**Number of Shares  
(in thousands)**

**Weighted Average Exercise Price**

**Weighted Average Remaining Contractual Term  
(in years)**

**Aggregate Intrinsic Value  
(in thousands)**

Outstanding at December 31, 2004

1,666

\$

35.94

Granted

247

8.16

Exercised

Forfeited or expired

(343

)

42.00

Outstanding at December 31, 2005

1,570

\$

30.24

Granted

432

11.64

Exercised

Forfeited or expired

(66

)

25.32

Outstanding at December 31, 2006

1,936

\$

26.22

Granted

316

1.40

Exercised

Forfeited or expired

(97

)

16.38

Outstanding at December 31, 2007

2,155

\$

23.05

5.1

\$

Vested and expected to vest at December 31, 2007

1,293

\$

23.05

5.1

\$

Exercisable at December 31, 2007

1,304

\$

24.25

3.3

\$

There is no intrinsic value to outstanding stock options as the exercise prices of all outstanding options are above the market price of the Company's stock at December 31, 2007. The weighted-average grant-date fair value of options granted during the year ended December 31, 2007 was \$1.16.

As of December 31, 2007, there was approximately \$0.9 million of total unrecognized compensation cost related to non-vested share-based compensation granted under the 1998 Plan, which is expected to be recognized over a weighted-average period of 1.4 years.

In September 2007, the Company granted 60,000 Restricted Stock Units (RSUs), which contain performance vesting criteria, to a member of senior management. RSUs entitle the holder to receive at the end of a vesting term, a specified number of shares of Genta common stock and were accounted for at fair value at the date of the grant. This particular grant of 60,000 RSUs consists of three tranches of 20,000 shares each. The first two equal tranches of 20,000 shares each vest upon the completion of one or more financial transactions including, but not limited to, partnerships, asset sales or other transactions that raise working capital for the Company. At December 31, 2007, the performance condition for the 40,000 RSUs had not been met; accordingly, there is no amortization related to these RSUs reflected in the Company's financial statements. One tranche of 20,000 shares vests on July 1, 2008 upon satisfactory provision of certain other financial and accounting services. The fair value of the grant, \$28 thousand, based on a grant date fair value per share of \$1.42, is being amortized evenly over the vesting period.

#### *1998 Non-Employee Directors' Plan*

Pursuant to the Company's 1998 Non-Employee Directors' Plan as amended (the *Directors' Plan*), 0.6 million shares have been provided for the grant of non-qualified stock options to the Company's non-employee members of the Board

of Directors. Option awards must be granted with an exercise price at not less than the fair market price of the Company's common stock on the date of the grant. Initial option grants vest over a three-year period in equal increments, beginning on the first anniversary of the date of the grant. Subsequent grants, generally vest on the date of the grant. All options granted have contractual terms of ten years from the date of the grant.

The fair value of each option award is estimated on the date using the same valuation model used for options granted under the 1998 Plan.



The following table summarizes the option activity under the Directors Plan as of December 31, 2007 and changes during the three years then ended:

**Stock Options**

**Number of Shares  
(in thousands)**

**Weighted Average Exercise Price**

**Weighted Average Remaining Contractual Term  
(in years)**

**Aggregate Intrinsic Value  
(in thousands)**

Outstanding at December 31, 2004

171

\$

43.02

Granted

32

6.90

Exercised

Forfeited or expired

(10

)

31.50

Outstanding at December 31, 2005

193

\$

37.56

Granted

23

12.42

Exercised

(26

)

6.00

Forfeited or expired

(90

)

40.98

Outstanding at December 31, 2006

100

\$

37.02

Granted

20

1.80

Exercised

Forfeited or expired

(7

)

40.08

Outstanding at December 31, 2007

113

\$

30.61

6.4

\$

Vested and expected to vest at December 31, 2007

68

\$

30.61

6.4

\$

Exercisable at December 31, 2007

111

\$

31.18

6.3

\$

There is no intrinsic value to outstanding stock options as the exercise prices of all outstanding options are above the market price of the Company's stock at December 31, 2007. The weighted-average grant-date fair value of options granted during the year ended December 31, 2007 was \$1.48.

Stock option grants for a combination of both the 1998 Plan and the 1998 Directors Plan were as follows:

**Year**

**Options Granted  
(in Thousands)**

**Weighted Average  
Grant Date Per  
Share Fair Value**

2007

336

\$

1.42

2006

455

11.70

2005

279

7.98

An analysis of all options outstanding as of December 31, 2007 is presented below, (option figures are in thousands):

**Range of  
Prices**

**Options Outstanding**

**Weighted Average Remaining Life  
in Years**

**Weighted Average Exercise Price**

**Options Exercisable**

**Weighted Average Exercise Price of Options Exercisable**

\$0.67 - \$1.98

239

9.9

\$

.88

20

\$

1.80

\$2.73 - \$9.54

270

8.3

6.39

81

7.36

\$9.66 - \$12.96

351

8.0

12.10

132

11.94

\$14.58 - \$19.02

823

2.0

15.98

823

15.98

\$34.38 - \$56.10

223

3.9

43.35

224

43.35

\$59.28 - \$109.50

362

5.2

66.60

135

74.06

2,268

5.2

\$

23.43

1,415

\$

24.79

65

---



**18.**

**Employee Savings Plan**

In 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 \$0.3 million, \$0.4 million, and \$0.4 million for 2007, 2006 and 2005, respectively.

**19.**

**Comprehensive Loss**

An analysis of comprehensive loss is presented below:

**Years Ended December 31,**

(\$ in thousands)

**2007**

**2006**

**2005**

Net loss

\$

(23,320

)

\$

(56,781

)

\$

(2,203

)

Change in market value on available-for-sale marketable securities

29

31

60

Total comprehensive loss

\$

(23,291

)

\$

(56,750

)

\$

(2,143

)

20.

## 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, or the Court, 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 were consolidated into a single action and alleged 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 the Company's securities. The shareholder class action complaint sought monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. The Company reached an agreement with plaintiffs to settle the class action litigation in consideration for the issuance of 2.0 million shares of common stock of the Company (adjusted for any subsequent event that results in a change in the number of shares outstanding as of January 31, 2007) and \$18.0 million in cash for the benefit of plaintiffs and the shareholder class. The cash portion of the proposed settlement will be covered by the Company's insurance carriers. Effective June 25, 2007, the Company and plaintiffs executed a written Stipulation and Agreement of Settlement which was filed with the Court on August 13, 2007, seeking preliminary approval. The unopposed Motion for Preliminary Approval of Settlement was granted on October 30, 2007, and the Court issued final approval of the Settlement at the Settlement Fairness Hearing on March 3, 2008.

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.

Genta reached a final agreement with the Federal shareholder derivative plaintiffs to settle the Federal shareholder derivative action. On October 10, 2006, the United States District Court for the District of New Jersey gave preliminary approval to the parties' settlement agreement. On May 7, 2007, the proposed settlement received final approval from the court. On October 31, 2006, Genta and the defendants entered into a Release and Settlement Agreement with the Company's insurance carrier, pursuant to which the Company's insurance covered the \$200 thousand payment for plaintiffs' attorney fees, the costs of notice to shareholders required by the Court's preliminary approval order and defense costs incurred in connection with the action, and this amount was paid by the Company's insurance carrier during the three months ended June 30, 2007.

The Company has continued to deny all of the allegations in all of these proceedings, and settlement and potential settlement do not constitute an admission of guilt or liability.





Based on facts substantially similar to those asserted in the shareholder class actions, the State derivative plaintiffs claimed that defendants had 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' motion for reconsideration was denied and they filed a notice of appeal. On December 11, 2006, plaintiffs filed their appellate brief and on January 18, 2007, the Company filed its response. In view of the settlement of the Federal derivative action, on June 4, 2007, the Company filed a motion to dismiss plaintiffs' appeal. That motion was granted on June 25, 2007.

In February 2007, a complaint against the Company was filed in the Superior Court of New Jersey by Howard H. Fingert, M.D., a former employee of the Company. The complaint alleges, among other things, breach of contract as to the Company's stock option plan and as to a consulting agreement allegedly entered into by the Company and Dr. Fingert subsequent to termination of Dr. Fingert's employment with the Company, breach of implied covenant of good faith and fair dealing with respect to the Company's stock option plan and the alleged consulting agreement, promissory estoppel with respect to the exercise of stock options and provision of consulting services after termination of employment, and fraud and negligent misrepresentation with respect to the exercise of stock options and provision of consulting services after termination of employment. The complaint seeks monetary damages, including punitive and consequential damages. The Company filed an answer to the complaint on May 29, 2007, and on August 8, 2007, filed a request for production of documents. On January 4, 2008, the Court dismissed the complaint without prejudice due to Dr. Fingert's failure to produce the requested discovery. Dr. Fingert has ninety days in which to move to vacate the order. The Company denies the allegations in the complaint and intends to vigorously defend this lawsuit.

In November 2007, a complaint against the Company was filed in the United States District Court for the District of New Jersey by Ridge Clearing & Outsourcing Solutions, Inc. The complaint alleges, among other things, that the Company caused or contributed to losses suffered by a Company shareholder which have been incurred by Ridge. The Company filed its Answer and Affirmative Defenses on February 27, 2008 to respond to the complaint. The Company denies the allegations in the complaint and intends to vigorously defend this lawsuit.

## 21.

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

As a result of the Aventis notice of termination in 2004, 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, \$6.0 million of reimbursement due to Genta was applied to the balance of the Line of Credit. In addition, in 2005, the Company recorded a gain on the forgiveness of debt of \$1.3 million.

No interest was paid for the twelve months ended December 31, 2007, 2006, and 2005, respectively.



22.

**Selected Quarterly Financial Data (Unaudited)**

**Quarter Ended**

**2007**

**Mar. 31**

**Jun. 30**

**Sep. 30**

**Dec. 31**

(\$ thousands, except per share data)

Revenues

\$

94

\$

105

\$

115

\$

266

Gross margin

72

79

95

244

Operating expenses-net

5,875

8,594

8,046

3,601

Net loss

(5,605)

)

(8,235

)

(7,732

)

(1,748

)

Net loss per common share:

Basic and diluted \*\*

\$

(0.21

)

\$

(0.27

)

\$

(0.25

)

\$

(0.06

)

**Quarter Ended**

**2006**

**Mar. 31**

**Jun. 30**

**Sep. 30**

**Dec. 31**

(\$ thousands, except per share data)

Revenues

\$

67

\$

379

\$

145

\$

117

Gross margin

51

357

104

88

Operating expenses net

10,206

15,353

15,453

18,752

Net loss

(9,895

)

(14,642

)

(14,940

)

(17,304

)

Net loss per common share:

Basic and diluted \*\*

\$  
(0.50  
)  
\$  
(0.66  
)  
\$  
(0.66  
)  
\$  
(0.68  
)

\*\* Net loss 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.

In December 2006, the Company reached an agreement to settle a class action litigation in consideration for issuance of 2.0 million shares of common stock of the Company (adjusted for any subsequent event that results in a change in the number of shares outstanding as of January 31, 2007) and \$18.0 million in cash for the benefit of plaintiffs and the shareholder class, (see Note 20 to the Consolidated Financial Statements). The cash portion of the proposed settlement will be covered by the Company's insurance carriers. The Company recorded an expense of \$5.3 million, comprised of 2.0 million shares of the Company's common stock valued at a market price of \$2.64 on December 31, 2006.

At December 31, 2007, the revised estimated value of the common shares portion of the litigation settlement is \$1.0 million, based on a closing price of Genta's common stock of \$0.52 per share as of December 31, 2007, resulting in a reduction in the provision of \$4.2 million recognized in the year ended December 31, 2007. The amount of the liability will continue to be adjusted based on the market price of the Company's stock until final approval of the settlement by the Court, at which time the value of the shares to be issued will be fixed.

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

During the fourth quarter of 2007, the Company revised its estimate of certain accrued expenses in the amount of \$4.7 million, since such amount is no longer deemed probable.





23.

**Subsequent Events**

On February 13, 2008, the Company sold 6.1 million shares of the Company's common stock at a price of \$0.50 per share, raising approximately \$3.1 million, net of estimated fees and expenses.

On March 7, 2008, the Company entered into a License Agreement (the Agreement) with Daiichi Sankyo Company, Limited, a Japanese corporation based in Tokyo, Japan, whereby Genta obtained the exclusive license for tesetaxel. Pursuant to the agreement, Genta will pay Daiichi Sankyo \$250,000 within 30 days from signing the agreement. The Company will also pay four equal installments of \$562,000 per quarter beginning at the end of the second quarter 2008, and also at the end of each subsequent calendar quarter, until the end of the first quarter 2009, for a total of \$2.25 million. The agreement also provides for payments by Genta upon achievement of certain clinical and regulatory milestones and royalties on net product sales. The Company will purchase Daiichi's current inventory of tesetaxel and will be responsible for all future development, commercialization, and manufacturing of the drug.

69

---

**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 Principal Accounting and Finance Officer conducted an evaluation as of the end of the period covered by this report of the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)). Based on that evaluation, our Chief Executive Officer and Principal Accounting and Finance Officer concluded that as of December 31, 2007, our disclosure controls and procedures were (1) effective in that they were designed to ensure that material information relating to us is made known to our Chief Executive Officer and Principal Accounting and Finance Officer by others within this entity, as appropriate to allow timely decisions regarding required disclosures, and (2) effective in that they provide that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

***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, 2007.

Deloitte & Touche LLP, an independent registered public accounting firm, has audited our consolidated financial statements included in this report on Form 10-K and issued its report on the effectiveness of our internal control over financial reporting as of December 31, 2007, 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 the internal control over financial reporting of Genta Incorporated and subsidiaries (the Company) as of December 31, 2007, 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, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, 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, 2007 of the Company and our report dated March 17, 2008 expressed an unqualified opinion on those financial statements and included explanatory paragraphs relating to the Company's ability to continue as a going concern and the Company's adoption of Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment*, effective January 1, 2006, and Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* and

*Interpretation of FASB Statement No. 109, effective January 1, 2007.*

/s/ DELOITTE & TOUCHE LLP

Parsippany, New Jersey

March 17, 2008

71

---



**Item 9B. Other Information**

None.

**PART III**

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

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, 2008 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, 2008 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, 2008 pursuant to Regulation 14A.

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

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, 2008 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, 2008 pursuant to Regulation 14A.

**PART IV**

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

**Exhibit  
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

Certificate 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)

3.1.m

Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, Commission File No. 0-19635)

3.1.n

Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on July 13, 2007, 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)

73

---



**Exhibit  
Number**

**Description of Document**

4.2

Rights Agreement, dated September 20, 2005, between the Company and Mellon 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 File No. 0-19635)

10.1

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

10.2

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)

10.3

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)

10.4

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)

10.5

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)

10.6

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)

10.7

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)

10.8

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)

10.8A

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)

10.9\*

U.S. Commercialization Agreement dated April 26, 2002, by and 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 June, 30, 2002, Commission File No. 0-19635)

10.9A\*

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

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, Commission File No. 0-19635).

10.10\*

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)

10.11\*

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)

10.12\*

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)

10.13

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)

74

---



**Exhibit  
Number**

**Description of Document**

10.14

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)

10.15

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)

10.16\*

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)

10.17\*

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)

10.18\*

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)

10.19\*

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)

10.19A\*

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)

10.19AA\*

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)

10.20

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)

10.21

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)

10.22

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)

10.23

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

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)

10.24

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)

10.25

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)

10.26

Form of Confirmation of Purchase, dated March 10, 2006 by and between the Company and certain Investors (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005, Commission File No. 0-19635)

10.27

Form of Amendment No. 1 to Placement Agent Agreement, dated as of March 10, 2006 by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005, Commission File No. 0-19635)

75

---



**Exhibit  
Number**

**Description of Document**

10.28

Development and License Agreement, dated March 22, 2006 by and between the Company and Emisphere Technologies, Inc. \* (incorporated by reference to Exhibit 10.5 to the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, Commission File No. 0-19635)

10.29

1998 Stock Incentive Plan, as amended and restated, effective April 5, 2006 (incorporated by reference to the company's Definitive Proxy statement on Schedule 14A filed on April 28, 2006, Commission File No. 0-19635)

10.30

Employment Agreement, dated as of March 28, 2006, 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, 2006, Commission File No. 0-19635)

10.31

Form of Securities Purchase Agreement, dated September 19, 2006, between the Company and each Purchaser (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on September 20, 2006, Commission File No. 0-19635)

10.32

Form of Placement Agent Agreement, dated September 19, 2006, by and between the Company and Rodman & Renshaw LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on September 20, 2006, Commission File No. 0-19635)

10.33

Supply and Distribution Agreement between the Company and IDIS Limited, dated March 6, 2007 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed on May 8, 2007, Commission File No. 0-19635)

10.34

Form of Purchase Agreement by and among the Company and the Purchasers, dated March 13, 2007 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on March 14, 2007, Commission File No. 0-19635)

10.35

Placement Agent Agreement, by and between the Company and Rodman & Renshaw, LLC, dated February 23, 2007 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on March 14, 2007, Commission File No. 0-19635)

10.36

Form of Acquisition Bonus Program Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on September 21, 2007, Commission File No. 0-19635)

10.37\*

Project Contract with ICON Clinical Research, L.P., dated November 19, 2007 (filed herewith)

10.38

Amended and Restated Employment Agreement, dated as of November 30, 2007, between the Company and Raymond P. Warrell, Jr. M.D. (filed herewith)

10.39

Form of Securities Purchase Agreement, dated February 8, 2008, by and between the Company each Purchaser (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on February 11, 2008, Commission File No. 0-19635)

10.40

Placement Agent Agreement, dated February 8, 2008, by and between the Company and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on February 11, 2008, Commission File No. 0-19635)

21

#### Subsidiaries of the Registrant

23.1

#### Consent of Deloitte & Touche LLP

31.1

Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)

31.2

Certification by Vice President, Finance pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)

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 (furnished herewith)

32.2

Certification by Vice President, Finance pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)

---

\*

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, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 17th day of March 2008.

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, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

**Signature**

**Capacity**

**Date**

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

Chairman and Chief Executive Officer and Director (principal executive officer)

March 17, 2008

Raymond P. Warrell, Jr., M.D.

/s/ GARY SIEGEL

Vice President, Finance (principal financial and accounting officer)

March 17, 2008

Gary Siegel

/s/ MARTIN J. DRISCOLL

Director

March 17, 2008

Martin J. Driscoll

/s/ CHRISTOPHER P. PARIOS

Director

March 17, 2008

Christopher P. Parios

/s/ DANIEL D. VON HOFF, M.D.

Director

March 17, 2008

Daniel D. Von Hoff, M.D.

/s/ DOUGLAS G. WATSON

Director

March 17, 2008

Douglas G. Watson

77

---

**Exhibit  
Number**

**Description of Document**

**Sequentially  
Numbered 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

Certificate 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)

3.1.m

Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, Commission File No. 0-19635)



**Exhibit  
Number**

**Description of Document**

**Sequentially  
Numbered Pages**

3.1.n

Certificate of Amendment of Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on July 13, 2007, 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 Mellon 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 File No. 0-19635)

10.1

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

10.2

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)

10.3

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)

10.4

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)

10.5

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)

10.6

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)

10.7

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)

10.8

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)

10.8A

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)

79

---



**Exhibit  
Number**

**Description of Document**

**Sequentially  
Numbered Pages**

10.9\*

U.S. Commercialization Agreement dated April 26, 2002, by and 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 June, 30, 2002, Commission File No. 0-19635)

10.9A\*

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, Commission File No. 0-19635).

10.10\*

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)

10.11\*

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)

10.12\*

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)

10.13

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)

10.14

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)

10.15

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

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)

10.16\*

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)

10.17\*

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)

10.18\*

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)

10.19\*

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)

10.19A\*

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)

80

---



**Exhibit  
Number**

**Description of Document**

**Sequentially  
Numbered Pages**

10.19AA\*

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)

10.20

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)

10.21

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)

10.22

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)

10.23

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)

10.24

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)

10.25

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)

10.26

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

Form of Confirmation of Purchase, dated March 10, 2006 by and between the Company and certain Investors (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005, Commission File No. 0-19635)

10.27

Form of Amendment No. 1 to Placement Agent Agreement, dated as of March 10, 2006 by and among the Company, Cowen & Co., LLC and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005, Commission File No. 0-19635)

10.28

Development and License Agreement, dated March 22, 2006 by and between the Company and Emisphere Technologies, Inc. \* (incorporated by reference to Exhibit 10.5 to the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, Commission File No. 0-19635)

10.29

1998 Stock Incentive Plan, as amended and restated, effective April 5, 2006 (incorporated by reference to the company's Definitive Proxy statement on Schedule 14A filed on April 28, 2006, Commission File No. 0-19635)

10.30

Employment Agreement, dated as of March 28, 2006, 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, 2006, Commission File No. 0-19635)

81

---



**Exhibit  
Number**

**Description of Document**

**Sequentially  
Numbered Pages**

10.31

Form of Securities Purchase Agreement, dated September 19, 2006, between the Company and each Purchaser (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on September 20, 2006, Commission File No. 0-19635)

10.32

Form of Placement Agent Agreement, dated September 19, 2006, by and between the Company and Rodman & Renshaw LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on September 20, 2006, Commission File No. 0-19635)

10.33

Supply and Distribution Agreement between the Company and IDIS Limited, dated March 6, 2007 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed on May 8, 2007, Commission File No. 0-19635)

10.34

Form of Purchase Agreement by and among the Company and the Purchasers, dated March 13, 2007 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on March 14, 2007, Commission File No. 0-19635)

10.35

Placement Agent Agreement, by and between the Company and Rodman & Renshaw, LLC, dated February 23, 2007 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on March 14, 2007, Commission File No. 0-19635)

10.36

Form of Acquisition Bonus Program Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on September 21, 2007, Commission File No. 0-19635)

10.37\*

Project Contract with ICON Clinical Research, L.P., dated November 19, 2007 (filed herewith)

10.38

Amended and Restated Employment Agreement, dated as of November 30, 2007, between the Company and Raymond P. Warrell, Jr. M.D. (filed herewith)

10.39

Form of Securities Purchase Agreement, dated February 8, 2008, by and between the Company each Purchaser (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed on February 11, 2008, Commission File No. 0-19635)

10.40

Placement Agent Agreement, dated February 8, 2008, by and between the Company and Rodman & Renshaw, LLC (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed on February 11, 2008, Commission File No. 0-19635)

21

Subsidiaries of the Registrant

23.1

Consent of Deloitte & Touche LLP

31.1

Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)

31.2

Certification by Vice President, Finance pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)

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 (furnished herewith)

32.2

Certification by Vice President, Finance pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)

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

82

---